Issued in Washington, D.C. on October 21, 1994.

Phil Olekszyk,

Acting Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 94–26693 Filed 10–27–94; 8:45 am]

BILLING CODE 4910–06–P

Petition for Exemption or Waiver of Compliance

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received from the Association of American Railroads (AAR) a request for an interim waiver of compliance with a requirement of Federal rail safety standards. The petition is described below, including the regulatory provisions involved and the nature of the relief being requested.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number RSFC–94–2) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street SW., Washington, DC 20590. Communications received before December 1, 1994, will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in Room 8201, Nassif Building, 400 Seventh Street SW., Washington, DC 20590.

Association of American Railroads (AAR)—(Waiver Petition Docket Number RSFC–94–2)

The Association of American Railroads (AAR) seeks an interim waiver of compliance with certain provisions of the Railroad Freight Car Safety Standards, 49 CFR Part 215. The AAR is requesting an exemption from the requirement of 49 CFR 215.103(h) which requires the removal from service of freight car wheels that show signs of having been overheated as evidenced by reddish brown discoloration, as it is applied to heat-treated curved-plate wheels. As a result of a petition by the AAR (Rulemaking Petition No. 93–1), the FRA intends to initiate a rulemaking addressing the proposal to revise 49 CFR 215.103(h) as it applies to heat-treated curved-plate (HT–CP) freight car wheels.

AAR indicates that it is filing this petition for an interim waiver to address the situation while the rulemaking process proceeds.

AAR requests that FRA issue a waiver providing in substance, that:

49 CFR 215.103 shall not prohibit a railroad from placing or continuing in service a freight car if the only reason for such prohibition is one or more wheels that are discolored as described in 49 CFR 215.103(h), provided:

(i) Each such discolored wheel is heat-treated and is of curve-plate design,

(ii) Each such wheel is identified as a heat-treated curved-plate wheel in accordance with AAR interchange rules, and

(iii) The railroad has submitted to FRA and to AAR a written agreement to participate in the Data Collection Program on Premature Wheel Failure.

AAR cites the following justification for the waiver request:

1. HT–CP wheels are extraordinarily resistant to the development of residual tensile rim stresses which are a precondition for wheel fracture.

2. The resistance of HT–CP wheels to development of residual tensile rim stress is a function of the design of the wheels and the manufacturing processes used.

3. In-service wheel failure data and experimental data show that HT–CP wheels have an incidence of residual tensile rim stress and of wheel failure that is approximately the same as non-discolored HT–CP wheels.

4. Transport Canada, the Canadian rail safety agency, does not prohibit the use of discolored curved-plate wheels on railroad freight cars. Canadian data collected over nine years similarly show that discolored and non-discolored HT–CP wheels fail for residual tensile rim stress related reasons at approximately the same rate.

5. New air brake testing procedures have significantly reduced the likelihood of sticking brakes—the principal cause of the development of residual tensile rim stress in HT–CP wheels.

6. Removal of HT–CP wheels costs the railroad industry approximately $40 million per year, yet provides no discernible safety benefit.

Data Collection on Premature Wheel Failure

AAR proposes a data collection program that will provide a data base which can be used to make sound decisions about railroad freight car wheels, particularly HT–CP wheels.

Issued in Washington, DC on October 21, 1994.

Phil Olekszyk,

Acting Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 94–26694 Filed 10–27–94; 8:45 am]

BILLING CODE 4910–06–M

Technical Meeting on Commercial Feasibility Study

AGENCY: Federal Railroad Administration; Department of Transportation.

ACTION: Notice of Public Meetings.

SUMMARY: The Federal Railroad Administration will present two technical briefings on the scope, methodology and approach of the *Commercial Feasibility Study of High Speed Ground Transportation*. An overview of the study content, timetable, methodology, and progress to date will be presented. The presentation will cover the following topics in the order shown: Overview, Schedule, and Relationship to the National High-Speed Ground Transportation Policy; Technologies Covered (i.e. types of High-Speed Ground Transportation); Corridor Scope; Revenue & Ridership Methodology; Capital & Operating Cost Methodology; Financial Analysis Approach; and Public Benefits Approach.

The first briefing in Albuquerque, New Mexico will be held as two identical back to back sessions. Each session will begin with a one hour presentation on the above topics, followed by a half hour for questions and discussion. The briefing will be held on Saturday, November 12, 1994, at the Hyatt Regency, 330 Tijeras NW, Albuquerque, NM 87102, in the FIESTA Room 2, second floor. The times for the briefing sessions are 9:00 a.m. to 10:30 a.m., and 10:30 a.m. to 12 noon.

The second, more detailed briefing in Washington, D.C., will cover each of the above topics with questions and discussion after each topic. The briefing will be held from 9:00 a.m. to 4:00 p.m. on Monday, November 21, 1994, at USDOT, NASSIF Building, 400 Seventh Street, SW, Washington, DC 20590 in Room 6200.

FOR FURTHER INFORMATION CONTACT: John F. Cikota, (202) 366–6933.

SUPPLEMENTARY INFORMATION: The study is required by Section 1036(c) of the Intermodal Surface Transportation Efficiency Act of 1991, Public Law 102–240 (49 U.S.C. § 309(d)). Both briefings are open to the public.

Issued in Washington, D.C. on October 24, 1994.

Jolene M. Molitoris,

Federal Railroad Administrator.

[FR Doc. 94–26723 Filed 10–27–94; 8:45 am]

BILLING CODE 4910–13–P

Sunshine Act Meetings

Federal Register
Vol. 59, No. 208
Friday, October 28, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:02 a.m. on Tuesday, October 25, 1994, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's supervisory activities.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Mr. Stephen R. Steinbrink, acting in the place and stead of Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Vice Chairman Andrew C. Hove, Jr., and Chairman Ricki R. Tigert, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b) (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, N.W., Washington, D.C.

Dated: October 25, 1994.

Federal Deposit Insurance Corporation.

Leneta G. Gregorie,

Acting Assistant Executive Secretary.

[FR Doc. 94-26910 Filed 10-26-94; 1:39 pm]

BILLING CODE 6714-0-M

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE-94-35]

TIME AND DATE: November 14, 1994 at 11:00 a.m.

PLACE: Room 101, 500 E Street S.W., Washington, DC 20436.

STATUS:

1. Agenda for future meeting.
2. Minutes.
3. Ratification List.
4. Inv. No. 731-TA-722 (Preliminary) (Honey from China)—briefing and vote.
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:

Issued: October 25, 1994.

Donna R. Koehnke,

Secretary.

[FR Doc. 94-26867 Filed 10-26-94; 11:26 am]

BILLING CODE 7020-02-P

federal register

Friday
October 28, 1994

Part II

Department of Health and Human Services

Centers for Disease Control and Prevention

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, HHS.

ACTION: Notice of Final Revisions to the "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994."

SUMMARY: The purpose of this notice is to print the final "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994," and a summary of comments and responses to those comments.

EFFECTIVE DATE: October 28, 1994.

ADDRESSES: This document is also being printed in its entirety as a *Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports.* For copies of the *MMWR* printing, call CDC's Voice Information System (VIS) at (404) 639–1819 or write to the Centers for Disease Control and Prevention (CDC), Information Services Office, Mailstop E–06, Atlanta, GA 30333. An electronic version of this document will be available via Anonymous FTP from ftp.cdc.gov after November 18. Type "Anonymous" for the user name and your e-mail address for the password. Select the pub directory, then the tbdoc subdirectory. Retrieve the README file for instructions on document viewing and printing.

FOR FURTHER INFORMATION CONTACT: CDC's Voice Information System at (404) 639–1819.

SUPPLEMENTARY INFORMATION:

Background

On October 12, 1993, CDC published "Draft Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition," in the **Federal Register** at 58 FR 52810 with a 60-day comment period (which was extended to January 13, 1994). More than 2500 comments were received and reviewed. The following represents a summary of all major comments and a response to each. All comments were reviewed and considered in developing the final guidelines. Changes were also made to increase clarity and readability.

Comments and Responses

Section I. Introduction

Section II. Recommendations

A. Assignment of Responsibility

No comments received on this section.

B. Risk Assessment, Development of the TB Control Plan, and Periodic Reassessment

Comments: Provide more flexibility in levels of risk to accommodate facilities that rarely or never provide services to patients with tuberculosis.

Response: Two new categories—"very low risk" and "minimal risk"—were added to accommodate such facilities.

Comments: Rationale for selecting six patients per year in a given area as a criterion for risk level seems arbitrarily defined.

Response: This criterion is based on surveys conducted by CDC in conjunction with the American Hospital Association, the Society for Health Care Epidemiology of America, and the Association for Professionals in Infection Control and Epidemiology. These surveys suggest an increased risk of tuberculin skin test conversion in employees working in facilities admitting six or more TB patients per year.

Comments: Repeat skin testing at 3-month intervals in high-risk settings is too frequent.

Response: The high-risk setting is essentially an outbreak setting, in which there is evidence of transmission of *Mycobacterium tuberculosis.* In this situation, it is reasonable to conduct follow-up skin testing 12 weeks (3 months) after the initial testing. If there is no evidence of further transmission and any deficiencies in infection control practices and facilities have been corrected, the area is no longer considered high risk, and there is no need to continue testing every 3 months.

Comments: A cluster of skin test conversions is defined as two or more conversions in one area within 3 months; however, because of the limitations of skin testing, this may not represent true conversions due to nosocomial transmission.

Response: It is assumed that a cluster would be investigated to determine the likelihood that it truly represents nosocomial transmission. The situation would be classified as high risk only if this evaluation supported a conclusion that nosocomial transmission had occurred. The recommendation will be modified to clarify this point.

Comments: Retesting all employees in a area when a single conversion has occurred may not be warranted.

Response: Clarified wording of this section.

C. Detection of Patients Who Have Active TB

Comments: Provide more information and place more emphasis on early detection, specifically those categories of patients in whom TB should be suspected.

Response: Reemphasized the need for protocols for early detection and the need to review and revise these protocols periodically. In addition, explained that the index of suspicion varies from place to place, depending on various factors, including the prevalence of infection in the population served.

Comments: Increase the recommended turnaround time for stat smears for laboratories unable to use rapid methods and remove the term "stat smears" from recommendations.

Response: Reemphasized the importance of rapid laboratory results. Discouraged batching of specimens and added the recommendation that laboratories that perform mycobacterial tests infrequently refer specimens to an experienced laboratory. Removed the term "stat smears".

D. Management of Patients in Ambulatory Care Settings and Emergency Rooms

Comments: Clarify the requirement that patients should wear surgical masks but that health care workers (HCWs) must wear particulate respirators.

Response: Added a footnote to explain the rationale for each: one to protect the worker from infection and the other to decrease the amount of droplet nuclei in the air produced by the patient.

Comments: Do not require isolation rooms in all ambulatory care settings.

Response: Restated and clarified that if TB patients are seen infrequently or not at all in a facility, an isolation room is not needed. However, there must be a protocol for referral and periodic risk assessment.

E. Management of Hospitalized Patients With TB

Comments: Do not require isolation for most or all pediatric patients.

Response: Provided some examples of potentially infectious pediatric TB patients and added a section explaining the need to evaluate parents as possible source of infection.

Comments: Radiology should not, and in many facilities, cannot have a separate area for TB patients.

Response: Clarified the section to refer only to facilities where many TB patients are seen.

Comments: Provide clearer recommendations for visitors and their use of respiratory protection.

Response: Expanded the recommendations to make clearer.

Comments: Requiring three negative smears to release a patient from isolation is excessive and unnecessary, especially for suspected TB cases.

Response: Clarified: if TB has been ruled out, there is no need to retain the petient in isolation. Reiterated that if TB has been confirmed the patient should have three consecutive negative sputum smears collected on different days.

Comments: The recommendation that TB patients not be discharged to home if an HIV-infected person or young children are in the household is potentially problematic.

Response: Clarified that this is one of many factors that should be taken into consideration when planning to discharge TB patients, not a hard-and-fast rule.

Comments: Labeling door TB Isolation would breach patient confidentiality.

Response: Recommended using the term *Isolation* rather than *TB Isolation* giving hospitals the flexibility to label doors according to individual policies or practices.

F. Engineering Controls

Ultraviolet Germicidal Irradiation

Comments: Data are insufficient to recommend the use of UVGI. Greater emphasis should be placed on the use of UVGI in health care settings.

Response: No change. No new information was provided and the current guidelines were considered appropriate.

Ventilation

Comments: Provide specific recommendations on engineering controls as they relate to risk level. Provide information on how to evaluate air changes per hour (ACHs). There are no data to support requirement for six or more ACHs.

Response: Clarified: 6 ACHs are an absolute minimum, and a level of 12 or more ACHs are recommended, especially in new construction. Referred to table S3–1, which provides the number of air changes per hour and the minutes required for removal efficiencies of 90.0%, 99.0%, and 99.9%. The 12 ACHs or more recommendation was arrived at by both use of this table and NIOSH experimental data. Added discussion on the benefits of higher ventilation and recommended ideal performance criteria.

Comments: Provide retrofit information and some examples of alternative methods for achieving required ventilation.

Response: In response to requests for information on alternative methods, retrofit information, and interim guidelines, expanded the introduction to this section and introduced a clearer hierarchy of ventilation methods.

Comments: Provide clearer directions on bronchoscopy location and ventilation requirements.

Response: The confusion about bronchoscopy location resulted from inconsistency in the guidelines in relation to performing the procedure in the operating room vs. an area of patient isolation. Clarified this point.

Room Units

Comments: Provide information on room air "cleaning" units. Can these units serve as a substitute for not having six or more ACHs?

Response: Revised the document to present more clearly the potential use of air cleaning units in areas where air changes are limited and to set their place in a control hierarchy. In addition, further clarified the importance of placement, performance, and potential limitations. Added a statement that manufacturers of these units should provide documentation of both the efficiency of the HEPA filter and the efficiency of the device in lowering air contaminant levels.

Negative Pressure

Comments: Because smoke can be an irritant, the use of smoke tubes for continuous pressure monitoring should be replaced with flutter strips. Daily monitoring of negative pressure is unnecessary and labor intensive.

Response: Made no change in the recommended monitoring schedule. The concern over the use of smoke tubes is unfounded. Controlled tests by NIOSH have shown that the quantity of smoke that is released is so minute that it is not measurable in the air. The location of the patient and the length of time the patient is exposed dilute the smoke to several orders of magnitude below an 8-hour exposure limit. It is not practical and often not effective to use flutter strips or continuous monitoring devices as alternatives to indicate directional air movement. The air flow (due usually to the small clearance area under a door) is insufficient to move the flutter strip. Likewise, low negative pressure, which will satisfactorily provide adequate directional air flow into the isolation room, may not be readable on continuous monitoring devices. Devices must be capable of reading 0.001 inch of water, the established minimum, to be effective. Clarified the overall guidance in this area by indicating the use of smoke as the optimum test procedure and clearly stating the potential results of flutter strips and continuous instrumentation. Used illustrations to clarify procedures for setting negative pressure.

HEPA Filtration

Comments: The recommendations on the use of HEPA filtration in a ventilation system are not supported by the data. The purpose of its use is unclear.

Response: Addressed the general confusion on the use of HEPA filtration by rewording the section.

Comments: Provide information on the necessity of "bag in—bag out" and "red bag" use when changing filters.

Response: Eliminated the bag in—bag out requirement since there is no evidence that it is needed. Retained the red bag recommendation (treating filters as infectious waste).

G. Respiratory Protection and Supplement 4. Respiratory Protection

Comments: HEPA filtered masks are too expensive, and no data support their use. Instituting a fit-testing program and, in general, a respiratory protection program is too expensive. HCWs will not wear the masks. The masks are uncomfortable, impede communication, and interfere with general patient care.

Response: Retained the original performance criteria on respiratory protection; however, details on specific respirators such as dust-mist and dust-fume-mist were removed. Removed the respiratory protection table and accompanying performance characteristics in the supplement in anticipation of the new certification process. Retained the explanations about fit, fit testing and fit checking, and the elements of a respiratory protection program. Added a statement about ongoing research being conducted on various forms of respiratory protection.

Comments: The performance criteria for respiratory protection for HCWs exposed to tuberculosis fail to take into consideration the potential higher level of risk for workers in selected settings (e.g., bronchoscopy performed on patients suspected of having TB or autopsy performed on deceased persons suspected of having TB at the time of death).

Response: Clarified that the facility's risk assessment may identify those limited settings where the estimated risk for transmission of *M. tuberculosis* may

be such that a level of respiratory protection exceeding the standard criteria is appropriate.

Comments: NIOSH certification process should be changed to accommodate the certification of a more appropriate mask for use in health care settings.

Response: On May 24, 1994, CDC published in the **Federal Register** (59 FR 26850) a Notice of Proposed Rule Making on revised certification requirements for respiratory protective devices. The certification of air-purifying respirators under these proposed requirements would enable respirator users to select from a broader range of certified respirators that meet the current performance criteria in this document.

Comments: Provide information on the storage and reuse of respirators.

Response: Expanded the general guidelines on the reuse of respirators classified as disposable and those with replaceable filters. Retained the original suggestion to refer to manufacturers recommendations concerning storage and reuse.

Comment: It is unclear which facilities must have a respiratory protection program.

Response: Clarified that facilities that do not have isolation rooms for TB, that do not perform cough-inducing procedures, and refer all potential TB patients need not have a respirator program but must perform a periodic risk assessment, have protocols for referral, and an infection control plan that is periodically reviewed.

H. Cough-Inducing Procedures

No comments were received that differed substantively from those covered in other sections of the document.

I. Education and Training of Health-Care Workers

Comments: In general, the comments supported the concept of education for HCWs. Persons from a number of specialties noted that educational programs should be flexible and should allow for the selection of information to be included in these programs and that the frequency of training should be based on the risk of TB transmission in the facility or area. Some suggested emphasis on educating physicians in the early recognition and proper treatment for persons with tuberculosis. Because of difficulties with compliance with attendance and the time needed away from the job in the busy health care environment, concern was expressed about the increasing requirements for mandatory annual educational training sessions on various subjects (bloodborne pathogens, fire safety, hazardous exposure). A few persons suggested that CDC provide standardized training materials. A few commented on the expense of the training program, including the respirator training program.

Response: Modified section to allow more flexibility in selection of topics to cover and frequency of education.

J. Health Care Worker Counseling, Screening and Evaluation

Counseling

Comments: Most of the comments on this section were very favorable. Some persons commented that the HIV-infected HCW may not report their infection to the facility and asked about the facility's responsibility to HCWs and to patients should this occur. Some expressed concern about confidentiality and about the Americans with Disabilities Act.

Response: No changes were considered necessary.

Screening HCWs for Active Disease

Comments: Evaluation of every HCW with a cough of 2 weeks or greater duration is excessive.

Response: Reemphasized the need to tailor each program to fit the situation. The infection rate in a particular facility, the time of year (e.g., flu season), the potential exposure of individual workers—all these need to be taken into consideration.

Screening HCWs for Latent TB Infection

Comments: Annual PPD testing in areas of low prevalence is unnecessary. It is unclear which HCWs should be tested. Provide clearer information on the number of conversions during a specified period to trigger the testing of others from the same area or group.

Response: Modified this section and coordinated it with recommendations in the risk assessment and the skin testing supplement, which give clearer guidance on who should be tested and how frequently.

Comments: Two-step skin testing is not necessary for all HCWs, especially those who are transferring from hospitals and whose PPD results are negative and those from areas where the prevalence of booster phenomenon is low or where boosting was assessed as no problem.

Response: Clarified that 2-step testing is not necessary if an HCW has had a documented negative PPD result in the past 12 months or if the institution has determined that boosting is not common in their population. Also added the potential consequences of misinterpreting a boosted reaction as a new infection.

Evaluation and Management of Health Care Workers With Positive PPD Tests

Evaluation

Comments: M. tuberculosis antimicrobial susceptibilities should be recorded in the HCW's medical record and given to the employee if he or she leaves the facility. The HCW can then be put on appropriate therapy if active disease develops. Persons who are PPD positive and have not had adequate preventive therapy should be monitored at least annually.

Response: Added these recommendations to this section.

Routine and Follow-Up Chest Radiographs

Comments: Consideration should be given to performing chest radiographs on HCWs whose PPD tests are positive.

Response: Reemphasized the need to monitor more frequently for symptoms of TB in high-risk persons but retained the statement that regular chest radiographs have not been shown to be effective in detecting TB in these persons.

Work Restrictions

Comments: Requiring three consecutive negative smears before an HCW who is receiving treatment for active TB can return to work is excessive. A person who has improved does not cough and does not produce sputum and may be kept off duty unnecessarily.

Response: Confusion had been caused by an incorrect wording in the guidelines, that "negative smears on consecutive days" were required. This has been clarified. The recommendation for 3 consecutive negative smears collected on separate days was deemed appropriate and retained.

Comments: If an HCW who has a positive skin test result does not take preventive therapy, the HCW should be required to be seen and interviewed frequently.

Response: The frequency of follow-up was not specified to allow for flexibility.

Supplement 2

Comment: HCWs should be allowed to read their own skin test results.

Response: Retained the recommendation that they not read their own test results and cited a reference as to why they should not.

Comment: Clarification is needed on what constitutes a positive skin test result for HCWs.

Response: Added to the recommendation that a HCW may be

considered positive if the induration is 10 mm or more and referred to the Diagnostic Standards (ATS/CDC statement).

K. Problem Evaluation

Comments and subsequent changes made in the risk assessment section also apply here. Revised this section.

L. Coordination With Public Health Department

No substantive comments or questions received on this section.

M. Additional Considerations for Selected Areas

Comment: What controls are needed in special areas such as hospices and nursing homes?

Response: Added a statement on the need to conduct a risk assessment and have an infection control plan, which should be reviewed and revised regularly. For hospices and nursing homes, it was clarified that TB isolation rooms are not needed if they do not provide care to TB patients. Restated the need for a referral protocol with periodic review.

Supplement 5 Decontamination: Cleaning, Disinfecting, and Sterilizing of Patient-Care Equipment

Comments: Only one comment on this section concerned the cleaning of ventilation ducts.

Response: No changes were considered necessary.

Revised Guidelines

Following are the final guidelines based on analysis of the comments described above.

Dated: October 19, 1994.

Arthur C. Jackson,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994

Contents

Executive Summary

This document updates and replaces all previously published guidelines for the prevention of *Mycobacterium tuberculosis* transmission in health-care facilities. The purpose of this revision is to emphasize the importance of (a) the hierarchy of control measures, including administrative and engineering controls and personal respiratory protection; (b) the use of risk assessments for developing a written tuberculosis (TB) control plan; (c) early identification and management of persons who have TB; (d) TB screening programs for health-care workers (HCWs); (e) HCW training and education; and (f) the evaluation of TB infection-control programs.

Transmission of *M. tuberculosis* is a recognized risk to patients and HCWs in health-care facilities. Transmission is most likely to occur from patients who have unrecognized pulmonary or laryngeal TB, are not on effective anti-TB therapy, and have not been placed in TB isolation. Several recent TB outbreaks in health-care facilities, including outbreaks of multidrug-resistant TB, have heightened concern about nosocomial transmission. Patients who have multidrug-resistant TB can remain infectious for prolonged periods, which increases the risk for nosocomial and/or occupational transmission of *M. tuberculosis*. Increases in the incidence of TB have been observed in some geographic areas; these increases are related partially to the high risk for TB among immunosuppressed persons, particularly those infected with human immunodeficiency virus (HIV). Transmission of *M. tuberculosis* to HIV-infected persons is of particular concern because these persons are at high risk for developing active TB if they become infected with the bacteria. Thus, health-care facilities should be particularly alert to the need for preventing transmission of *M. tuberculosis* in settings in which HIV-infected persons work or receive care.

Supervisory responsibility for the TB infection-control program should be assigned to a designated person or group of persons who should be given the authority to implement and enforce TB infection-control policies. An effective TB infection-control program requires early identification, isolation, and treatment of persons who have active TB. The primary emphasis of TB infection-control plans in health-care facilities should be achieving these three goals by the application of a hierarchy of control measures, including (a) the use of administrative measures to reduce the risk for exposure to persons who have infectious TB, (b) the use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei, and (c) the use of personal respiratory protective equipment in areas where there is still a risk for exposure to *M. tuberculosis* (e.g., TB isolation rooms). Implementation of a TB infection-control program requires risk assessment and development of a TB infection-control plan; early identification, treatment, and isolation of infectious TB patients; effective engineering controls; an appropriate respiratory protection program; HCW TB training, education, counseling, and screening; and evaluation of the program's effectiveness.

Although completely eliminating the risk for transmission of *M. tuberculosis* in all health-care facilities may not be possible at the present time, adherence to these guidelines should reduce the risk to persons in these settings. Recently, nosocomial TB outbreaks have demonstrated the substantial morbidity and mortality among patients and HCWs that have been associated with incomplete implementation of CDC's *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, with Special Focus on HIV-Related Issues* published in 1990.* Follow-up investigations at some of these hospitals have documented that complete implementation of measures similar or identical to those in the *1990 TB Guidelines* significantly reduced or eliminated nosocomial transmission of *M. tuberculosis* to patients and/or HCWs.

I. Introduction

A. Purpose of Document

In April 1992, the National MDR–TB Task Force published the *National Action Plan to Combat Multidrug-Resistant Tuberculosis* (*1*). The publication was a response to reported nosocomial outbreaks of tuberculosis (TB), including outbreaks of multidrug-resistant TB (MDR–TB), and the increasing incidence of TB in some geographic areas. The plan called for the update and revision of the guidelines for preventing nosocomial transmission of *Mycobacterium tuberculosis* published December 7, 1990 (*2*).

Public meetings were held in October 1992 and January 1993 to discuss revision of the *1990 TB Guidelines* (*2*). CDC received considerable input on various aspects of infection control, including health-care worker (HCW) education; administrative controls (e.g., having protocols for the early identification and management of patients who have TB); the need for more specific recommendations regarding ventilation; and clarification on the use of respiratory protection in health-care settings. On the basis of these events and the input received, on October 12, 1993, CDC published in the **Federal Register** the *Draft Guidelines For Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition* (*3*). During and after the 90-day comment period following publication of this draft, CDC's TB Infection-Control Guidelines Work Group received and reviewed more than 2,500 comments.

The purpose of this document is to make recommendations for reducing the risk for transmitting *M. tuberculosis* to HCWs, patients, volunteers, visitors, and other persons in these settings. The information also may serve as a useful resource for educating HCWs about TB.

These recommendations update and replace all previously published CDC recommendations for TB infection control in health-care facilities (*2, 4*). The recommendations in this document are applicable primarily to inpatient facilities in which health care is provided (e.g., hospitals, medical wards in correctional facilities, nursing homes,

*CDC. *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, with Special Focus on HIV-Related Issues.* MMWR 1990; 39 (No. RR–17).

and hospices). Recommendations applicable to ambulatory-care facilities, emergency departments, home-health-care settings, emergency medical services, medical offices, dental settings, and other facilities or residential settings that provide medical care are provided in separate sections, with cross-references to other sections of the guidelines if appropriate.

Designated personnel at health-care facilities should conduct a risk assessment for the entire facility and for each area* and occupational group, determine the risk for nosocomial or occupational transmission of *M. tuberculosis*, and implement an appropriate TB infection-control program. The extent of the TB infection-control program may range from a simple program emphasizing administrative controls in settings where there is minimal risk for exposure to *M. tuberculosis*, to a comprehensive program that includes administrative controls, engineering controls, and respiratory protection in settings where the risk for exposure is high. In all settings, administrative measures should be used to minimize the number of HCWs exposed to *M. tuberculosis* while still providing optimal care for TB patients. HCWs providing care to patients who have TB should be informed about the level of risk for transmission of *M. tuberculosis* and the appropriate control measures to minimize that risk.

In this document, the term "HCWs" refers to all the paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis*. This may include, but is not limited to, physicians; nurses; aides; dental workers; technicians; workers in laboratories and morgues; emergency medical service (EMS) personnel; students; part-time personnel; temporary staff not employed by the health-care facility; and persons not involved directly in patient care but who are potentially at risk for occupational exposure to *M. tuberculosis* (e.g., volunteer workers and dietary, housekeeping, maintenance, clerical, and janitorial staff).

Although the purpose of this document is to make recommendations for reducing the risk for transmission of *M. tuberculosis* in health-care facilities, the process of implementing these recommendations must safeguard, in accordance with applicable state and federal laws, the confidentiality and civil rights of persons who have TB.

B. Epidemiology, Transmission, and Pathogenesis of TB

The prevalence of TB is not distributed evenly throughout all segments of the U.S. population. Some subgroups or persons have a higher risk for TB either because they are more likely than other persons in the general population to have been exposed to and infected with *M. tuberculosis* or because their infection is more likely to progress to active TB after they have been infected (*5*). In some cases, both of these factors may be present. Groups of persons known to have a higher prevalence of TB infection include contacts of persons who have active TB, foreign-born persons from areas of the world with a high prevalence of TB (e.g., Asia, Africa, the Caribbean, and Latin America), medically underserved populations (e.g., some African-Americans, Hispanics, Asians and Pacific Islanders, American Indians, and Alaskan Natives), homeless persons, current or former correctional-facility inmates, alcoholics, injecting-drug users, and the elderly. Groups with a higher risk for progression from latent TB infection to active disease include persons who have been infected recently (i.e., within the previous 2 years), children less than <4 years of age, persons with fibrotic lesions on chest radiographs, and persons with certain medical conditions (i.e., human immunodeficiency virus [HIV] infection, silicosis, gastrectomy or jejuno-ileal bypass, being ≥10% below ideal body weight, chronic renal failure with renal dialysis, diabetes mellitus, immunosuppression resulting from receipt of high-dose corticosteroid or other immunosuppressive therapy, and some malignancies) (*5*).

M. tuberculosis is carried in airborne particles, or droplet nuclei, that can be generated when persons who have pulmonary or laryngeal TB sneeze, cough, speak, or sing (*6*). The particles are an estimated 1–5 μm in size, and normal air currents can keep them airborne for prolonged time periods and spread them throughout a room or building (*7*). Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, and these droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli of the lungs. Once in the alveoli, the organisms are taken up by alveolar macrophages and spread throughout the body. Usually within 2–10 weeks after initial infection with *M. tuberculosis*, the immune response limits further multiplication and spread of the tubercle bacilli; however, some of the bacilli remain dormant and viable for many years. This condition is referred to as latent TB infection. Persons with latent TB infection usually have positive purified protein derivative (PPD)-tuberculin skin-test results, but they do not have symptoms of active TB, and they are not infectious.

In general, persons who become infected with *M. tuberculosis* have approximately a 10% risk for developing active TB during their lifetimes. This risk is greatest during the first 2 years after infection. Immunocompromised persons have a greater risk for the progression of latent TB infection to active TB disease; HIV infection is the strongest known risk factor for this progression. Persons with latent TB infection who become coinfected with HIV have approximately an 8%–10% risk per year for developing active TB (*8*). HIV-infected persons who are already severely immunosuppressed and who become newly infected with *M. tuberculosis* have an even greater risk for developing active TB (*9–12*).

The probability that a person who is exposed to *M. tuberculosis* will become infected depends primarily on the concentration of infectious droplet nuclei in the air and the duration of exposure. Characteristics of the TB patient that enhance transmission include (a) disease in the lungs, airways, or larynx; (b) presence of cough or other forceful expiratory measures; (c) presence of acid-fast bacilli (AFB) in the sputum; (d) failure of the patient to cover the mouth and nose when coughing or sneezing; (e) presence of cavitation on chest radiograph; (f) inappropriate or short duration of chemotherapy; and (g) administration of procedures that can induce coughing or cause aerosolization of *M. tuberculosis* (e.g., sputum induction). Environmental factors that enhance the likelihood of transmission include (a) exposure in relatively small, enclosed spaces; (b) inadequate local or general ventilation that results in insufficient dilution and/or removal of infectious droplet nuclei; and (c) recirculation of air containing infectious droplet nuclei. Characteristics of the persons exposed to *M. tuberculosis* that may affect the risk for becoming infected are not as well defined. In general, persons who have been infected previously with *M. tuberculosis* may be less susceptible to subsequent infection. However, reinfection can occur among previously infected persons, especially if they are

* Area: a structural unit (e.g., a hospital ward or laboratory) or functional unit (e.g., an internal medicine service) in which HCWs provide services to and share air with a specific patient population or work with clinical specimens that may contain viable *M. tuberculosis* organisms. The risk for exposure to *M. tuberculosis* in a given area depends on the prevalence of TB in the population served and the characteristics of the environment.

severely immunocompromised. Vaccination with Bacille of Calmette and Guérin (BCG) probably does not affect the risk for infection; rather, it decreases the risk for progressing from latent TB infection to active TB (*13*). Finally, although it is well established that HIV infection increases the likelihood of progressing from latent TB infection to active TB, it is unknown whether HIV infection increases the risk for becoming infected if exposed to *M. tuberculosis*.

C. Risk for Nosocomial Transmission of *M. Tuberclosis*

Transmission of *M. tuberclosis* is a recognized risk in health-care facilities (*14–22*). The magnitude of the risk varies considerably by the type of health-care facility, the prevalence of TB in the community, the patient population served, the HCW's occupational group, the area of the health-care facility in which the HCW works, and the effectiveness of TB infection-control interventions. The risk may be higher in areas where patients with TB are provided care before diagnosis and initiation of TB treatment and isolation precautions (e.g., in clinic waiting areas and emergency departments) or where diagnostic or treatment procedures that stimulate coughing are performed. Nosocomial transmission of *M. tuberclosis* has been associated with close contact with persons who have infectious TB and with the performance of certain procedures (e.g., bronchoscopy [*17*], endotracheal intubation and suctioning [*18*], open abscess irrigation [*20*], and autopsy [*21,22*]). Sputum induction and aerosol treatments that induce coughing may also increase the potential for transmission of *M. tuberclosis* (*23,24*). Personnel of health-care facilities should be particularly alert to the need for preventing transmission of *M. tuberclosis* in those facilities in which immunocompromised persons (e.g., HIV-infected persons) work or receive care—especially if cough-inducing procedures, such as sputum induction and aerosolized pentamidine treatments, are being performed.

Several TB outbreaks among persons in health-care facilities have been reported recently (*11,24–28*; CDC, unpublished data). Many of these outbreaks involved transmission of multidrug-resistant strains of *M. tuberclosis* to both patients and HCWs. Most of the patients and some of the HCWs were HIV-infected persons in whom new infection progressed rapidly to active disease. Mortality associated with those outbreaks was high (range: 43%–93%). Furthermore, the interval between diagnosis and death was brief (range of median intervals: 4–16 weeks). Factors contributing to these outbreaks included delayed diagnosis of TB, delayed recognition of drug resistance, and delayed initiation of effective therapy—all of which resulted in prolonged infectiousness, delayed initiation and inadequate duration of TB isolation, inadequate ventilation in TB isolation rooms, lapses in TB isolation practices and inadequate precautions for cough-inducing procedures, and lack of adequate respiratory protection. Analysis of data collected from three of the health-care facilities involved in the outbreaks indicates that transmission of *M. tuberclosis* decreased significantly or ceased entirely in areas where measures similar to those in the *1990 TB Guidelines* were implemented (*2,29–32*). However, several interventions were implemented simultaneously, and the effectiveness of the separate interventions could not be determined.

D. Fundamentals of TB Infection Control

An effective TB infection-control program requires early identification, isolation, and effective treatment of persons who have active TB. The primary emphasis of the TB infection-control plan should be on achieving these three goals. In all health-care facilities, particularly those in which persons who are at high risk for TB work or receive care, policies and procedures for TB control should be developed, reviewed periodically, and evaluated for effectiveness to determine the actions necessary to minimize the risk for transmission of *M. tuberclosis*.

The TB infection-control program should be based on a hierarchy of control measures. The first level of the hierarchy, and that which affects the largest number of persons, is using administrative measures intended primarily to reduce the risk for exposing uninfected persons to persons who have infectious TB. These measures include (a) developing and implementing effective written policies and protocols to ensure the rapid identification, isolation, diagnostic evaluation, and treatment of persons likely to have TB; (b) implementing effective work practices among HCWs in the health-care facility (e.g., correctly wearing respiratory protection and keeping doors to isolation rooms closed); (c) educating, training, and counseling HCWs about TB; and (d) screening HCWs for TB infection and disease.

The second level of the hierarchy is the use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei. These controls include (a) direct source control using local exhaust ventilation, (b) controlling direction of airflow to prevent contamination of air in areas adjacent to the infectious source, (c) diluting and removing contaminated air via general ventilation, and (d) air cleaning via air filtration or ultraviolet germicidal irradiation (UVGI).

The first two levels of the hierarchy minimize the number of areas in the health-care facility where exposure to infectious TB may occur, and they reduce, but do not eliminate, the risk in those few areas where exposure to *M. tuberculosis* can still occur (e.g., rooms in which patients with known or suspected infectious TB are being isolated and treatment rooms in which cough-inducing or aerosol-generating procedures are performed on such patients). Because persons entering such rooms may be exposed to *M. tuberculosis*, the third level of the hierarchy is the use of personal respiratory protective equipment in these and certain other situations in which the risk for infection with *M. tuberculosis* may be relatively higher.

Specific measures to reduce the risk for transmission of *M. tuberculosis* include the following:

- Assigning to specific persons in the health-care facility the supervisory responsibility for designing, implementing, evaluating, and maintaining the TB infection-control program (Section II.A).
- Conducting a risk assessment to evaluate the risk for transmission of *M. tuberculosis* in all areas of the health-care facility, developing a written TB infection-control program based on the risk assessment, and periodically repeating the risk assessment to evaluate the effectiveness of the TB infection-control program (Section II.B).
- Developing, implementing, and enforcing policies and protocols to ensure early identification, diagnostic evaluation, and effective treatment of patients who may have infectious TB (Section II.C; Suppl. 2).
- Providing prompt triage for and appropriate management of patients in the outpatient setting who may have infectious TB (Section II.D).
- Promptly initiating and maintaining TB isolation for persons who may have infectious TB and who are admitted to the inpatient setting (Section II.E; Suppl. 1).
- Effectively planning arrangements for discharge (Section II.E).
- Developing, installing, maintaining, and evaluating ventilation and other engineering controls to reduce the

potential for airborne exposure to *M. tuberculosis* (Section II.F; Suppl. 3).

• Developing, implementing, maintaining, and evaluating a respiratory protection program (Section II.G; Suppl. 4).

• Using precautions while performing cough-inducing procedures (Section II.H; Suppl. 3).

• Educating and training HCWs about TB, effective methods for preventing transmission of *M. tuberculosis*, and the benefits of medical screening programs (Section II.I).

• Developing and implementing a program for routine periodic counseling and screening of HCWs for active TB and latent TB infection (Section II.J; Suppl. 2).

• Promptly evaluating possible episodes of *M. tuberculosis* transmission in health-care facilities, including PPD skin-test conversions among HCWs, epidemiologically associated cases among HCWs or patients, and contacts of patients or HCWs who have TB and who were not promptly identified and isolated (Section II.K).

• Coordinating activities with the local public health department, emphasizing reporting, and ensuring adequate discharge follow-up and the continuation and completion of therapy (Section II.L).

II. Recommendations

A. Assignment of Responsibility

• Supervisory responsibility for the TB infection-control program should be assigned to a designated person or group of persons with expertise in infection control, occupational health, and engineering. These persons should be given the authority to implement and enforce TB infection-control policies.

• If supervisory responsibility is assigned to a committee, one person should be designated as the TB contact person. Questions and problems can then be addressed to this person.

B. Risk Assessment, Development of the TB Infection-Control Plan, and Periodic Reassessment

1. Risk Assessment

a. General.

• TB infection-control measures for each health-care facility should be based on a careful assessment of the risk for transmission of *M. tuberculosis* in that particular setting. The first step in developing the TB infection-control program should be to conduct a baseline risk assessment to evaluate the risk for transmission of *M. tuberculosis* in each area and occupational group in the facility (Table 1, Figure 1). Appropriate infection-control interventions can then be developed on the basis of actual risk. Risk assessments should be performed for all inpatient and outpatient settings (e.g., medical and dental offices).

• Regardless of risk level, the management of patients with known or suspected infectious TB should not vary. However, the index of suspicion for infectious TB among patients, the frequency of HCW PPD skin testing, the number of TB isolation rooms, and other factors will depend on whether the risk for transmission of *M. tuberculosis* in the facility, area, or occupational group is high, intermediate, low, very low, or minimal.

• The risk assessment should be conducted by a qualified person or group of persons (e.g., hospital epidemiologists, infectious disease specialists, pulmonary disease specialists, infection-control practitioners, health-care administrators, occupational health personnel, engineers, HCWs, or local public health personnel).

• The risk assessment should be conducted for the entire facility and for specific areas within the facility (e.g., medical, TB, pulmonary, or HIV wards; HIV, infectious disease, or pulmonary clinics; and emergency departments or other areas where TB patients might receive care or where cough-inducing procedures are performed). This should include both inpatient and outpatient areas. In addition, risk assessments should be conducted for groups of HCWs who work throughout the facility rather than in a specific area (e.g., respiratory therapists; bronchoscopists; environmental services, dietary, and maintenance personnel; and students, interns, residents, and fellows).

• Classification of risk for a facility, for a specific area, and for a specific occupational group should be based on (a) the profile of TB in the community; (b) the number of infectious TB patients admitted to the area or ward, or the estimated number of infectious TB patients to whom HCWs in an occupational group may be exposed; and (c) the results of analysis of HCW PPD test conversions (where applicable) and possible person-to-person transmission of *M. tuberculosis* (Figure 1).

• All TB infection-control programs should include periodic reassessments of risk. The frequency of repeat risk assessments should be based on the results of the most recent risk assessment (Table 2, Figure 1).

• The "minimal-risk" category applies only to an entire facility. A "minimal-risk" facility does not admit TB patients to inpatient or outpatient areas and is not located in a community with TB (i.e., counties or communities in which TB cases have not been reported during the previous year). Thus, there is essentially no risk for exposure to TB patients in the facility. This category may also apply to many outpatient settings (e.g., many medical and dental offices).

Table 1. Elements of a Risk Assessment for Tuberculosis (TB) in Health-care Facilities

1. Review the community TB profile (from public health department data).
2. Review the number of TB patients who were treated in each area of the facility (both inpatient and outpatient). (This information can be obtained by analyzing laboratory surveillance data and by reviewing discharge diagnoses or medical and infection-control records.)
3. Review the drug-susceptibility patterns of TB isolates of patients who were treated at the facility.
4. Analyze purified protein derivative (PPD)-tuberculin skin-test results of health-care workers (HCWs), by area or by occupational group for HCWs not assigned to specific area (e.g., respiratory therapists).
5. To evaluate infection-control parameters, review medical records of a sample of TB patients seen at the facility.

Calculate Intervals From

• Admission until TB suspected;
• Admission until TB evaluation performed;
• Admission until acid-fast bacilli (AFB) specimens ordered;
• AFB specimens ordered until AFB specimens collected;
• AFB specimens collected until AFB smears performed and reported;
• AFB specimens collected until cultures performed and reported;
• AFB specimens collected until species identification conducted and reported;
• AFB specimens collected until drug-susceptibility tests performed and reported;
• Admission until TB isolation initiated;
• Admission until TB treatment initiated; and
• Duration of TB isolation.

Obtain the Following Additional Information

• Were appropriate criteria used for discontinuing isolation?
• Did the patient have a history of prior admission to the facility?
• Was the TB treatment regimen adequate?
• Were follow-up sputum specimens collected properly?

- Was appropriate discharge planning conducted?

6. Perform an observational review of TB infection control practices.

7. Review the most recent environmental evaluation and maintenance procedures.

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FIGURE 1. Protocol for conducting a tuberculosis (TB) risk assessment in a health-care facility

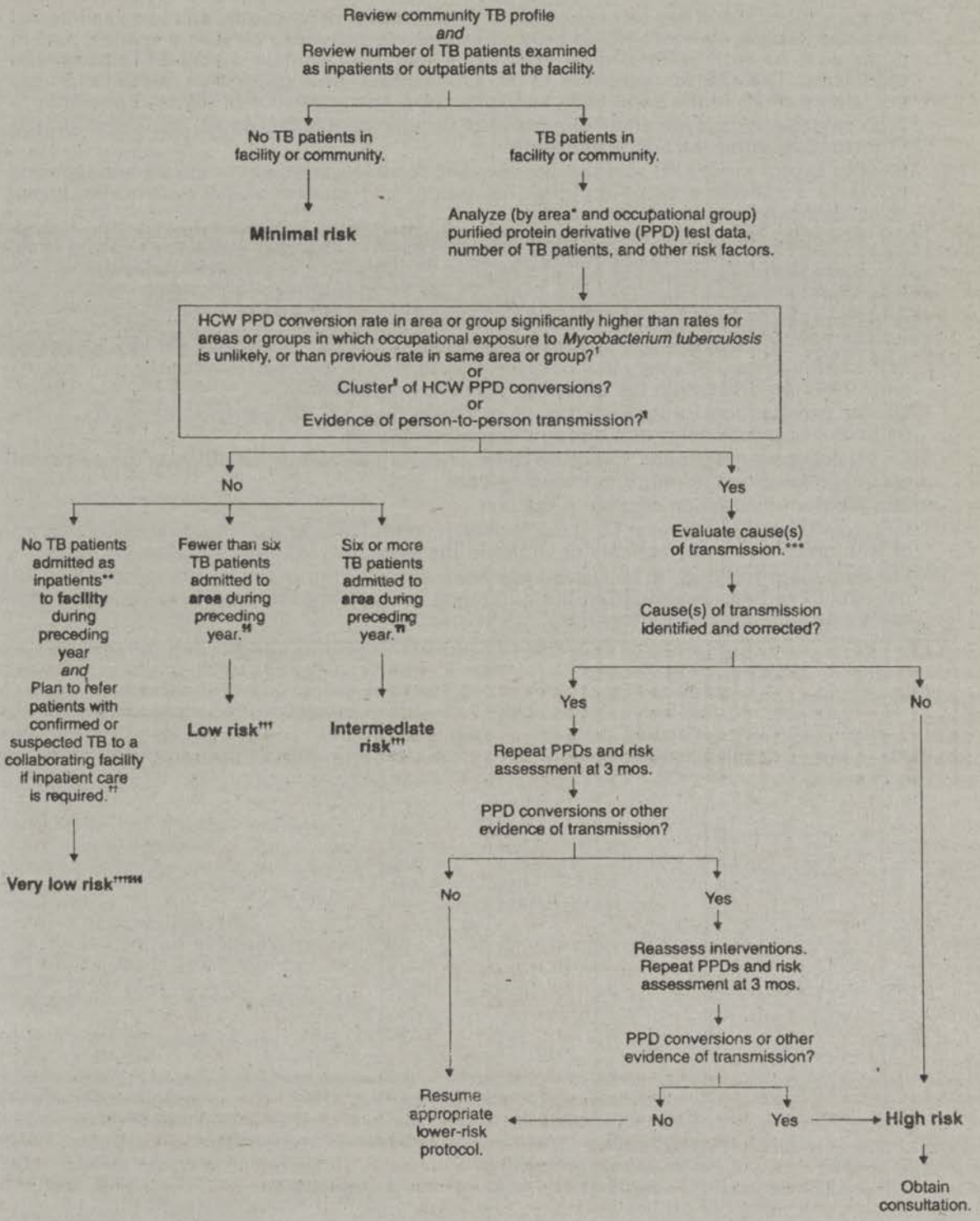

FIGURE 1. Protocol for conducting a TB risk assessment in a health-care facility — Continued

*Area: a structural unit (e.g., a hospital ward or laboratory) or functional unit (e.g., an internal medicine service) in which HCWs provide services to and share air with a specific patient population or work with clinical specimens that may contain viable *M. tuberculosis* organisms. The risk for exposure to *M. tuberculosis* in a given area depends on the prevalence of TB in the population served and the characteristics of the environment.

†With epidemiologic evaluation suggestive of occupational (nosocomial) transmission (see Problem Evaluation section in the text).

§Cluster: two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational (nosocomial) transmission.

¶For example, clusters of *M. tuberculosis* isolates with identical DNA fingerprint (RFLP) patterns or drug-resistance patterns, with epidemiologic evaluation suggestive of nosocomial transmission (see Problem Evaluation section in the text).

**Does not include patients identified in triage system and referred to a collaborating facility or patients being managed in outpatient areas.

††To prevent inappropriate management and potential loss to follow-up of patients identified in the triage system of a very low-risk facility as having suspected TB, an agreement should exist for referral between the referring and receiving facilities.

§§Or, for occupational groups, exposure to fewer than six TB patients for HCWs in the particular occupational group during the preceding year.

¶¶Or, for occupational groups, exposure to six or more TB patients for HCWs in the particular occupational group during the preceding year.

***See Problem Evaluation section in the text.

†††Occurrence of drug-resistant TB in the facility or community, or a relatively high prevalence of HIV infection among patients or HCWs in the area, may warrant a higher risk rating.

§§§For outpatient facilities, if TB cases have been documented in the community but no TB patients have been examined in the outpatient area during the preceding year, the area can be designated as very low risk.

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TABLE 2.—ELEMENTS OF A TUBERCULOSIS (TB) INFECTION-CONTROL PROGRAM

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Assigning responsibility (Section II.A)					
Designated TB control officer or committee	R	R	R	R	R
Conducting a risk assessment (Section II.B.1)					
Baseline risk assessment	R	R	R	R	R
Community TB profile: incidence, prevalence, and drug-susceptibility patterns.	Y	Y	Y	Y	Y
Facility case surveillance (laboratory- and discharge-diagnosis-based).	C	C	C	C	C
Analysis of purified protein derivative (PPD) test results among health-care workers (HCWs).	N/A	V*	Y	Every 6–12 mos	Every 3 mos.
Review of TB patient medical records	N/A	O†	Y	Every 6–12 mos	Every 3 mos.
Observation of infection-control practices	N/A	N/A	Y	Every 6–12 mos	Every 3 mos.
Evaluation of engineering control maintenance	O§	O§	Y	Every 6–12 mos	Every 3 mos.
Developing a TB infection control plan (Section II.B.2)					
Written TB infection control plan	R	R	R	R	R
Periodically reassessing risk (Section II.B.3)					
Reassessment of risk	Y	Y	Y	Every 6–12 mos	Every 3 mos.
Identifying, evaluating, and initiating treatment for patients who may have active TB (Section II.C)					
Protocol (clinical prediction rules¶ for identifying patients who may have active TB.	R	R	R	R	R
Protocol for diagnostic evaluation of patients who may have active TB**.	N/A	R	R	R	R
Protocol for reporting laboratory results to clinicians, infection-control practitioners, collaborating referral facilities, and appropriate health department(s).	N/A	R	R	R	R
Protocol for initiating treatment of patients who may have active TB**.	N/A	R	R	R	R
Managing patients who may have TB in ambulatory-care settings and emergency departments (Section II.D)					
Triage system for identifying patients who have active TB in emergency departments and ambulatory-care settings.	R	R	R	R	R
Protocol for managing patients who may have active TB in emergency departments and ambulatory-care settings.	R	R	R	R	R
Protocol for referring patients who may have active TB to collaborating facility.	R	R	N/A††	N/A††	N/A††
Managing hospitalized patients who may have TB (Section II.E)					
Appropriate number of TB isolation rooms N/A§§	N/A	N/A	R	R	R
Protocol for initiating TB isolation	N/A	N/A	R	R	R
Protocol for TB isolation practices	N/A	N/A	R	R	R
Protocol for discontinuing TB isolation	N/A	N/A	R	R	R
Protocol for discharge planning	N/A	N/A	R	R	R
Engineering controls (Suppl. 3, Section II.F)					
Protocol(s) for maintenance of engineering controls	O§	O§	R	R	R
Respiratory protection (Suppl. 4, Section II.G)					
Respiratory protection program	N/A	V*	R	R	R
Cough-inducing and aerosol-generating procedures (Section II.H)					
Protocol(s) for performing cough-inducing or aerosol-generating procedures.	O	O¶¶	R	R	R
Engineering controls for performing cough-inducing or aerosol-generating procedures.	O§	O¶¶	R	R	R
Educating and Training HCWs (Section II.I)					
Educating and training HCWs regarding TB	R	R	R	R	R
Counseling and screening HCWs (Section II.J)					
Counseling HCWs regarding TB	R	R	R	R	R
Protocol for identifying and evaluating HCWs who have signs or symptoms of active TB.	R	R	R	R	R
Baseline PPD testing of HCWs	O***	R	R	R	R
Routine periodic PPD screening of HCWs for latent TB infection.	N/A	V*	Y	Every 6–12 mos	Every 3 mos.
Protocol for evaluating and managing HCWs who have positive PPD tests.	R	R	R	R	R
Protocol for managing HCWs who have active TB	R	R	R	R	R
Conducting a problem evaluation (Section II.K)					
Protocol for investigating PPD conversions and active TB in HCWs.	R	R	R	R	R

TABLE 2.—ELEMENTS OF A TUBERCULOSIS (TB) INFECTION-CONTROL PROGRAM—Continued

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Protocol for investigating possible patient-to-patient transmission of *Mycobacterium tuberculosis.*	R	R	R	R	R
Protocol for investigating possible contacts of TB patients who were not diagnosed initially as having TB and were not placed in isolation.	R	R	R	R	R
Coordination with the public health department (Section II.L)					
Effective system for reporting patients who have suspected or confirmed TB to appropriate health department(s).	R	R	R	R	R

R=recommended; Y=yearly; C=continual; N/A=not applicable; O=optional; V=variable.

*Because very low-risk facilities do not admit patients who may have active TB to inpatient areas, most HCWs in such facilities do not need routine follow-up PPD screening after baseline PPD testing is done. However, those who are involved in the initial assessment and diagnostic evaluation of patients in the ambulatory-care, emergency, and admitting departments of such facilities or in the outpatient management of patients with active TB could be exposed potentially to a patient who has active TB. These HCWs may need to receive routine periodic PPD screening. Similarly, these HCWs may need to be included in a respiratory protection program.

†Because very low-risk facilities do not admit patients suspected of having active TB, review of TB patient medical records is not applicable. However, follow-up of patients who were identified during triage as possibly having active TB and referred to another institution for further evaluation and management may be useful in evaluating the effectiveness of the triage system.

§Some minimal or very low-risk facilities may elect to use engineering controls (e.g., booths for cough-inducing procedures, portable high-efficiency particulate [HEPA] filtration units, ultraviolet germicidal irradiation units) in triage/waiting areas. In such situations, appropriate protocols for maintaining this equipment should be in place, and this maintenance should be evaluated periodically.

¶The criteria used in clinical prediction rules will probably vary from facility to facility depending on the prevalence of TB in the population served by the facility and on the clinical, radiographic, and laboratory characteristics of TB patients examined in the facility.

**The protocols should be consistent with CDC/American Thoracic Society recommendations (*33*).

††Protocols for referring patients who require specialized treatment (e.g., patients with multidrug-resistant TB) may be appropriate.

§§Based on maximum daily number of patients requiring TB isolation for suspected or confirmed active TB. Isolation rooms should meet the performance criteria specified in these guidelines.

¶¶If such procedures are used in the triage protocol(s) for identifying patients who may have active TB.

***Minimal-risk facilities do not need to maintain an ongoing PPD skin-testing program. However, baseline PPD testing of HCWs may be advisable so that if an unexpected exposure does occur, conversions can be distinguished from positive PPD test results caused by previous exposures.

• The "very low-risk" category generally applies only to an entire facility. A very low-risk facility is one in which (a) patients with active TB are not admitted to inpatient areas but may receive initial assessment and diagnostic evaluation or outpatient management in outpatient areas (e.g., ambulatory-care and emergency departments) and (b) patients who may have active TB and need inpatient care are promptly referred to a collaborating facility. In such facilities, the outpatient areas in which exposure to patients with active TB could occur should be assessed and assigned to the appropriate low-, intermediate-, or high-risk category. Categorical assignment will depend on the number of TB patients examined in the area during the preceding year and whether there is evidence of nosocomial transmission of *M. tuberculosis* in the area. If TB cases have been reported in the community, but no patients with active TB have been examined in the outpatient area during the preceding year, the area can be designated as very low risk (e.g., many medical offices).

The referring and receiving facilities should establish a referral agreement to prevent inappropriate management and potential loss to follow-up of patients suspected of having TB during evaluation in the triage system of a very low-risk facility.

In some facilities in which TB patients are admitted to inpatient areas, a very low-risk protocol may be appropriate for areas (e.g., administrative areas) or occupational groups that have only a very remote possibility of exposure to *M. tuberculosis.*

The very low-risk category may also be appropriate for outpatient facilities that do not provide initial assessment of persons who may have TB, but do screen patients for active TB as part of a limited medical screening before undertaking specialty care (e.g., dental settings).

• "Low-risk" areas or occupational groups are those in which (a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, (b) no clusters* of PPD test conversions have occurred, (c) person-to-person transmission of *M. tuberculosis* has not been detected, and (d) fewer than six TB patients are examined or treated per year.

• "Intermediate-risk" areas or occupational groups are those in which (a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, (b) no clusters of PPD test conversions have occurred, (c) person-to-person transmission of *M. tuberculosis)* has not been detected, and (d) six or more patients with active TB are examined or treated each year. Survey data suggest that facilities in which six or more TB patients are examined or treated each year may have an increased risk for transmission of *M. tuberculosis* (CDC, unpublished data); thus, areas in which six or more patients with active TB are examined or treated each year (or occupational groups in which HCWs are likely to be exposed to six or more TB patients per year) should be classified as "intermediate risk."

• "High-risk" areas or occupational groups are those in which (a) the PPD test conversion rate is significantly greater than for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or

*Cluster: two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational (nosocomial) transmission.

group, and epidemiologic evaluation suggests nosocomial transmission; or (b) a cluster of PPD test conversions has occurred, and epidemiologic evaluation suggests nosocomial transmission of *M. tuberculosis*; or (c) possible person-to-person transmission of *M. tuberculosis* has been detected.

• If no data or insufficient data for adequate determination of risk have been collected, such data should be compiled, analyzed, and reviewed expeditiously.

b. Community TB profile.

• A profile of TB in the community that is served by the facility should be obtained from the public health department. This profile should include, at a minimum, the incidence (and prevalence, if available) of active TB in the community and the drug-susceptibility patterns of *M. tuberculosis* isolates (i.e., the antituberculous agents to which each isolate is susceptible and those to which it is resistant) from patients in the community.

c. Case surveillance.

• Data concerning the number of suspected and confirmed active TB cases among patients and HCWs in the facility should be systematically collected, reviewed, and used to estimate the number of TB isolation rooms needed, to recognize possible clusters of nosocomial transmission, and to assess the level of potential occupational risk. The number of TB patients in specific areas of a facility can be obtained from laboratory surveillance data on specimens positive for AFB smears or *M. tuberculosis* cultures, from infection-control records, and from databases containing information about hospital discharge diagnoses.

• Drug-susceptibility patterns of *M. tuberculosis* isolates from TB patients treated in the facility should be reviewed to identify the frequency and patterns of drug resistance. This information may indicate a need to modify the initial treatment regimen or may suggest possible nosocomial transmission or increased occupational risk.

d. Analysis of HCW PPD test screening data.

• Results of HCW PPD testing should be recorded in the individual HCW's employee health record and in a retrievable aggregate database of all HCW PPD test results. Personal identifying information should be handled confidentially. PPD test conversion rates should be calculated at appropriate intervals to estimate the risk for PPD test conversions for each area of the facility and for each specific occupational group not assigned to a specific area (Table 2). To calculate PPD test conversion rates, the total number of previously PPD-negative HCWs tested in each area or group (i.e., the denominator) and the number of PPD test conversions among HCWs in each area or group (the numerator) must be obtained.

• PPD test conversion rates for each area or occupational group should be compared with rates for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely and with previous conversion rates in the same area or group to identify areas or groups where the risk for occupational PPD test conversions may be increased. A low number of HCWs in a specific area may result in a greatly increased rate of conversion for that area, although the actual risk may not be significantly greater than that for other areas. Testing for statistical significance (e.g., Fisher's exact test or chi square test) may assist interpretation; however, lack of statistical significance may not rule out a problem (i.e., if the number of HCWs tested is low, there may not be adequate statistical power to detect a significant difference). Thus, interpretation of individual situations is necessary.

• An epidemiologic investigation to evaluate the likelihood of nosocomial transmission should be conducted if PPD test conversions are noted (Section II.K.1).

• The frequency and comprehensiveness of the HCW PPD testing program should be evaluated periodically to ensure that all HCWs who should be included in the program are being tested at appropriate intervals. For surveillance purposes, earlier detection of transmission may be enhanced if HCWs in a given area or occupational group are tested on different scheduled dates rather than all being tested on the same date (Section II.J.3).

e. Review of TB patient medical records.

• The medical records of a sample of TB patients examined at the facility can be reviewed periodically to evaluate infection-control parameters (Table 1). Parameters to examine may include the intervals from date of admission until (a) TB was suspected, (b) specimens for AFB smears were ordered, (c) these specimens were collected, (d) tests were performed, and (e) results were reported. Moreover, the adequacy of the TB treatment regimens that were used should be evaluated.

• Medical record reviews should note previous hospital admissions of TB patients before the onset of TB symptoms. Patient-to-patient transmission may be suspected if active TB occurs in a patient who had a prior hospitalization during which exposure to another TB patient occurred or if isolates from two or more TB patients have identical characteristic drug-susceptibility or DNA fingerprint patterns.

• Data from the case review should be used to determine if there is a need to modify (a) protocols for identifying and isolating patients who may have infectious TB, (b) laboratory procedures, (c) administrative policies and practices, or (d) protocols for patient management.

f. Observation of TB infection-control practices.

• Assessing adherence to the policies of the TB infection-control program should be part of the evaluation process. This assessment should be performed on a regular basis and whenever an increase occurs in the number of TB patients or HCW PPD test conversions. Areas at high risk for transmission of *M. tuberculosis* should be monitored more frequently than other areas. The review of patient medical records provides information on HCW adherence to some of the policies of the TB infection-control program. In addition, work practices related to TB isolation (e.g., keeping doors to isolation rooms closed) should be observed to determine if employers are enforcing, and HCWs are adhering to, these policies and if patient adherence is being enforced. If these policies are not being enforced or adhered to, appropriate education and other corrective action should be implemented.

g. Engineering evaluation

• Results of engineering maintenance measures should be reviewed at regular intervals (Table 3). Data from the most recent evaluation and from maintenance procedures and logs should be reviewed carefully as part of the risk assessment.

2. Development of the TB Infection-Control Plan

• Based on the results of the risk assessment, a written TB infection-control plan should be developed and implemented for each area of the facility and for each occupational group of HCWs not assigned to a specific area of the facility (Table 2; Table 3).

• The occurrence of drug-resistant TB in the facility or the community, or a relatively high prevalence of HIV infection among patients or HCWs in the community, may increase the concern about transmission of *M. tuberculosis* and may influence the decision regarding which protocol to follow (i.e., a higher-risk classification may be selected).

• Health-care facilities are likely to have a combination of low-, intermediate-, and high-risk areas or

occupational groups during the same time period. The appropriate protocol should be implemented for each area or group.

• Areas in which cough-inducing procedures are performed on patients who may have active TB should, at the minimum, implement the intermediate-risk protocol.

3. Periodic Reassessment

• Follow-up risk assessment should be performed at the interval indicated by the most recent risk assessment (Figure 1; Table 2). Based on the results of the follow-up assessment, problem evaluation may need to be conducted or the protocol may need to be modified to a higher- or lower-risk level.

Table 3. Characteristics of an Effective Tuberculosis (TB) Infection-Control Program *

I. Assignment of responsibility
- A. Assign responsibility for the TB infection-control program to qualified person(s).
- B. Ensure that persons with expertise in infection control, occupational health, and engineering are identified and included.

II. Risk assessment, TB infection-control plan, and periodic reassessment
- A. Initial risk assessments
  1. Obtain information concerning TB in the community.
  2. Evaluate data concerning TB patients in the facility.
  3. Evaluate data concerning purified protein derivative (PPD)-tuberculin skin-test conversions among health-care workers (HCWs) in the facility.
  4. Rule out evidence of person-to-person transmission.
- B. Written TB infection-control program
  1. Select initial risk protocol(s).
  2. Develop written TB infection-control protocols.
- C. Repeat risk assessment at appropriate intervals.
  1. Review current community and facility surveillance data and PPD-tuberculin skin-test results.
  2. Review records of TB patients.
  3. Observe HCW infection-control practices.
  4. Evaluate maintenance of engineering controls.

III. Identification, evaluation, and treatment of patients who have TB
- A. Screen patients for signs and symptoms of active TB:
  1. On initial encounter in emergency department or ambulatory-care setting.
  2. Before or at the time of admission.
- B. Perform radiologic and bacteriologic evaluation of patients who have signs and symptoms suggestive of TB.
- C. Promptly initiate treatment.

IV. Managing outpatients who have possible infectious TB
- A. Promptly initiate TB precautions.
- B. Place patients in separate waiting areas or TB isolation rooms.
- C. Give patients a surgical mask, a box of tissues, and instructions regarding the use of these items.

V. Managing inpatients who have possible infectious TB
- A. Promptly isolate patients who have suspected or known infectious TB.
- B. Monitor the response to treatment.
- C. Follow appropriate criteria for discontinuing isolation.

VI. Engineering recommendations
- A. Design local exhaust and general ventilation in collaboration with persons who have expertise in ventilation engineering.
- B. Use a single-pass air system or air recirculation after high-efficiency particulate air (HEPA) filtration in areas where infectious TB patients receive care.
- C. Use additional measures, if needed, in areas where TB patients may receive care.
- D. Design TB isolation rooms in health-care facilities to achieve ≥6 air changes per hour (ACH) for existing facilities and ≥12 ACH for new or renovated facilities.
- E. Regularly monitor and maintain engineering controls.
- F. TB isolation rooms that are being used should be monitored daily to ensure they maintain negative pressure relative to the hallway and all surrounding areas.
- G. Exhaust TB isolation room air to outside or, if absolutely unavoidable, recirculate after HEPA filtration.

VII. Respiratory protection
- A. Respiratory protective devices should meet recommended performance criteria.
- B. Respiratory protection should be used by persons entering rooms in which patients with known or suspected infectious TB are being isolated, by HCWs when performing cough-inducing or aerosol-generating procedures on such patients, and by persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei.
- C. A respiratory protection program is required at all facilities in which respiratory protection is used.

VIII. Cough-inducing procedures
- A. Do not perform such procedures on TB patients unless absolutely necessary.
- B. Perform such procedures in areas that have local exhaust ventilation devices (e.g., booths or special enclosures) or, if this is not feasible, in a room that meets the ventilation requirements for TB isolation.
- C. After completion of procedures, TB patients should remain in the booth or special enclosure until their coughing subsidies.

IX. HCW TB training and education
- A. All HCWs should receive periodic TB education appropriate for their work responsibilities and duties.
- B. Training should include the epidemiology of TB in the facility.
- C. TB education should emphasize concepts of the pathogenesis of and occupational risk for TB.
- D. Training should describe work practices that reduce the likelihood of transmitting *M. tuberculosis.*

X. HCW counseling and screening
- A. Counsel all HCWs regarding TB and TB infection.
- B. Counsel all HCWs about the increased risk to immunocompromised persons for developing active TB.
- C. Perform PPD skin tests on HCWs at the beginning of their employment, and repeat PPD tests at periodic intervals.
- D. Evaluate symptomatic HCWs for active TB.

XI. Evaluate HCW PPD test conversions and possible nosocomial transmission of *M. tuberculosis.*

XII. Coordinate efforts with public health department(s)

*A program such as this is appropriate for health-care facilities in which there is a high risk for transmission of *Mycobacterium tuberculosis.*

• After each risk assessment, the staff responsible for TB control, in conjunction with other appropriate HCWs, should review all TB control policies to ensure that they are effective and meet current needs.

4. Examples of Risk Assessment

Examples of six hypothetical situations and the means by which surveillance data are used to select a TB control protocol are described as follows:

Hospital A. The overall HCW PPD test conversion rate in the facility is 1.6%. No areas or HCW occupational groups have a significantly greater PPD test conversion rate than areas or groups in which occupational exposure to *M. tuberculosis* is unlikely (or than previous rates for the same area or group). No clusters of PPD test conversions have occurred. Patient-to-patient transmission has not been

detected. Patients who have TB are admitted to the facility, but no area admits six or more TB patients per year. The low-risk protocol will be followed in all areas.

Hospital B. The overall HCW PPD test conversion rate in the facility is 1.8%. The PPD test conversion rate for the medical intensive-care unit rate is significantly higher than all other areas in the facility. The problem identification process is initiated (Section II.K). It is determined that all TB patients have been isolated appropriately. Other potential problems are then evaluated, and the cause for the higher rate is not identified. After consulting the public health department TB infection-control program, the high-risk protocol is followed in the unit until the PPD test conversion rate is similar to areas of the facility in which occupational exposure to TB patients is unlikely. If the rate remains significantly higher than other areas, further evaluation, including environmental and procedural studies, will be performed to identify possible reasons for the high conversion rate.

Hospital C. The overall HCW PPD test conversion rate in the facility is 2.4%. Rates range from 0 to 2.6% for the individual areas and occupational groups. None of these rates is significantly higher than rates for areas in which occupational exposure to *M. tuberculosis* is unlikely. No particular HCW group has higher conversion rates than the other groups. No clusters of HCW PPD test conversions have occurred. In two of the areas, HCWs cared for more than six TB patients during the preceding year. These two areas will follow the intermediate-risk protocol, and all other areas will follow the low-risk protocol. This hospital is located in the southeastern United States, and these conversion rates may reflect cross-reactivity with nontuberculous mycobacteria.

Hospital D. The overall HCW PPD test conversion rate in the facility is 1.2%. In no area did HCWs care for six or more TB patients during the preceding year. Three of the 20 respiratory therapists tested had PPD conversions, for a rate of 15%. The respiratory therapists who had PPD test conversions had spent all or part of their time in the pulmonary function laboratory, where induced sputum specimens were obtained. A low-risk protocol is maintained for all areas and occupational groups in the facility except for respiratory therapists. A problem evaluation is conducted in the pulmonary function laboratory (Section II.K). It is determined that the ventilation in this area is inadequate. Booths are installed for sputum induction. PPD testing and the risk assessment are repeated 3 months later. If the repeat testing at 3 months indicates that no more conversions have occurred, the respiratory therapists will return to the low-risk protocol.

Hospital E. Hospital E is located in a community that has a relatively low incidence of TB. To optimize TB services in the community, the four hospitals in the community have developed an agreement that one of them (e.g., Hospital G) will provide all inpatient services to persons who have suspected or confirmed TB. The other hospitals have implemented protocols in their ambulatory-care clinics and emergency departments to identify patients who may have active TB. These patients are then transferred to Hospital G for inpatient care if such care is considered necessary. After discharge from Hospital G, they receive follow-up care in the public health department's TB clinic. During the preceding year, Hospital E has identified fewer than six TB patients in its ambulatory-care and emergency departments and has had no PPD test conversions or other evidence of *M. tuberculosis* transmission among HCWs or patients in these areas. These areas are classified as low risk, and all other areas are classified as very low risk.

Hospital F. Hospital F is located in a county in which no TB cases have been reported during the preceding 2 years. A risk assessment conducted at the facility did not identify any patients who had suspected or confirmed TB during the preceding year. The facility is classified as minimal risk.

C. Identifying, Evaluating, and Initiating Treatment for Patients Who May Have Active TB

The most important factors in preventing transmission of *M. tuberculosis* are the early identification of patients who may have infectious TB, prompt implementation of TB precautions for such patients, and prompt initiation of effective treatment for those who are likely to have TB.

1. Identifying Patients Who May Have Active TB

- Health-care personnel who are assigned responsibility for TB infection control in ambulatory-care and inpatient settings should develop, implement, and enforce protocols for the early identification of patients who may have infectious TB.
- The criteria used in these protocols should be based on the prevalence and characteristics of TB in the population served by the specific facility. These protocols should be evaluated periodically and revised according to the results of the evaluation. Review of medical records of patients who were examined in the facility and diagnosed as having TB may serve as a guide for developing or revising these protocols.
- A diagnosis of TB may be considered for any patient who has a persistent cough (i.e., a cough lasting for ≥3 weeks) or other signs or symptoms compatible with active TB (e.g., bloody sputum, night sweats, weight loss, anorexia, or fever). However, the index of suspicion for TB will vary in different geographic areas and will depend on the prevalence of TB and other characteristics of the population served by the facility. The index of suspicion for TB should be very high in geographic areas or among groups of patients in which the prevalence of TB is high (Section I.B). Appropriate diagnostic measures should be conducted and TB precautions implemented for patients in whom active TB is suspected.

2. Diagnostic Evaluation for Active TB

- Diagnostic measures for identifying TB should be conducted for patients in whom active TB is being considered. These measures include obtaining a medical history and performing a physical examination, PPD skin test, chest radiograph, and microscopic examination and culture of sputum or other appropriate specimens (*6,34,35*). Other diagnostic procedures (e.g., bronchoscopy or biopsy) may be indicated for some patients (*36,37*).
- Prompt laboratory results are crucial to the proper treatment of the TB patient and to early initiation of infection control. To ensure timely results, laboratories performing mycobacteriologic tests should be proficient at both the laboratory and administrative aspects of specimen processing. Laboratories should use the most rapid methods available (e.g., fluorescent microscopy for AFB smears; radiometric culture methods for isolation of mycobacteria; p-nitro-α-acetylamino-β-hydroxy-proprophenone [NAP] test, nucleic acid probes, or high-pressure liquid chromatography [HPLC] for species identification; and radiometric methods for drug-susceptibility testing). As other more rapid or sensitive tests become available, practical, and affordable, such tests should be incorporated promptly into the mycobacteriology laboratory. Laboratories that rarely receive specimens for mycobacteriologic analysis should refer the specimens to a laboratory that more frequently performs these tests.

• Results of AFB sputum smears should be available within 24 hours of specimen collection (*38*).

• The probability of TB is greater among patients who have positive PPD test results or a history of positive PPD test results, who have previously had TB or have been exposed to *M. tuberculosis*, or who belong to a group at high risk for TB (Section I.B). Active TB is strongly suggested if the diagnostic evaluation reveals AFB in sputum, a chest radiograph suggestive of TB, or symptoms highly suggestive of TB. TB can occur simultaneously in immunosuppressed persons who have pulmonary infections caused by other organisms (e.g., *Pneumocystis carinii* or *Mycobacterium avium* complex) and should be considered in the diagnostic evaluation of all patients who have symptoms compatible with TB (Suppl. 1; Suppl. 2).

• TB may be more difficult to diagnose among persons who have HIV infection (or other conditions associated with severe suppression of cell-mediated immunity) because of a nonclassical clinical or radiographic presentation and/or the simultaneous occurrence of other pulmonary infections (e.g., *P. carinii* pneumonia and *M. avium* complex). The difficulty in diagnosing TB in HIV-infected persons may be further compounded by impaired responses to PPD skin tests (*39,40*), the possibly lower sensitivity of sputum smears for detecting AFB (*41*), or the overgrowth of cultures with *M. avium* complex in specimens from patients infected with both *M. avium* complex and *M. tuberculosis* (*42*).

• Immunosuppressed patients who have pulmonary signs or symptoms that are ascribed initially to infections or conditions other than TB should be evaluated initially for coexisting TB. The evaluation for TB should be repeated if the patient does not respond to appropriate therapy for the presumed cause(s) of the pulmonary abnormalities (Suppl. 1; Suppl. 2).

• Patients with suspected or confirmed TB should be reported immediately to the appropriate public health department so that standard procedures for identifying and evaluating TB contacts can be initiated.

3. Initiation of Treatment for Suspected or Confirmed TB

• Patients who have confirmed active TB or who are considered highly likely to have active TB should be started promptly on appropriate treatment in accordance with current guidelines (Suppl. 2) (*43*). In geographic areas or facilities that have a high prevalence of MDR-TB, the initial regimen used may need to be enhanced while the results of drug-susceptibility tests are pending. The decision should be based on analysis of surveillance data.

• While the patient is in the health-care facility, anti-TB drugs should be administered by directly observed therapy (DOT), the process by which an HCW observes the patient swallowing the medications. Continuing DOT after the patient is discharged should be strongly considered. This decision and the arrangements for providing outpatient DOT should be made in collaboration with the public health department.

D. Management of Patients Who May Have Active TB in Ambulatory-Care Settings and Emergency Departments

• Triage of patients in ambulatory-care settings and emergency departments should include vigorous efforts to promptly identify patients who have active TB. HCWs who are the first points of contact in facilities that serve populations at risk for TB should be trained to ask questions that will facilitate identification of patients with signs and symptoms suggestive of TB.

• Patients with signs or symptoms suggestive of TB should be evaluated promptly to minimize the amount of time they are in ambulatory-care areas. TB precautions should be followed while the diagnostic evaluation is being conducted for these patients.

• TB precautions in the ambulatory-care setting should include (a) placing these patients in a separate area apart from other patients, and not in open waiting areas (ideally, in a room or enclosure meeting TB isolation requirements); (b) giving these patients surgical masks* to wear and instructing them to keep their masks on; and (c) giving these patients tissues and instructing them to cover their mouths and noses with the tissues when coughing or sneezing.

• TB precautions should be followed for patients who are known to have active TB and who have not completed therapy until a determination has been made that they are noninfectious (Suppl. 1).

• Patients with active TB who need to attend a health-care clinic should have appointments scheduled to avoid exposing HIV-infected or otherwise severely immunocompromised persons to *M. tuberculosis*. This recommendation could be accomplished by designating certain times of the day for appointments for these patients or by treating them in areas where immunocompromised persons are not treated.

• Ventilation in ambulatory-care areas where patients at high risk for TB are treated should be designed and maintained to reduce the risk for transmission of *M. tuberculosis*. General-use areas (e.g., waiting rooms) and special areas (e.g., treatment or TB isolation rooms in ambulatory areas) should be ventilated in the same manner as described for similar inpatient areas (Sections II.E.3, II.F; Suppl. 3). Enhanced general ventilation or the use of air-disinfection techniques (e.g., UVGI or recirculation of air within the room through high-efficiency particulate air [HEPA] filters) may be useful in general-use areas of facilities where many infectious TB patients receive care (Section II.F; Suppl. 3).

• Ideally, ambulatory-care settings in which patients with TB are frequently examined or treated should have a TB isolation room(s) available. Such rooms are not necessary in ambulatory-care settings in which patients who have confirmed or suspected TB are seen infrequently. However, these facilities should have a written protocol for early identification of patients with TB symptoms and referral to an area or a collaborating facility where the patient can be evaluated and managed appropriately. These protocols should be reviewed on a regular basis and revised as necessary. The additional guidelines in Section II.H should be followed in ambulatory-care settings where cough-inducing procedures are performed on patients who may have active TB.

E. Management of Hospitalized Patients Who Have Confirmed or Suspected TB

1. Initiation of Isolation for TB

• In hospitals and other inpatient facilities, any patient suspected of having or known to have infectious TB should be placed in a TB isolation room that has currently recommended ventilation characteristics (Section II.E.3; Suppl. 3). Written policies for initiating isolation should specify (a) the indications for isolation, (b) the person(s) authorized to initiate and discontinue isolation, (c) the isolation practices to follow, (d) the monitoring of isolation, (e) the management of patients who do not adhere to isolation

*Surgical masks are designed to prevent the respiratory secretions of the person wearing the mask from entering the air. When not in a TB isolation room, patients suspected of having TB should wear surgical masks to reduce the expulsion of droplet nuclei into the air. These patients do not need to wear particulate respirators, which are designed to filter the air before it is inhaled by the person wearing the mask. Patients suspected of having or known to have TB should never wear a respirator that has an exhalation valve, because the device would provide no barrier to the expulsion of droplet nuclei into the air.

practices, and (f) the criteria for discontinuing isolation.

• In rare circumstances, placing more than one TB patient together in the same room may be acceptable. This practice is sometimes referred to as "cohorting." Because of the risk for patients becoming superinfected with drug-resistant organisms, patients with TB should be placed in the same room only if all patients involved (a) have culture-confirmed TB, (b) have drug-susceptibility test results available on a current specimen obtained during the present hospitalization, (c) have identical drug-susceptibility patterns on these specimens, and (d) are on effective therapy. Having isolates with identical DNA fingerprint patterns is not adequate evidence for placing two TB patients together in the same room, because isolates with the same DNA fingerprint pattern can have different drug-susceptibility patterns.

• Pediatric patients with suspected or confirmed TB should be evaluated for potential infectiousness according to the same criteria as are adults (i.e., on the basis of symptoms, sputum AFB smears, radiologic findings, and other criteria) (Suppl. 1). Children who may be infectious should be placed in isolation until they are determined to be noninfectious. Pediatric patients who may be infectious include those who have laryngeal or extensive pulmonary involvement, pronounced cough, positive sputum AFB smears, or cavitary TB or those for whom cough-inducing procedures are performed (*44*).

• The source of infection for a child with TB is often a member of the child's family (*45*). Therefore, parents and other visitors of all pediatric TB patients should be evaluated for TB as soon as possible. Until they have been evaluated, or the source case is identified, they should wear surgical masks when in areas of the facility outside of the child's room, and they should refrain from visiting common areas in the facility (e.g., the cafeteria or lounge areas).

• TB patients in intensive-care units should be treated the same as patients in noncritical-care settings. They should be placed in TB isolation and have respiratory secretions submitted for AFB smear and culture if they have undiagnosed pulmonary symptoms suggestive of TB.

• If readmitted to a health-care facility, patients who are known to have active TB and who have not completed therapy should have TB precautions applied until a determination has been made that they are noninfectious (Suppl. 1).

2. TB Isolation Practices

• Patients who are placed in TB isolation should be educated about the mechanisms of *M. tuberculosis* transmission and the reasons for their being placed in isolation. They should be taught to cover their mouths and noses with a tissue when coughing or sneezing, even while in the isolation room, to contain liquid drops and droplets before they are expelled into the air (*46*).

• Efforts should be made to facilitate patient adherence to isolation measures (e.g., staying in the TB isolation room). Such efforts might include the use of incentives (e.g., providing them with telephones, televisions, or radios in their rooms or allowing special dietary requests). Efforts should also be made to address other problems that could interfere with adherence to isolation (e.g., management of the patient's withdrawal from addictive substances [including tobacco]).

• Patients placed in isolation should remain in their isolation rooms with the door closed. If possible, diagnostic and treatment procedures should be performed in the isolation rooms to avoid transporting patients through other areas of the facility. If patients who may have infectious TB must be transported outside their isolation rooms for medically essential procedures that cannot be performed in the isolation rooms, they should wear surgical masks that cover their mouths and noses during transport. Persons transporting the patients do not need to wear respiratory protection outside the TB isolation rooms. Procedures for these patients should be scheduled at times when they can be performed rapidly and when waiting areas are less crowded.

• Treatment and procedure rooms in which patients who have infectious TB or who have an undiagnosed pulmonary disease and are at high risk for active TB receive care should meet the ventilation recommendations for isolation rooms (Section II.E.3; Suppl. 3). Ideally, facilities in which TB patients are frequently treated should have an area in the radiology department that is ventilated separately for TB patients. If this is not possible, TB patients should wear surgical masks and should stay in the radiology suite the minimum amount of time possible, then be returned promptly to their isolation rooms.

• The number of persons entering an isolation room should be minimal. All persons who enter an isolation room should wear respiratory protection (Section II.G; Suppl. 4). The patient's visitors should be given respirators to wear while in the isolation room, and they should be given general instructions on how to use their respirators.

• Disposable items contaminated with respiratory secretions are not associated with transmission of *M. tuberculosis*. However, for general infection-control purposes, these items should be handled and transported in a manner that reduces the risk for transmitting other microorganisms to patients, HCWs, and visitors and that decreases environmental contamination in the health-care facility. Such items should be disposed of in accordance with hospital policy and applicable regulations (Suppl. 5).

3. The TB Isolation Room

• TB isolation rooms should be single-patient rooms with special ventilation characteristics appropriate for the purposes of isolation (Suppl. 3). The primary purposes of TB isolation rooms are to (a) separate patients who are likely to have infectious TB from other persons; (b) provide an environment that will allow reduction of the concentration of droplet nuclei through various engineering methods; and (c) prevent the escape of droplet nuclei from the TB isolation room and treatment room, thus preventing entry of *M. tuberculosis* into the corridor and other areas of the facility.

• To prevent the escape of droplet nuclei, the TB isolation room should be maintained under negative pressure (Suppl. 3). Doors to isolation rooms should be kept closed, except when patients or personnel must enter or exit the room, so that negative pressure can be maintained.

• Negative pressure in the room should be monitored daily while the room is being used for TB isolation.

• The American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE) (*47*), the American Institute of Architects (AIA) (*48*), and the Health Resources and Services Administration (*49*) recommend a minimum of 6 air changes per hour (ACH) for TB isolation and treatment rooms. This ventilation rate is based on comfort and odor control considerations. The effectiveness of this level of airflow in reducing the concentration of droplet nuclei in the room, thus reducing the transmission of airborne pathogens, has not been evaluated directly or adequately.

Ventilation rates of >6 ACH are likely to produce an incrementally greater reduction in the concentration of bacteria in a room than are lower rates (*50–52*). However, accurate quantitation

of decreases in risk that would result from specific increases in general ventilation levels has not been performed and may not be possible.

For the purposes of reducing the concentration of droplet nuclei, TB isolation and treatment rooms in existing health-care facilities should have an airflow of ≥6 ACH. Where feasible, this airflow rate should be increased to ≥12 ACH by adjusting or modifying the ventilation system or by using auxiliary means (e.g., recirculation of air through fixed HEPA filtration systems or portable air cleaners) (Suppl. 3, Section II.B.5.a) (*53*). New construction or renovation of existing health-care facilities should be designed so that TB isolation rooms achieve an airflow of ≥12 ACH.

• Air from TB isolation rooms and treatment rooms used to treat patients who have known or suspected infectious TB should be exhausted to the outside in accordance with applicable federal, state, and local regulations. The air should not be recirculated into the general ventilation. In some instances, recirculation of air into the general ventilation system from such rooms is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust to the outside impossible). In such cases, HEPA filters should be installed in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before it is returned to the general ventilation system (Section II.F; Suppl. 3). Air from TB isolation and treatment rooms in new or renovated facilities should not be recirculated into the general ventilation system.

• Although not required, an anteroom may increase the effectiveness of the isolation room by minimizing the potential escape of droplet nuclei into the corridor when the door is opened. To work effectively, the anteroom should have positive air pressure in relation to the isolation room. The pressure relationship between the anteroom and the corridor may vary according to ventilation design.

• Upper-room air UVGI may be used as an adjunct to general ventilation in the isolation room (Section II.F; Suppl. 3). Air in the isolation room may be recirculated within the room through HEPA filters or UVGI devices to increase the effective ACH and to increase thermal efficiency.

• Health-care facilities should have enough isolation rooms to appropriately isolate all patients who have suspected or confirmed active TB. This number should be estimated using the results of the risk assessment of the health-care facility. Except for minimal-and very low-risk health-care facilities, all acute-care inpatient facilities should have at least one TB isolation room (Section II.B).

• Grouping isolation rooms together in one area of the facility may reduce the possibility of transmitting *M. tuberculosis* to other patients and may facilitate care of TB patients and the installation and maintenance of optimal engineering (particularly ventilation) controls.

4. Discontinuation of TB Isolation

• TB isolation can be discontinued if the diagnosis of TB is ruled out. For some patients, TB can be ruled out when another diagnosis is confirmed. If a diagnosis of TB cannot be ruled out, the patient should remain in isolation until a determination has been made that the patient is noninfectious. However, patients can be discharged from the health-care facility while still potentially infectious if appropriate postdischarge arrangements can be ensured (Section II.E.5).

• The length of time required for a TB patient to become noninfectious after starting anti-TB therapy varies considerably (Suppl. 1). Isolation should be discontinued only when the patient is on effective therapy, is improving clinically, and has had three consecutive negative sputum AFB smears collected on different days.

• Hospitalized patients who have active TB should be monitored for relapse by having sputum AFB smears examined regularly (e.g., every 2 weeks). Nonadherence to therapy (i.e., failure to take medications as prescribed) and the presence of drug-resistant organisms are the two most common reasons why patients remain infectious despite treatment. These reasons should be considered if a patient does not respond clinically to therapy within 2–3 weeks.

• Continued isolation throughout the hospitalization should be strongly considered for patients who have MDR-TB because of the tendency for treatment failure or relapse (i.e., difficulty in maintaining noninfectiousness) that has been observed in such cases.

5. Discharge Planning

• Before a TB patient is discharged from the health-care facility, the facility's staff and public health authorities should collaborate to ensure continuation of therapy. Discharge planning in the health-care facility should include, at a minimum, (a) a confirmed outpatient appointment with the provider who will manage the patient until the patient is cured, (b) sufficient medication to take until the outpatient appointment, and (c) placement into case management (e.g., DOT) or outreach programs of the public health department. These plans should be initiated and in place before the patient's discharge.

• Patients who may be infectious at the time of discharge should only be discharged to facilities that have isolation capability or to their homes. Plans for discharging a patient who will return home must consider whether all the household members were infected previously and whether any uninfected household members are at very high risk for active TB if infected (e.g., children <4 years of age or persons infected with HIV or otherwise severely immunocompromised). If the household does include such persons, arrangements should be made to prevent them from being exposed to the TB patient until a determination has been made that the patient is noninfectious.

F. Engineering Control Recommendations

1. General Ventilation

This section deals only with engineering controls for general-use areas of health-care facilities (e.g., waiting-room areas and emergency departments). Recommendations for engineering controls for specific areas of the facility (e.g., TB isolation rooms) are contained in the sections encompassing those areas. Details regarding ventilation design, evaluation, and supplemental approaches are described in Supplement 3.

• Health-care facilities should either (a) include as part of their staff an engineer or other professional with expertise in ventilation or (b) have this expertise available from a consultant who is an expert in ventilation engineering and who also has hospital experience. These persons should work closely with infection-control staff to assist in controlling airborne infections.

• Ventilation system designs in health-care facilities should meet any applicable federal, state, and local requirements.

• The direction of airflow in health-care facilities should be designed, constructed, and maintained so that air flows from clean areas to less-clean areas.

• Health-care facilities serving populations that have a high prevalence of TB may need to supplement the general ventilation or use additional engineering approaches (i.e., HEPA filtration or UVGI) in general-use areas

where TB patients are likely to go (e.g., waiting-room areas, emergency departments, and radiology suites). A single-pass, nonrecirculating system that exhausts air to the outside, a recirculation system that passes air through HEPA filters before recirculating it to the general ventilation system, or upper air UVGI may be used in such areas.

2. Additional Engineering Control Approaches

a. HEPA filtration.

HEPA filters may be used in a number of ways to reduce or eliminate infectious droplet nuclei from room air or exhaust (Suppl. 3). These methods include placement of HEPA filters (a) in exhaust ducts discharging air from booths or enclosures into the surrounding room; (b) in ducts or in ceiling- or wall-mounted units, for recirculation of air within an individual room (fixed recirculation systems); (c) in portable air cleaners; (d) in exhaust ducts to remove droplet nuclei from air being discharged to the outside, either directly or through ventilation equipment; and (e) in ducts discharging air from the TB isolation room into the general ventilation system. In any application, HEPA filters should be installed carefully and maintained meticulously to ensure adequate functioning.

The manufacturers of in-room air cleaning equipment should provide documentation of the HEPA filter efficiency and the efficiency of the device in lowering room air contaminant levels.

b. UVGI.

For general-use areas in which the risk for transmission of *M. tuberculosis* is relatively high, UVGI lamps may be used as an adjunct to ventilation for reducing the concentration of infectious droplet nuclei (Suppl. 3), although the effectiveness of such units has not been evaluated adequately. Ultraviolet (UV) units can be installed in a room or corridor to irradiate the air in the upper portion of the room (i.e., upper-room air irradiation), or they can be installed in ducts to irradiate air passing through the ducts. UV units installed in ducts should not be substituted for HEPA filters in ducts that discharge air from TB isolation rooms into the general ventilation system. However, UV units can be used in ducts that recirculate air back into the same room.

To function properly and decrease hazards to HCWs and others in the health-care facility, UV lamps should be installed properly and maintained adequately, which includes the monitoring of irradiance levels. UV tubes should be changed according to the manufacturer's instructions or when meter readings indicate tube failure. An employee trained in the use and handling of UV lamps should be responsible for these measures and for keeping maintenance records. Applicable safety guidelines should be followed. Caution should be exercised to protect HCWs, patients, visitors, and others from excessive exposure to UV radiation.

G. Respiratory Protection

- Personal respiratory protection should be used by (a) persons entering rooms in which patients with known or suspected infectious TB are being isolated, (b) persons present during cough-inducing or aerosol-generating procedures performed on such patients, and (c) persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei (Suppl. 4). These other settings include transporting patients who may have infectious TB in emergency transport vehicles and providing urgent surgical or dental care to patients who may have infectious TB before a determination has been made that the patient is noninfectious (Suppl. 1).
- Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following standard performance criteria:

1. The ability to filter particles 1 μm in size in the unloaded* state with a filter efficiency of ≥95% (i.e., filter leakage of ≤5%), given flow rates of up to 50 L per minute.

2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of ≤10% (*54,55*).

3. The ability to fit the different facial sizes and characteristics of HCWs, which can usually be met by making the respirators available in at least three sizes.

4. The ability to be checked for facepiece fit, in accordance with standards established by the Occupational Safety and Health Administration (OSHA) and good industrial hygiene practice, by HCWs each time they put on their respirators (*54,55*).

- The facility's risk assessment may identify a limited number of selected settings (e.g., bronchoscopy performed on patients suspected of having TB or autopsy performed on deceased persons suspected of having had active TB at the time of death) where the estimated risk for transmission of *M. tuberculosis* may be such that a level of respiratory protection exceeding the standard performance criteria is appropriate. In such circumstances, a level of respiratory protection exceeding the standard criteria and compatible with patient-care delivery (e.g., more protective negative-pressure respirators; powered air-purifying particulate respirators [PAPRs]; or positive-pressure air-line, half-mask respirators) should be provided by employers to HCWs who are exposed to *M. tuberculosis*. Information on these and other respirators is in the *NIOSH Guide to Industrial Respiratory Protection* (*55*) and in Supplement 4 of this document.
- In some settings, HCWs may be at risk for two types of exposure: (a) inhalation of *M. tuberculosis* and (b) mucous membrane exposure to fluids that may contain bloodborne pathogens. In these settings, protection against both types of exposure should be used.
- When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW should serve two functions: (a) It should protect the surgical field from the respiratory secretions of the HCW, and (b) it should protect the HCW from infectious droplet nuclei that may be expelled by the patient or generated by the procedure. Respirators with exhalation valves and most positive-pressure respirators do not protect the sterile field.
- Health-care facilities in which respiratory protection is used to prevent inhalation of *M. tuberculosis* are required by OSHA to develop, implement, and maintain a respiratory protection program (Suppl. 4). All HCWs who use respiratory protection should be included in this program. Visitors to TB patients should be given respirators to wear while in isolation rooms, and they should be given general instructions on how to use their respirators.
- Facilities that do not have isolation rooms and do not perform cough-inducing procedures on patients who may have TB may not need to have a respiratory protection program for TB. However, such facilities should have written protocols for the early identification of patients who have signs or symptoms of TB and procedures for referring these patients to a facility where they can be evaluated and managed appropriately. These protocols should be evaluated regularly and revised as needed.

*Some filters become more efficient as they become loaded with dust. Health-care settings do not have enough dust in the air to load a filter on a respirator. Therefore, the filter efficiency for respirators used in health-care settings must be determined in the unloaded state.

• Surgical masks are designed to prevent the respiratory secretions of the person wearing the mask from entering the air. To reduce the expulsion of droplet nuclei into the air, patients suspected of having TB should wear surgical masks when not in TB isolation rooms. These patients do not need to wear particulate respirators, which are designed to filter the air before it is inhaled by the person wearing the respirator. Patients suspected of having or known to have TB should never wear a respirator that has an exhalation valve, because this type of respirator does not prevent expulsion of droplet nuclei into the air.

H. Cough-Inducing and Aerosol-Generating Procedures

1. General Guidelines

Procedures that involve instrumentation of the lower respiratory tract or induce coughing can increase the likelihood of droplet nuclei being expelled into the air. These cough-inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (e.g., pentamidine therapy), and bronchoscopy. Other procedures that can generate aerosols (e.g., irrigation of tuberculous abscesses, homogenizing or lyophilizing tissue, or other processing of tissue that may contain tubercle bacilli) are also covered by these recommendations.

• Cough-inducing procedures should not be performed on patients who may have infectious TB unless the procedures are absolutely necessary and can be performed with appropriate precautions.

• All cough-inducing procedures performed on patients who may have infectious TB should be performed using local exhaust ventilation devices (e.g., booths or special enclosures) or, if this is not feasible, in a room that meets the ventilation requirements for TB isolation.

• HCWs should wear respiratory protection when present in rooms or enclosures in which cough-inducing procedures are being performed on patients who may have infectious TB.

• After completion of cough-inducing procedures, patients who may have infectious TB should remain in their isolation rooms or enclosures and not return to common waiting areas until coughing subsides. They should be given tissues and instructed to cover their mouths and noses with the tissues when coughing. If TB patients must recover from sedatives or anesthesia after a procedure (e.g, after a bronchoscopy), they should be placed in separate isolation rooms (and not in recovery rooms with other patients) while they are being monitored.

• Before the booth, enclosure, or room is used for another patient, enough time should be allowed to pass for at least 99% of airborne contaminants to be removed. This time will vary according to the efficiency of the ventilation or filtration used (Suppl. 3, Table S3–1).

2. Special Considerations for Bronchoscopy

• If performing bronchoscopy in positive-pressure rooms (e.g., operating rooms) is unavoidable, TB should be ruled out as a diagnosis before the procedure is performed. If the bronchoscopy is being performed for the purpose of diagnosing pulmonary disease and that diagnosis could include TB, the procedure should be performed in a room that meets TB isolation ventilation requirements.

3. Special Considerations for the Administration of Aerosolized Pentamidine

• Patients should be screened for active TB before prophylactic therapy with aerosolized pentamidine is initiated. Screening should include obtaining a medical history and performing skin testing and chest radiography.

• Before each subsequent treatment with aerosolized pentamidine, patients should be screened for symptoms suggestive of TB (e.g., development of a productive cough). If such symptoms are elicited, a diagnostic evaluation for TB should be initiated.

• Patients who have suspected or confirmed active TB should take, if clinically practical, oral prophylaxis for *P. carinii* pneumonia.

I. Education and Training of HCWs

All HCWs, including physicians, should receive education regarding TB that is relevant to persons in their particular occupational group. Ideally, training should be conducted before initial assignment, and the need for additional training should be reevaluated periodically (e.g., once a year). The level and detail of this education will vary according to the HCW's work responsibilities and the level of risk in the facility (or area of the facility) in which the HCW works. However, the program may include the following elements:

• The basic concepts of *M. tuberculosis* transmission, pathogenesis, and diagnosis, including information concerning the difference between latent TB infection and active TB disease, the signs and symptoms of TB, and the possibility of reinfection.

• The potential for occupational exposure to persons who have infectious TB in the health-care facility, including information concerning the prevalence of TB in the community and facility, the ability of the facility to properly isolate patients who have active TB, and situations with increased risk for exposure to *M. tuberculosis*.

• The principles and practices of infection control that reduce the risk for transmission of *M. tuberculosis*, including information concerning the hierarchy of TB infection-control measures and the written policies and procedures of the facility. Site-specific control measures should be provided to HCWs working in areas that require control measures in addition to those of the basic TB infection-control program.

• The purpose of PPD skin testing, the significance of a positive PPD test result, and the importance of participating in the skin-test program.

• The principles of preventive therapy for latent TB infection. These principles include the indications, use, effectiveness, and the potential adverse effects of the drugs (Suppl. 2).

• The HCW's responsibility to seek prompt medical evaluation if a PPD test conversion occurs or if symptoms develop that could be caused by TB. Medical evaluation will enable HCWs who have TB to receive appropriate therapy and will help to prevent transmission of *M. tuberculosis* to patients and other HCWs.

• The principles of drug therapy for active TB.

• The importance of notifying the facility if the HCW is diagnosed with active TB so that contact investigation procedures can be initiated.

• The responsibilities of the facility to maintain the confidentiality of the HCW while ensuring that the HCW who has TB receives appropriate therapy and is noninfectious before returning to duty.

• The higher risks associated with TB infection in persons who have HIV infection or other causes of severely impaired cell-mediated immunity, including (a) the more frequent and rapid development of clinical TB after infection with *M. tuberculosis*, (b) the differences in the clinical presentation of disease, and (c) the high mortality rate associated with MDR–TB in such persons.

• The potential development of cutaneous anergy as immune function (as measured by CD4+ T-lymphocyte counts) declines.

• Information regarding the efficacy and safety of BCG vaccination and the

principles of PPD screening among BCG recipients.

• The facility's policy on voluntary work reassignment options for immunocompromised HCWs.

J. HCW Counseling, Screening, and Evaluation

A TB counseling, screening, and prevention program for HCWs should be established to protect both HCWs and patients. HCWs who have positive PPD test results, PPD test conversions, or symptoms suggestive of TB should be identified, evaluated to rule out a diagnosis of active TB, and started on therapy or preventive therapy if indicated (*5*). In addition, the results of the HCW PPD screening program will contribute to evaluation of the effectiveness of current infection-control practices.

1. Counseling HCWs Regarding TB

• Because of the increased risk for rapid progression from latent TB infection to active TB in HIV-infected or otherwise severely immunocompromised persons, all HCWs should know if they have a medical condition or are receiving a medical treatment that may lead to severely impaired cell-mediated immunity. HCWs who may be at risk for HIV infection should know their HIV status (i.e., they should be encouraged to voluntarily seek counseling and testing for HIV antibody status). Existing guidelines for counseling and testing should be followed routinely (*56*). Knowledge of these conditions allows the HCW to seek the appropriate preventive measures outlined in this document and to consider voluntary work reassignments. Of particular importance is that HCWs need to know their HIV status if they are at risk for HIV infection and they work in settings where patients who have drug-resistant TB may be encountered.

• All HCWs should be informed about the need to follow existing recommendations for infection control to minimize the risk for exposure to infectious agents; implementation of these recommendations will greatly reduce the risk for occupational infections among HCWs (*57*). All HCWs should also be informed about the potential risks to severely immunocompromised persons associated with caring for patients who have some infectious diseases, including TB. It should be emphasized that limiting exposure to TB patients is the most protective measure that severely immunosuppressed HCWs can take to avoid becoming infected with *M. tuberculosis*. HCWs who have severely impaired cell-mediated immunity and who may be exposed to *M. tuberculosis* may consider a change in job setting to avoid such exposure. HCWs should be advised of the option that severely immunocompromised HCWs can choose to transfer voluntarily to areas and work activities in which there is the lowest possible risk for exposure to *M. tuberculosis*. This choice should be a personal decision for HCWs after they have been informed of the risks to their health.

• Employers should make reasonable accommodations (e.g., alternative job assignments) for employees who have a health condition that compromises cell-mediated immunity and who work in settings where they may be exposed to *M. tuberculosis*. HCWs who are known to be immunocompromised should be referred to employee health professionals who can individually counsel the employees regarding their risk for TB. Upon the request of the immunocompromised HCW, employers should offer, but not compel, a work setting in which the HCW would have the lowest possible risk for occupational exposure to *M. tuberculosis*. Evaluation of these situations should also include consideration of the provisions of the Americans With Disabilities Act of 1990* and other applicable federal, state, and local laws.

• All HCWs should be informed that immunosuppressed HCWs should have appropriate follow-up and screening for infectious diseases, including TB, provided by their medical practitioner. HCWs who are known to be HIV-infected or otherwise severely immunosuppressed should be tested for cutaneous anergy at the time of PPD testing (Suppl. 2). Consideration should be given to retesting, at least every 6 months, those immunocompromised HCWs who are potentially exposed to *M. tuberculosis* because of the high risk for rapid progression to active TB if they become infected.

• Information provided by HCWs regarding their immune status should be treated confidentially. If the HCW requests voluntary job reassignment, the confidentiality of the HCW should be maintained. Facilities should have written procedures on confidential handling of such information.

2. Screening HCWs for Active TB

• Any HCW who has a persistent cough (i.e., a cough lasting ≥3 weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, bloody sputum, anorexia, or fever), should be evaluated promptly for TB. The HCW should not return to the workplace until a diagnosis of TB has been excluded or until the HCW is on therapy and a determination has been made that the HCW is noninfectious.

3. Screening HCWs for Latent TB Infection

• The risk assessment should identify which HCWs have potential for exposure to *M. tuberculosis* and the frequency with which the exposure may occur. This information is used to determine which HCWs to include in the skin-testing program and the frequency with which they should be tested (Table 2).

• If HCWs are from risks groups with increased prevalence of TB, consideration may be given to including them in the skin-testing program, even if they do not have potential occupational exposure to *M. tuberculosis*, so that converters can be identified and preventive therapy offered.

• Administrators of health-care facilities should ensure that physicians and other personnel not paid by, but working in, the facility receive skin testing at appropriate intervals for their occupational group and work location.

• During the pre-employment physical or when applying for hospital privileges, HCWs who have potential for exposure to *M. tuberculosis* (Table 2), including those with a history of BCG vaccination, should have baseline PPD skin testing performed (Suppl. 2). For HCWs who have not had a documented negative PPD test result during the preceding 12 months, the baseline PPD testing should employ the two-step method; this will detect boosting phenomena that might be misinterpreted as a skin-test conversion. Decisions concerning the use of the two-step procedure for baseline testing in a particular facility should be based on the frequency of boosting in that facility.

• HCWs who have a documented history of a positive PPD test, adequate treatment for disease, or adequate preventive therapy for infection, should be exempt from further PPD screening unless they develop signs or symptoms suggestive of TB.

• PPD-negative HCWs should undergo repeat PPD testing at regular intervals as determined by the risk assessment (Section II.B). In addition, these HCWs should be tested whenever they have been exposed to a TB patient and appropriate precautions were not observed at the time of exposure (Section II.K.3). Performing PPD testing of HCWs who work in the same area or

*Americans With Disabilities Act of 1990, P.L. 101-336, 42 U.S.C. 12101 et seq.

occupational group on different scheduled dates (e.g., test them on their birthdays or on their employment anniversary dates), rather than testing all HCWs in the area or group on the same day, may lead to earlier detection of *M. tuberculosis* transmission.

• All PPD tests should be administered, read, and interpreted in accordance with current guidelines by specified trained personnel (Suppl. 2). At the time their test results are read, HCWs should be informed about the interpretation of both positive and negative PPD test results. This information should indicate that the interpretation of an induration that is 5–9 mm in diameter depends on the HCW's immune status and history of exposure to persons who have infectious TB. Specifically, HCWs who have indurations of 5–9 mm in diameter should be advised that such results may be considered positive for HCWs who are contacts of persons with infectious TB or who have HIV infection or other causes of severe immunosuppression (e.g., immunosuppressive therapy for organ transplantation).

• When an HCW who is not assigned regularly to a single work area has a PPD test conversion, appropriate personnel should identify the areas where the HCW worked during the time when infection was likely to have occurred. This information can then be considered in analyzing the risk for transmission in those areas.

• In any area of the facility where transmission of *M. tuberculosis* is known to have occurred, a problem evaluation should be conducted (Section II.K), and the frequency of skin testing should be determined according to the applicable risk category (Section II.B).

• PPD test results should be recorded confidentially in the individual HCW's employee health record and in an aggregate database of all HCW PPD test results. The database can be analyzed periodically to estimate the risk for acquiring new infection in specific areas or occupational groups in the facility.

4. Evaluation and Management of HCWs Who Have Positive PPD Test Results or Active TB

a. Evaluation

• All HCWs with newly recognized positive PPD test results or PPD test conversions should be evaluated promptly for active TB. This evaluation should include a clinical examination and a chest radiograph. If the history, clinical examination, or chest radiograph is compatible with active TB, additional tests should be performed (Section II.C.2). If symptoms compatible with TB are present, the HCW should be excluded from the workplace until either a) a diagnosis of active TB is ruled out or b) a diagnosis of active TB was established, the HCW is being treated, and a determination has been made that the HCW is noninfectious (Suppl. 2). HCWs who do not have active TB should be evaluated for preventive therapy according to published guidelines (Suppl. 2).

• If an HCW's PPD test result converts to positive, a history of confirmed or suspected TB exposure should be obtained in an attempt to determine the potential source. When the source of exposure is known, the drug-susceptibility pattern of the *M. tuberculosis* isolated from the source should be identified so that the correct curative or preventive therapy can be initiated for the HCW with the PPD test conversion. The drug-susceptibility pattern should be recorded in the HCW's medical record, where it will be available if the HCW subsequently develops active TB and needs therapy specific for the drug-susceptibility pattern.

• All HCWs, including those with histories of positive PPD test results, should be reminded periodically about the symptoms of TB and the need for prompt evaluation of any pulmonary symptoms suggestive of TB.

b. Routine and follow-up chest radiographs.

• Routine chest radiographs are not required for asymptomatic, PPD-negative HCWs. HCWs with positive PPD test results should have a chest radiograph as part of the initial evaluation of their PPD test; if negative, repeat chest radiographs are not needed unless symptoms develop that could be attributed to TB (*58*). However, more frequent monitoring for symptoms of TB may be considered for recent converters and other PPD-positive HCWs who are at increased risk for developing active TB (e.g., HIV-infected or otherwise severely immunocompromised HCWs).

c. Workplace restrictions.

(1) Active TB.

• HCWs with pulmonary or laryngeal TB pose a risk to patients and other HCWs while they are infectious, and they should be excluded from the workplace until they are noninfectious. The same work restrictions apply to all HCWs regardless of their immune status.

• Before the HCW who has TB can return to the workplace, the health-care facility should have documentation from the HCW's health-care provider that the HCW is receiving adequate therapy, the cough has resolved, and the HCW has had three consecutive negative sputum smears collected on different days. After work duties are resumed and while the HCW remains on anti-TB therapy, facility staff should receive periodic documentation from the HCW's health-care provider that the HCW is being maintained on effective drug therapy for the recommended time period and that the sputum AFB smears continue to be negative.

• HCWs with active laryngeal or pulmonary TB who discontinue treatment before they are cured should be evaluated promptly for infectiousness. If the evaluation determines that they are still infectious, they should be excluded from the workplace until treatment has been resumed, an adequate response to therapy has been documented, and three more consecutive sputum AFB smears collected on different days have been negative.

• HCWs who have TB at sites other than the lung or larynx usually do not need to be excluded from the workplace if a diagnosis of concurrent pulmonary TB has been ruled out.

(2) Latent TB infection.

• HCWs receiving preventive treatment for latent TB infection should not be restricted from their usual work activities.

• HCWs with latent TB infection who cannot take or who do not accept or complete a full course of preventive therapy should not be excluded from the workplace. These HCWs should be counseled about the risk for developing active TB and instructed regularly to seek prompt evaluation if signs or symptoms develop that could be caused by TB.

K. Problem Evaluation

Epidemiologic investigations may be indicated for several situations. These include, but are not limited to, (a) the occurrence of PPD test conversions or active TB in HCWs; (b) the occurrence of possible person-to-person transmission of *M. tuberculosis*; and (c) situations in which patients or HCWs with active TB are not promptly identified and isolated, thus exposing other persons in the facility to *M. tuberculosis*. The general objectives of the epidemiologic investigations in these situations are as follows:

(1) To determine the likelihood that transmission of and infection with *M. tuberculosis* has occurred in the facility;

(2) To determine the extent to which *M. tuberculosis* has been transmitted;

(3) To identify those persons who have been exposed and infected, enabling them to receive appropriate clinical management;

(4) To identify factors that could have contributed to transmission and infection and to implement appropriate interventions; and

(5) To evaluate the effectiveness of any interventions that are implemented and to ensure that exposure to and transmission of *M. tuberculosis* have been terminated.

The exact circumstances of these situations are likely to vary considerably, and the associated epidemiologic investigations should be tailored to the individual circumstances. The following sections provide general guidance for conducting these investigations.

1. Investigating PPD Test Conversions and Active TB in HCWs

a. Investigating PPD test conversions in HCWs.

PPD test conversions may be detected in HCWs as a result of a contact investigation, in which case the probable source of exposure and transmission is already known (Section II.K.3.), or as a result of routine screening, in which case the probable source of exposure and infection is not already known and may not be immediately apparent.

If a skin-test conversion in an HCW is identified as part of routine screening, the following steps should be considered (Figure 2):

- The HCW should be evaluated promptly for active TB. The initial evaluation should include a thorough history, physical examination, and chest radiograph. On the basis of the initial evaluation, other diagnostic procedures (e.g., sputum examination) may be indicated.
- If appropriate, the HCW should be placed on preventive or curative therapy in accordance with current guidelines (Suppl. 2) (5).
- A history of possible exposure to *M. tuberculosis* should be obtained from the HCW to determine the most likely source of infection. When the source of infection is known, the drug-susceptibility pattern of the *M. tuberculosis* isolate from the source patient should be identified to determine appropriate preventive or curative therapy regimens.
- If the history suggests that the HCW was exposed to and infected with *M. tuberculosis* outside the facility, no further epidemiologic investigation to identify a source in the facility is necessary.
- If the history does not suggest that the HCW was exposed and infected outside the facility but does identify a probable source of exposure in the facility, contacts of the suspected source patient should be identified and evaluated. Possible reasons for the exposure and transmission should be evaluated (Table 4), interventions should be implemented to correct these causes, and PPD testing of PPD-negative HCWs should be performed immediately and repeated after 3 months.

If no additional PPD test conversions are detected on follow-up testing, the investigation can be terminated.

If additional PPD test conversions are detected on follow-up testing, the possible reasons for exposure and transmission should be reassessed, the appropriateness of and degree of adherence to the interventions implemented should be evaluated, and PPD testing of PPD-negative HCWs should be repeated after another 3 months.

If no additional PPD test conversions are detected on the second round of follow-up testing, the investigation can be terminated. However, if additional PPD conversions are detected on the second round of follow-up testing, a high-risk protocol should be implemented in the affected area or occupational group, and the public health department or other persons with expertise in TB infection control should be consulted.

- If the history does not suggest that the HCW was exposed to and infected with *M. tuberculosis* outside the facility and does not identify a probable source of exposure in the facility, further investigation to identify the probable source patient in the facility is warranted.

The interval during which the HCW could have been infected should be estimated. Generally, this would be the interval from 10 weeks before the most recent negative PPD test through 2 weeks before the first positive PPD test (i.e., the conversion).

Laboratory and infection-control records should be reviewed to identify all patients or HCWs who have suspected or confirmed infectious TB and who could have transmitted *M. tuberculosis* to the HCW.

If this process does identify a likely source patient, contacts of the suspected source patient should be identified and evaluated, and possible reasons for the exposure and transmission should be evaluated (Table 4). Interventions should be implemented to correct these causes, and PPD testing of PPD-negative HCWs should be repeated after 3 months. However, if this process does not identify a probable source case, PPD screening results of other HCWs in the same area or occupational group should be reviewed for additional evidence of *M. tuberculosis* transmission. If sufficient additional PPD screening results are not available, appropriate personnel should consider conducting additional PPD screening of other HCWs in the same area or occupational group.

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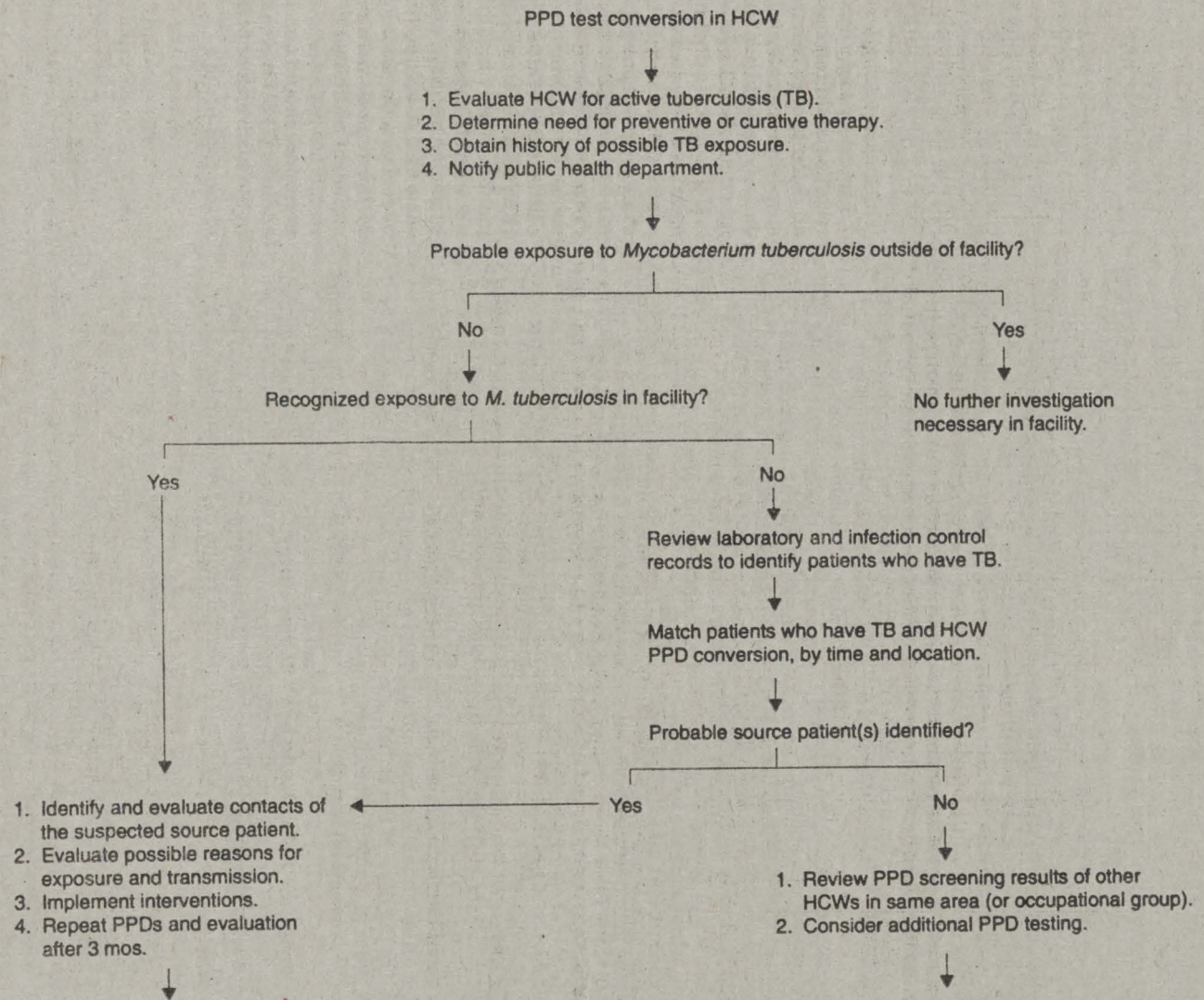
FIGURE 2. Protocol for investigating purified protein derivative (PPD)-tuberculin skin-test conversions in health-care workers (HCWs)



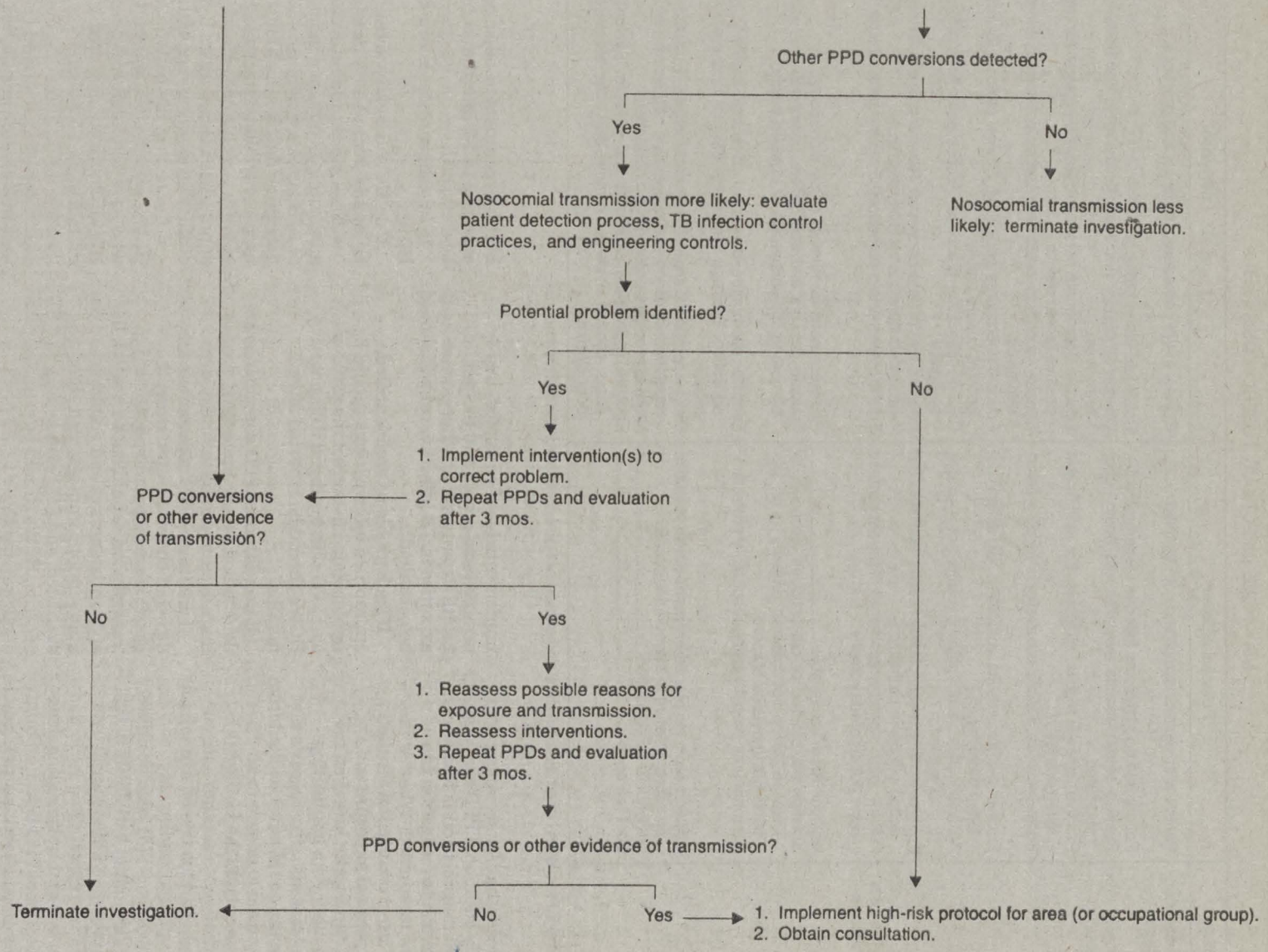


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TABLE 4.—EXAMPLES OF POTENTIAL PROBLEMS THAT CAN OCCUR WHEN IDENTIFYING OR ISOLATING PATIENTS WHO MAY HAVE INFECTIOUS TUBERCULOSIS (TB)

Situation	Potential problem	Intervention
Patient identification during triage	Patient with signs or symptoms not identified	Review triage procedures, facilities, and practices.
	Patient had no symptoms listed in triage protocol ..	Revaluate triage protocol.
During review of laboratory results	Positive smear: results available >24 hours* after submitted.	Change laboratory practices. Assess potential barriers. Explore alternatives.
	Positive smear: results available but action not taken promptly.	Educate appropriate personnel. Review protocol for management of positive smear results.
	Positive culture: results not available for >3 weeks*	Change laboratory practices. Assess potential barriers. Explore alternatives.
	Postive culture: results available but action not taken promptly.	Educate appropriate personnel. Review protocol for management of positive culture results.
	Positive culture: susceptibility results not available for >6 weeks*.	Change laboratory practices. Assess potential barriers. Explore alternatives.
	Positive culture: susceptibility results available but action not taken promptly.	Educate appropriate personnel. Review protocol for management of positive culture susceptibility results.
At time of diagnosis and during isolation	Patient with signs/symptoms of TB: appropriate tests not ordered promptly.	Educate appropriate personnel. Evaluate protocols for TB detection.
	Isolation room unavailable	Reassess need for number of isolation rooms.
	Isolation not ordered or discontinued too soon, or isolation policy not followed properly (e.g., patients going outside of room).	Educate patients and appropriate personnel. Evaluate institutional barriers to implementation of isolation policy.
	Personnel not properly using respiratory protection	Educate appropriate personnel. Evaluate regularly scheduled re-education. Evaluate institutional barriers to use of respiratory protection.
	Isolation room or procedure room not at negative pressure reslative to surrounding areas.	Make appropriate engineering modifications. Establish protocols for regularly monitoring and maintaining negative pressure.
	Inadequate air circulation	Make appropriate engineering modifications.
	Door left open	Educate appropriate personnel and patients. Evaluate self-closing doors, comfort levels in the room, and other measures to promote door closing.

*These time intervals are used as examples and should not be considered absolute standards.

If this review and/or screening does not identify additional PPD conversions, nosocomial transmission is less likely, and the contact investigation can probably be terminated. Whether the HCW's PPD test conversion resulted from occupational exposure and infection is uncertain; however, the absence of other data implicating nosocomial transmission suggests that the conversion could have resulted from (a) unrecognized exposure to *M. tuberculosis* outside the facility; (b) cross-reactivity with another antigen (e.g., nontuberculous mycobacteria); (c) errors in applying, reading, or interpreting the test; (d) false positivity caused by the normal variability of the test; or (e) false positivity caused by a defective PPD preparation.

If this review and/or screening does identify additional PPD test conversions, nosocomial transmission is more likely. In this situation, the patient identification (i.e., triage) process, TB infection-control policies and practices, and engineering controls should be evaluated to identify problems that could have led to exposure and transmission (Table 4).

If no such problems are identified, a high-risk protocol should be implemented in the affected area or occupational group, and the public health department or other persons with expertise in TB infection control should be consulted.

If such problems are identified, appropriate interventions should be implemented to correct the problem(s), and PPD skin testing of PPD-negative HCWs should be repeated after 3 months.

If no additional PPD conversions are detected on follow-up testing, the investigation can be terminated.

If additional PPD conversions are detected on follow-up testing, the possible reasons for exposure and transmission should be reassessed, the appropriateness of and adherence to the interventions implemented should be evaluated, and PPD skin testing of PPD-negative HCWs should be repeated after another 3 months.

If no additional PPD test conversions are detected on this second round of follow-up testing, the investigation can be terminated. However, if additional PPD test conversions are detected on the second round of follow-up testing, a high-risk protocol should be implemented in the affected area or occupational group, and the public health department or other persons with expertise in TB infection control should be consulted.

b. Investigating cases of active TB in HCWs.

If an HCW develops active TB, the following steps should be taken:

- The case should be evaluated epidemiologically, in a manner similar to PPD test conversions in HCWs, to determine the likelihood that it resulted from occupational transmission and to identify possible causes and implement appropriate interventions if the evaluation suggests such transmission.
- Contacts of the HCW (e.g., other HCWs, patients, visitors, and others who have had intense exposure to the HCW) should be identified and evaluated for TB infection and disease (Section II.K.3; Suppl. 2). The public health department should be notified immediately for consultation and to allow for investigation of community contacts who were not exposed in the health-care facility.
- The public health department should notify facilities when HCWs with TB are reported by physicians so that an investigation of contacts can be conducted in the facility. The information provided by the health

department to facilities should be in accordance with state or local laws to protect the confidentiality of the HCW.

2. Investigating Possible Patient-to-Patient Transmission of *M. tuberculosis*

Surveillance of active TB cases in patients should be conducted. If this surveillance suggests the possibility of patient-to-patient transmission of *M. tuberculosis* (e.g., a high proportion of TB patients had prior admissions during the year preceding onset of their TB, the number of patients with drug-resistant TB increased suddenly, or isolates obtained from multiple patients had identical and characteristic drug-susceptibility or DNA fingerprint patterns), the following steps should be taken:

- Review the HCW PPD test results and patient surveillance data for the suspected areas to detect additional patients or HCWs with PPD test conversions or active disease.
- Look for possible exposures that patients with newly diagnosed TB could have had to other TB patients during previous admissions. For example, were the patients admitted to the same room or area, or did they receive the same procedure or go to the same treatment area on the same day?

If the evaluation thus far suggests transmission has occurred, the following steps should be taken:

- Evaluate possible causes of the transmission (e.g., problem with patient detection, institutional barriers to implementing appropriate isolation practices, or inadequate engineering controls) (Table 4).
- Ascertain whether other patients or HCWs could have been exposed; if so, evaluate these persons for TB infection and disease (Section II.K.3; Suppl. 2).
- Notify the public health department so they can begin a community contact investigation if necessary.

3. Investigating Contacts of Patients and HCWs Who Have Infectious TB

If a patient who has active TB is examined in a health-care facility and the illness is not diagnosed correctly, resulting in failure to apply appropriate precautions, or if an HCW develops active TB and exposes other persons in the facility, the following steps should be taken when the illness is later diagnosed correctly:

- To identify other patients and HCWs who were exposed to the source patient before isolation procedures were begun, interview the source patient and all applicable personnel and review that patient's medical record. Determine the areas of the facility in which the source patient was hospitalized, visited, or worked before being placed in isolation (e.g., outpatient clinics, hospital rooms, treatment rooms, radiology and procedure areas, and patient lounges) and the HCWs who may have been exposed during that time (e.g., persons providing direct care, therapists, clerks, transportation personnel, housekeepers, and social workers).
- The contact investigation should first determine if *M. tuberculosis* transmission has occurred from the source patient to those persons with whom the source patient had the most intense contact.
- Administer PPD tests to the most intensely exposed HCWs and patients as soon as possible after the exposure has occurred. If transmission did occur to the most intensely exposed persons, then those persons with whom the patient had less contact should be evaluated. If the initial PPD test result is negative, a second test should be administered 12 weeks after the exposure was terminated.
- Those persons who were exposed to *M. tuberculosis* and who have either a PPD test conversion or symptoms suggestive of TB should receive prompt clinical evaluation and, if indicated, chest radiographs and bacteriologic studies should be performed (Suppl. 2). Those persons who have evidence of newly acquired infection or active disease should be evaluated for preventive or curative therapy (Suppl. 2). Persons who have previously had positive PPD test results and who have been exposed to an infectious TB patient do not require a repeat PPD test or a chest radiograph unless they have symptoms suggestive of TB.
- In addition to PPD testing those HCWs and patients who have been exposed to *M. tuberculosis* because a patient was not isolated promptly or an HCW with active TB was not identified promptly, the investigation should determine why the diagnosis of TB was delayed. If the correct diagnosis was made but the patient was not isolated promptly, the reasons for the delay need to be defined so that corrective actions can be taken.

L. Coordination With the Public Health Department

- As soon as a patient or HCW is known or suspected to have active TB, the patient or HCW should be reported to the public health department so that appropriate follow-up can be arranged and a community contact investigation can be performed. The health department should be notified well before patient discharge to facilitate follow-up and continuation of therapy. A discharge plan coordinated with the patient or HCW, the health department, and the inpatient facility should be implemented.
- The public health department should protect the confidentiality of the patient or HCW in accordance with state and local laws.
- Health-care facilities and health departments should coordinate their efforts to perform appropriate contact investigations on patients and HCWs who have active TB.
- In accordance with state and local laws and regulations, results of all AFB-positive sputum smears, cultures positive for *M. tuberculosis*, and drug-susceptibility results on *M. tuberculosis* isolates should be reported to the public health department as soon as these results are available.
- The public health department may be able to assist facilities with planning and implementing various aspects of a TB infection-control program (e.g., surveillance, screening activities, and outbreak investigations). In addition, the state health department may be able to provide names of experts to assist with the engineering aspects of TB infection control.

M. Additional Considerations for Selected Areas in Health-Care Facilities and Other Health-Care Settings

This section contains additional information for selected areas in health-care facilities and for other health-care settings.

1. Selected Areas in Health-Care Facilities

a. Operating rooms.

- Elective operative procedures on patients who have TB should be delayed until the patient is no longer infectious.
- If operative procedures must be performed, they should be done, if possible, in operating rooms that have anterooms. For operating rooms without anterooms, the doors to the operating room should be closed, and traffic into and out of the room should be minimal to reduce the frequency of opening and closing the door. Attempts should be made to perform the procedure at a time when other patients are not present in the operative suite and when a minimum number of personnel are present (e.g., at the end of day).
- Placing a bacterial filter on the patient endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator or anesthesia machine if these are used) when operating on a patient who has confirmed or suspected TB may help reduce the risk for contaminating anesthesia equipment or discharging tubercle bacilli into the ambient air.

• During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended standards for ventilating TB isolation rooms.

• When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW must protect the field from the respiratory secretions of the HCW and protect the HCW from the infectious droplet nuclei generated by the patient. Valved or positive-pressure respirators do not protect the sterile field; therefore, a respirator that does not have a valve and that meets the criteria in Section II.G should be used.

b. Autopsy rooms.

• Because infectious aerosols are likely to be present in autopsy rooms, such areas should be at negative pressure with respect to adjacent areas (Suppl. 3), and the room air should be exhausted directly to the outside of the building. ASHRAE recommends that autopsy rooms have ventilation that provides an airflow of 12 ACH (*47*), although the effectiveness of this ventilation level in reducing the risk for *M. tuberculosis*, transmission has not been evaluated. Where possible, this level should be increased by means of ventilation system design or by auxiliary methods (e.g., recirculation of air within the room through HEPA filters) (Suppl. 3).

• Respiratory protection should be worn by personnel while performing autopsies on deceased persons who may have had TB at the time of death (Section II.G; Suppl. 4).

• Recirculation of HEPA-filtered air within the room or UVGI may be used as a supplement to the recommended ventilation (Suppl. 3).

c. Laboratories.

• Laboratories in which specimens for mycobacteriologic studies (e.g., AFB smears and cultures) are processed should be designed to conform with criteria specified by CDC and the National Institutes of Health (*59*).

2. Other Health-Care Settings

TB precautions may be appropriate in a number of other types of health care settings. The specific precautions that are applied will vary depending on the setting. At a minimum, a risk assessment should be performed yearly for these settings; a written TB infection-control plan should be developed, evaluated, and revised on a regular basis; protocols should be in place for identifying and managing patients who may have active TB; HCWs should receive appropriate training, education, and screening; protocols for problem evaluation should be in place; and coordination with the public health department should be arranged when necessary. Other recommendations specific to certain of these settings follow.

a. Emergency medical services.

• When EMS personnel or others must transport patients who have confirmed or suspected active TB, a surgical mask should be placed, if possible, over the patient's mouth and nose. Because administrative and engineering controls during emergency transport situations cannot be ensured, EMS personnel should wear respiratory protection when transporting such patients. If feasible, the windows of the vehicle should be kept open. The heating and air-conditioning system should be set on a nonrecirculating cycle.

• EMS personnel should be included in a comprehensive PPD screening program and should receive a baseline PPD test and follow-up testing as indicated by the risk assessment. They should also be included in the follow-up of contacts of a patient with infectious TB.*

b. Hospices.

• Hospice patients who have confirmed or suspected TB should be managed in the manner described in this document for management of TB patients in hospitals. General-use and specialized areas (e.g., treatment or TB isolation rooms) should be ventilated in the same manner as described for similar hospital areas.

c. Long-term care facilities.

• Recommendations published previously for preventing and controlling TB in long-term care facilities should be followed (*60*).

• Long-term care facilities should also follow the recommendations outlined in this document.

d. Correctional facilities.

• Recommendations published previously for preventing and controlling TB in correctional facilities should be followed (*61*).

• Prison medical facilities should also follow the recommendations outlined in this document.

e. Dental settings.

In general, the symptoms for which patients seek treatment in a dental-care setting are not likely to be caused by infectious TB. Unless a patient requiring dental care coincidentally has TB, it is unlikely that infectious TB will be encountered in the dental setting. Furthermore, generation of droplet nuclei containing *M. tuberculosis* during dental procedures has not been demonstrated (*62*). Therefore, the risk for transmission of *M. tuberculosis* in most dental settings is probably quite low. Nevertheless, during dental procedures, patients and dental workers share the same air for varying periods of time. Coughing may be stimulated occasionally by oral manipulations, although no specific dental procedures have been classified as "cough-inducing." In some instances, the population served by a dental-care facility, or the HCWs in the facility, may be at relatively high risk for TB. Because the potential exists for transmission of *M. tuberculosis* in dental settings, the following recommendations should be followed:

• A risk assessment (Section II.B) should be done periodically, and TB infection-control policies for each dental setting should be based on the risk assessment. The policies should include provisions for detection and referral of patients who may have undiagnosed active TB; management of patients with active TB, relative to provision of urgent dental care; and employer-sponsored HCW education, counseling, and screening.

• While taking patients' initial medical histories and at periodic updates, dental HCWs should routinely ask all patients whether they have a history of TB disease and symptoms suggestive of TB.

• Patients with a medical history or symptoms suggestive of undiagnosed active TB should be referred promptly for medical evaluation of possible infectiousness. Such patients should not remain in the dental-care facility any longer than required to arrange a referral. While in the dental-care facility, they should wear surgical masks and should be instructed to cover their mouths and noses when coughing or sneezing.

• Elective dental treatment should be deferred until a physician confirms that the patient does not have infectious TB. If the patient is diagnosed as having active TB, elective dental treatment should be deferred until the patient is no longer infectious.

• If urgent dental care must be provided for a patient who has, or is strongly suspected of having, infectious TB, such care should be provided in facilities that can provide TB isolation (Sections II.E and G). Dental HCWs should use respiratory protection while performing procedures on such patients.

• Any dental HCW who has a persistent cough (i.e., a cough lasting ≥3

*The Ryan White Comprehensive AIDS Resource Emergency Act of 1990, P.L. 101–381, mandates notification of EMS personnel after they have been exposed to infectious pulmonary TB (42 U.S.C. 300ff–82. 54 FR 13417 [March 21, 1994]).

weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, bloody sputum, anorexia, and fever), should be evaluated promptly for TB. The HCW should not return to the workplace until a diagnosis of TB has been excluded or until the HCW is on therapy and a determination has been made that the HCW is noninfectious.

• In dental-care facilities that provide care to populations at high risk for active TB, it may be appropriate to use engineering controls similar to those used in general-use areas (e.g., waiting rooms) of medical facilities that have a similar risk profile.

f. Home-health-care settings.

• HCWs who provide medical services in the homes of patients who have suspected or confirmed infectious TB should instruct such patients to cover their mouths and noses with a tissue when coughing or sneezing. Until such patients are no longer infectious, HCWs should wear respiratory protection when entering these patients' homes (Suppl. 4).

• Precautions in the home may be discontinued when the patient is no longer infectious (Suppl. 1).

• HCWs who provide health-care services in their patients' homes can assist in preventing transmission of *M. tuberculosis* by educating their patients regarding the importance of taking medications as prescribed and by administering DOT.

• Cough-inducing procedures performed on patients who have infectious TB should not be done in the patients' homes unless absolutely necessary. When medically necessary cough-inducing procedures (e.g., AFB sputum collection for evaluation of therapy) must be performed on patients who may have infectious TB, the procedures should be performed in a health-care facility in a room or booth that has the recommended ventilation for such procedures. If these procedures must be performed in a patient's home, they should be performed in a well-ventilated area away from other household members. If feasible, the HCW should consider opening a window to improve ventilation or collecting the specimen while outside the dwelling. The HCW collecting these specimens should wear respiratory protection during the procedure (Section II.G).

• HCWs who provide medical services in their patients' homes should be included in comprehensive employer-sponsored TB training, education, counseling, and screening programs. These programs should include provisions for identifying HCWs who have active TB, baseline PPD skin testing, and follow-up PPD testing at intervals appropriate to the degree of risk.

• Patients who are at risk for developing active TB and the HCWs who provide medical services in the homes of such patients should be reminded periodically of the importance of having pulmonary symptoms evaluated promptly to permit early detection of and treatment for TB.

g. Medical offices.

In general, the symptoms of active TB are symptoms for which patients are likely to seek treatment in a medical office. Furthermore, the populations served by some medical offices, or the HCWs in the office, may be at relatively high risk for TB. Thus, it is likely that infectious TB will be encountered in a medical office. Because of the potential for *M. tuberculosis* transmission, the following recommendations should be observed:

• A risk assessment should be conducted periodically, and TB infection-control policies based on results of the risk assessment should be developed for the medical office. The policies should include provisions for identifying and managing patients who may have undiagnosed active TB; managing patients who have active TB; and educating, training, counseling, and screening HCWs.

• While taking patients' initial medical histories and at periodic updates, HCWs who work in medical offices should routinely ask all patients whether they have a history of TB disease or have had symptoms suggestive of TB.

• Patients with a medical history and symptoms suggestive of active TB should receive an appropriate diagnostic evaluation for TB and be evaluated promptly for possible infectiousness. Ideally, this evaluation should be done in a facility that has TB isolation capability. At a minimum, the patient should be provided with and asked to wear a surgical mask, instructed to cover the mouth and nose with a tissue when coughing or sneezing, and separated as much as possible from other patients.

• Medical offices that provide evaluation or treatment services for TB patients should follow the recommendations for managing patients in ambulatory-care settings (Section II.D).

• If cough-inducing procedures are to be administered in a medical office to patients who may have active TB, appropriate precautions should be followed (Section II.H).

• Any HCW who has a persistent cough (i.e., a cough lasting ≥3 weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, bloody sputum, anorexia, or fever) should be evaluated promptly for TB. HCWs with such signs or symptoms should not return to the workplace until a diagnosis of TB has been excluded or until they are on therapy and a determination has been made that they are noninfectious.

• HCWs who work in medical offices in which there is a likelihood of exposure to patients who have infectious TB should be included in employer-sponsored education, training, counseling, and PPD testing programs appropriate to the level of risk in the office.

• In medical offices that provide care to populations at relatively high risk for active TB, use of engineering controls as described in this document for general-use areas (e.g., waiting rooms) may be appropriate (Section II.F; Suppl. 3).

Supplement 1: Determining the Infectiousness of a TB Patient

The infectiousness of patients with TB correlates with the number of organisms expelled into the air, which, in turn, correlates with the following factors: (a) Disease in the lungs, airways, or larynx; (b) presence of cough or other forceful expiratory measures; (c) presence of acid-fast bacilli (AFB) in the sputum; (d) failure of the patient to cover the mouth and nose when coughing; (e) presence of cavitation on chest radiograph; (f) inappropriate or short duration of chemotherapy; and (g) administration of procedures that can induce coughing or cause aerosolization of *M. tuberculosis* (e.g., sputum induction).

The most infectious persons are most likely those who have not been treated for TB and who have either (a) pulmonary or laryngeal TB and a cough or are undergoing cough-inducing procedures, (b) a positive AFB sputum smear, or (c) cavitation on chest radiograph. Persons with extrapulmonary TB usually are not infectious unless they have (a) concomitant pulmonary disease; (b) nonpulmonary disease located in the respiratory tract or oral cavity; or (c) extrapulmonary disease that includes an open abscess or lesion in which the concentration of organisms is high, especially if drainage from the abscess or lesion is extensive (*20,22*). Coinfection with HIV does not appear to affect the infectiousness of TB patients (*63–65*).

In general, children who have TB may be less likely than adults to be

infectious; however, transmission from children can occur. Therefore, children with TB should be evaluated for infectiousness using the same parameters as for adults (i.e., pulmonary or laryngeal TB, presence of cough or cough-inducing procedures, positive sputum AFB smear, cavitation on chest radiograph, and adequacy and duration of therapy). Pediatric patients who may be infectious include those who (a) are not on therapy, (b) have just been started on therapy, or (c) are on inadequate therapy, *and* who (a) have laryngeal or extensive pulmonary involvement, (b) have pronounced cough or are undergoing cough-inducing procedures, (c) have positive sputum AFB smears, or (d) have cavitary TB. Children who have typical primary tuberculous lesions and do not have any of the indicators of infectiousness listed previously usually do not need to be placed in isolation. Because the source case for pediatric TB patients often occurs in a member of the infected child's family (*45*), parents and other visitors of all pediatric TB patients should be evaluated for TB as soon as possible.

Infection is most likely to result from exposure to persons who have unsuspected pulmonary TB and are not receiving anti-TB therapy or from persons who have diagnosed TB and are not receiving adequate therapy. Administration of effective anti-TB therapy has been associated with decreased infectiousness among persons who have active TB (*66*). Effective therapy reduces coughing, the amount of sputum produced, and the number of organisms in the sputum. However, the period of time a patient must take effective therapy before becoming noninfectious varies between patients (*67*). For example, some TB patients are never infectious, whereas those with unrecognized or inadequately treated drug-resistant TB may remain infectious for weeks or months (*24*). Thus, decisions about infectiousness should be made on an individual basis.

In general, patients who have suspected or confirmed active TB should be considered infectious if they (a) are coughing, (b) are undergoing cough-inducing procedures, or (c) have positive AFB sputum smears, *and* if they (a) are not on chemotherapy, (b) have just started chemotherapy, or (c) have a poor clinical or bacteriologic response to chemotherapy. A patient who has drug-susceptible TB and who is on adequate chemotherapy and has had a significant clinical and bacteriologic response to therapy (i.e., reduction in cough, resolution of fever, and progressively decreasing quantity of bacilli on smear) is probably no longer infectious. However, because drug-susceptibility results are not usually known when the decision to discontinue isolation is made, all TB patients should remain in isolation while hospitalized until they have had three consecutive negative sputum smears collected on different days and they demonstrate clinical improvement.

Supplement 2: Diagnosis and Treatment of Latent TB Infection and Active TB

I. Diagnostic Procedures for TB Infection and Disease

A diagnosis of TB may be considered for any patient who has a persistent cough (i.e., a cough lasting ≥3 weeks) or other signs or symptoms compatible with TB (e.g., bloody sputum, night sweats, weight loss, anorexia, or fever). However, the index of suspicion for TB will vary in different geographic areas and will depend on the prevalence of TB and other characteristics of the population served by the facility. The index of suspicion for TB should be very high in areas or among groups of patients in which the prevalence of TB is high (Section I.B). Persons for whom a diagnosis of TB is being considered should receive appropriate diagnostic tests, which may include PPD skin testing, chest radiography, and bacteriologic studies (e.g., sputum microscopy and culture).

A. PPD Skin Testing and Anergy Testing

1. Application and Reading of PPD Skin Tests

The PPD skin test is the only method available for demonstrating infection with *M. tuberculosis*. Although currently available PPD tests are <100% sensitive and specific for detection of infection with *M. tuberculosis*, no better diagnostic methods have yet been devised. Interpretation of PPD test results requires knowledge of the antigen used, the immunologic basis for the reaction to this antigen, the technique used to administer and read the test, and the results of epidemiologic and clinical experience with the test (*2,5,6*). The PPD test, like all medical tests, is subject to variability, but many of the variations in administering and reading PPD tests can be avoided by proper training and careful attention to details.

The intracutaneous (Mantoux) administration of a measured amount of PPD-tuberculin is currently the preferred method for doing the test. One-tenth milliliter of PPD (5 TU) is injected just beneath the surface of the skin on either the volar or dorsal surface of the forearm. A discrete, pale elevation of the skin (i.e., a wheal) that is 6–10 mm in diameter should be produced.

PPD test results should be read by designated, trained personnel between 48 and 72 hours after injection. Patient or HCW self-reading of PPD test results should not be accepted (*68*). The result of the test is based on the presence or absence of an induration at the injection site. Redness or erythema should not be measured. The transverse diameter of induration should be recorded in millimeters.

2. Interpretation of PPD Skin Tests

a. General.

The interpretation of a PPD reaction should be influenced by the purpose for which the test was given (e.g., epidemiologic versus diagnostic purposes), by the prevalence of TB infection in the population being tested, and by the consequences of false classification. Errors in classification can be minimized by establishing an appropriate definition of a positive reaction (Table S2–1).

The positive-predictive value of PPD tests (i.e, the probability that a person with a positive PPD test is actually infected with *M. tuberculosis*) is dependent on the prevalence of TB infection in the population being tested and the specificity of the test (*69,70*). In populations with a low prevalence of TB infection, the probability that a positive PPD test represents true infection with *M. tuberculosis* is very low if the cut-point is set too low (i.e., the test is not adequately specific). In populations with a high prevalence of TB infection, the probability that a positive PPD test using the same cut-point represents true infection with *M. tuberculosis* is much higher. To ensure that few persons infected with tubercle bacilli will be misclassified as having negative reactions and few persons not infected with tubercle bacilli will be misclassified as having positive reactions, different cut-points are used to separate positive reactions from negative reactions for different populations, depending on the risk for TB infection in that population.

A lower cut-point (i.e., 5 mm) is used for persons in the highest risk groups, which include HIV-infected persons, recent close contacts of persons with TB (e.g., in the household or in an unprotected occupational exposure similar in intensity and duration to household contact), and persons who have abnormal chest radiographs with fibrotic changes consistent with inactive TB. A higher cut-point (i.e., 10 mm) is used for persons who are not in the highest risk group but who have other risk factors (e.g., injecting-drug users

known to be HIV seronegative; persons with certain medical conditions that increase the risk for progression from latent TB infection to active TB [Table S2–1]); medically underserved, low-income populations; persons born in foreign countries that have a high prevalence of TB; and residents of correctional institutions and nursing homes). An even higher cut-point (i.e., 15 mm) is used for all other persons who have none of the above risk factors.

Recent PPD converters are considered members of a high-risk group. A ≥10 mm increase in the size of the induration within a 2-year period is classified as a conversion from a negative to a positive test result for persons <35 years of age. An increase of induration of ≥15 mm within a 2-year period is classified as a conversion for persons ≥35 years of age (5).

b. HCWs.

In general, HCWs should have their skin-test results interpreted according to the recommendations in this supplement and in sections 1, 2, 3, and 5 of Table S2–1. However, the prevalence of TB in the facility should be considered when choosing the appropriate cut-point for defining a positive PPD reaction. In facilities where there is essentially no risk for exposure to TB patients (i.e., minimal- or very low-risk facilities [Section II.B]), an induration ≥15 mm may be an appropriate cut-point for HCWs who have no other risk factors. In other facilities where TB patients receive care, the appropriate cut-point for HCWs who have no other risk factors may be ≥10 mm.

A recent PPD test conversion in an HCW should be defined generally as an increase of ≥10 mm in the size of induration within a 2-year period. For HCWs in facilities where exposure to TB is very unlikely (e.g., minimal-risk facilities), an increase of ≥15 mm within a 2-year period may be more appropriate for defining a recent conversion because of the lower positive-predictive value of the test in such groups.

3. Anergy Testing

HIV-infected persons may have suppressed reactions to PPD skin tests because of anergy, particularly if their CD4+ T-lymphocyte counts decline (*71*). Persons with anergy will have a negative PPD test regardless of infection with *M. tuberculosis*. HIV-infected persons should be evaluated for anergy in conjunction with PPD testing (*72*). Two companion antigens (e.g., Candida antigen and tetanus toxoid) should be administered in addition to PPD. Persons with ≥3 mm of induration to any of the skin tests (including tuberculin) are considered not anergic. Reactions of ≥5 mm to PPD are considered to be evidence of TB infection in HIV-infected persons regardless of the reactions to the companion antigens. If there is no reaction (i.e., <3 mm induration) to any of the antigens, the person being tested is considered anergic. Determination of whether such persons are likely to be infected with *M. tuberculosis* must be based on other epidemiologic factors (e.g., the proportion of other persons with the same level of exposure who have positive PPD test results and the intensity or duration of exposure to infectious TB patients that the anergic person experienced).

4. Pregnancy and PPD Skin Testing

Although thousands (perhaps millions) of pregnant women have been PPD skin tested since the test was devised, thus far no documented episodes of fetal harm have resulted from use of the tuberculin test (*73*). Pregnancy should not exclude a female HCW from being skin tested as part of a contact investigation or as part of a regular skin-testing program.

Table S2–1. Summary of Interpretation of Purified Protein Derivative (PPD)-Tuberculin Skin-Test Results

1. An induration of ≥5 mm is classified as positive in:

- Persons who have human immunodeficiency virus (HIV) infection or risk factors for HIV infection but unknown HIV status;
- Persons who have had recent close contact* with persons who have active tuberculosis (TB);
- Persons who have fibrotic chest radiographs (consistent with healed TB).

2. An induration of ≥10 mm is classified as positive in all persons who do not meet any of the criteria above but who have other risk factors for TB, including:

High-Risk Groups

- Injecting-drug users known to be HIV seronegative;
- Persons who have other medical conditions that reportedly increase the risk for progressing from latent TB infection to active TB (e.g., silicosis; gastrectomy or jejuno-ileal bypass; being ≥10% below ideal body weight; chronic renal failure with renal dialysis; diabetes mellitus; high-dose corticosteroid or other immuno-suppressive therapy; some hematologic disorders, including malignancies such as leukemias and lymphomas; and other malignancies);
- Children <4 years of age.

High-prevalence Groups

- Persons born in countries in Asia, Africa, the Caribbean, and Latin America that have high prevalence of TB;
- Persons from medically underserved, low-income populations;
- Residents of long-term-care facilities (e.g., correctional institutions and nursing homes);
- Persons from high-risk populations in their communities, as determined by local public health authorities.

3. An induration of ≥15 mm is classified as positive in persons who do not meet any of the above criteria.

4. Recent converters are defined on the basis of both size of induration and age of the person being tested:

- ≥10 mm increase within a 2-year period is classified as a recent conversion for persons <35 years of age;
- ≥15 mm increase within a 2-year period is classified as a recent conversion for persons ≥35 years of age.

5. PPD skin-test results in health-care workers (HCWs)

- In general, the recommendations in sections 1, 2, and 3 of this table should be followed when interpreting skin-test results in HCWs.

However, the prevalence of TB in the facility should be considered when choosing the appropriate cut-point for defining a positive PPD reaction. In facilities where there is essentially no risk for exposure to *Mycobacterium tuberculosis* (i.e., minimal- or very low-risk facilities [Section II.B]), an induration ≥15 mm may be a suitable cut-point for HCWs who have no other risk factors. In facilities where TB patients receive care, the cut-point for HCWs with no other risk factors maybe ≥10 mm.

- A recent conversion in an HCW should be defined generally as a ≥10 mm increase in size of induration within a 2-year period. For HCWs who work in facilities where exposure to TB is very unlikely (e.g., minimal-risk facilities), an increase of ≥15 mm within a 2-year period may be more appropriate for defining a recent conversion because of the lower positive-predictive value of the test in such groups.

5. BCG Vaccination and PPD Skin Testing

BCG vaccination may produce a PPD reaction that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*. For a person who was vaccinated with BCG, the probability that a PPD test reaction

*Recent close contact implies either household or social contact or unprotected occupational exposure similar in intensity and duration to household contact.

results from infection with *M. tuberculosis* increases (a) as the size of the reaction increases, (b) when the person is a contact of a person with TB, (c) when the person's country of origin has a high prevalence of TB, and (d) as the length of time between vaccination and PPD testing increases. For example, a PPD test reaction of ≥10 mm probably can be attributed to *M. tuberculosis* infection in an adult who was vaccinated with BCG as a child and who is from a country with a high prevalence of TB (*74,75*).

6. The Booster Phenomenon

The ability of persons who have TB infection to react to PPD may gradually wane. For example, if tested with PPD, adults who were infected during their childhood may have a negative reaction. However, the PPD could boost the hypersensitivity, and the size of the reaction could be larger on a subsequent test. This boosted reaction may be misinterpreted as a PPD test conversion from a newly acquired infection. Misinterpretation of a boosted reaction as a new infection could result in unnecessary investigations of laboratory and patient records in an attempt to identify the source case and in unnecessary prescription of preventive therapy for HCWs. Although boosting can occur among persons in any age group, the likelihood of the reaction increases with the age of the person being tested (*6,76*).

When PPD testing of adults is to be repeated periodically (as in HCW skin-testing programs), two-step testing can be used to reduce the likelihood that a boosted reaction is misinterpreted as a new infection. Two-step testing should be performed on all newly employed HCWs who have an initial negative PPD test result at the time of employment and have not had a documented negative PPD test result during the 12 months preceding the initial test. A second test should be performed 1–3 weeks after the first test. If the second test result is positive, this is most likely a boosted reaction, and the HCW should be classified as previously infected. If the second test result remains negative, the HCW is classified as uninfected, and a positive reaction to a subsequent test is likely to represent a new infection with *M. tuberculosis*.

B. Chest Radiography

Patients who have positive skin-test results or symptoms suggestive of TB should be evaluated with a chest radiograph regardless of PPD test results. Radiographic abnormalities that strongly suggest active TB include upper-lobe infiltration, particularly if cavitation is seen (*77*), and patchy or nodular infiltrates in the apical or subapical posterior upper lobes or the superior segment of the lower lobe. If abnormalities are noted, or if the patient has symptoms suggestive of extrapulmonary TB, additional diagnostic tests should be conducted.

The radiographic presentation of pulmonary TB in HIV-infected patients may be unusual (*78*). Typical apical cavitary disease is less common among such patients. They may have infiltrates in any lung zone, a finding that is often associated with mediastinal and/or hilar adenopathy, or they may have a normal chest radiograph, although this latter finding occurs rarely.

C. Bacteriology

Smear and culture examination of at least three sputum specimens collected on different days is the main diagnostic procedure for pulmonary TB (*6*). Sputum smears that fail to demonstrate AFB do not exclude the diagnosis of TB. In the United States, approximately 60% of patients with positive sputum cultures have positive AFB sputum smears. HIV-infected patients who have pulmonary TB may be less likely than immunocompetent patients to have AFB present on sputum smears, which is consistent with the lower frequency of cavitary pulmonary disease observed among HIV-infected persons (*39,41*).

Specimens for smear and culture should contain an adequate amount of expectorated sputum but not much saliva. If a diagnosis of TB cannot be established from sputum, a bronchoscopy may be necessary (*36,37*). In young children who cannot produce an adequate amount of sputum, gastric aspirates may provide an adequate specimen for diagnosis.

A culture of sputum or other clinical specimen that contains *M. tuberculosis* provides a definitive diagnosis of TB. Conventional laboratory methods may require 4–8 weeks for species identification; however, the use of radiometric culture techniques and nucleic acid probes facilitates more rapid detection and identification of mycobacteria (*79,80*). Mixed mycobacterial infection, either simultaneous or sequential, can obscure the identification of *M. tuberculosis* during the clinical evaluation and the laboratory analysis (*42*). The use of nucleic acid probes for both *M. avium* complex and *M. tuberculosis* may be useful for identifying mixed mycobacterial infections in clinical specimens.

II. Preventive Therapy for Latent TB Infection and Treatment of Active TB

A. Preventive Therapy for Latent TB Infection

Determining whether a person with a positive PPD test reaction or conversion is a candidate for preventive therapy must be based on (a) the likelihood that the reaction represents true infection with *M. tuberculosis* (as determined by the cut-points), (b) the estimated risk for progression from latent infection to active TB, and (c) the risk for hepatitis associated with taking isoniazid (INH) preventive therapy (as determined by age and other factors).

HCWs with positive PPD test results should be evaluated for preventive therapy regardless of their ages if they (a) are recent converters, (b) are close contacts of persons who have active TB, (c) have a medical condition that increases the risk for TB, (d) have HIV infection, or (e) use injecting drugs (*5*). HCWs with positive PPD test results who do not have these risk factors should be evaluated for preventive therapy if they are <35 years of age.

Preventive therapy should be considered for anergic persons who are known contacts of infectious TB patients and for persons from populations in which the prevalence of TB infection is very high (e.g., a prevalence of >10%).

Because the risk for INH-associated hepatitis may be increased during the peripartum period, the decision to use preventive therapy during pregnancy should be made on an individual basis and should depend on the patient's estimated risk for progression to active disease. In general, preventive therapy can be delayed until after delivery. However, for pregnant women who were probably infected recently or who have high-risk medical conditions, especially HIV infection, INH preventive therapy should begin when the infection is documented (*81–84*). No evidence suggests that INH poses a carcinogenic risk to humans (*85–87*).

The usual preventive therapy regimen is oral INH 300 mg daily for adults and 10 mg/kg/day for children (*88*). The recommended duration of therapy is 12 months for persons with HIV infection and 9 months for children. Other persons should receive INH therapy for 6–12 months. For persons who have silicosis or a chest radiograph demonstrating inactive fibrotic lesions and who have no evidence of active TB, acceptable regimens include (a) 4 months of INH plus rifampin or (b) 12 months of INH, providing that infection with INH-resistant organisms is unlikely (*33*). For persons likely to be infected

with MDR-TB, alternative multidrug preventive therapy regimens should be considered (*89*).

All persons placed on preventive therapy should be educated regarding the possible adverse reactions associated with INH use, and they should be questioned carefully at monthly intervals by qualified personnel for signs or symptoms consistent with liver damage or other adverse effects (*81–84,88,90,91*). Because INH-associated hepatitis occurs more frequently among persons >35 years of age, a transaminase measurement should be obtained from persons in this age group before initiation of INH therapy and then obtained monthly until treatment has been completed. Other factors associated with an increased risk for hepatitis include daily alcohol use, chronic liver disease, and injecting-drug use. In addition, postpubertal black and Hispanic women may be at greater risk for hepatitis or drug interactions (*92*). More careful clinical monitoring of persons with these risk factors and possibly more frequent laboratory monitoring should be considered. If any of these tests exceeds three to five times the upper limit of normal, discontinuation of INH should be strongly considered. Liver function tests are not a substitute for monthly clinical evaluations or for the prompt assessment of signs or symptoms of adverse reactions that could occur between the regularly scheduled evaluations (*33*).

Persons who have latent TB infection should be advised that they can be reinfected with another strain of *M. tuberculosis* (*93*).

B. Treatment of Patients Who Have Active TB

Drug-susceptibility testing should be performed on all initial isolates from patients with TB. However, test results may not be available for several weeks, making selection of an initial regimen difficult, especially in areas where drug-resistant TB has been documented. Current recommendations for therapy and dosage schedules for the treatment of drug-susceptible TB should be followed (Table S2–2; Table S2–3) (*43*). Streptomycin is contraindicated in the treatment of pregnant women because of the risk for ototoxicity to the fetus. In geographic areas or facilities in which drug-resistant TB is highly prevalent, the initial treatment regimen used while results of drug-susceptibility tests are pending may need to be expanded. This decision should be based on analysis of surveillance data.

When results from drug-susceptibility tests become available, the regimen should be adjusted appropriately (*94–97*). If drug resistance is present, clinicians unfamiliar with the management of patients with drug-resistant TB should seek expert consultation.

For any regimen to be effective, adherence to the regimen must be ensured. The most effective method of ensuring adherence is the use of DOT after the patient has been discharged from the hospital (*43,91*). This practice should be coordinated with the public health department.

TABLE S2–2.—REGIMEN OPTIONS FOR THE TREATMENT OF TUBERCULOSIS (TB) IN CHILDREN AND ADULTS

Option	Indication	Total duration of therapy	Initial treatment phase		Continuation treatment phase		Comments
			Drugs*	Interval and duration	Drugs*	Interval and duration	
1	Pulmonary and extrapulmonary TB in adults and children.	6 mos	INH RIF PZA EMB or SM	Daily for 8 wks.	INH RIF	Daily or two or three times wkly† for 16 wks§.	• EMB or SM should be continued until susceptibility to INH and RIF is demonstrated. • In areas where primary INH resistance is <4%, EMB or SM may not be necessary for patients with no individual risk factors for drug resistance.
2	Pulmonary and extrapulmonary TB in adults and children.	6 mos	INH RIF PZA EMB or SM	Daily for 2 wks, then two times wkly† for 6 wks.	INH RIF	Two times wkly† for 16 wks§.	• Regimen should be directly observed. • After the initial phase, EMB or SM should be continued until susceptibility to INH and RIF is demonstrated, unless drug resistance is unlikely.
3	Pulmonary and extrapulmonary TB in adults and children.	6 mos	INH RIF PZA EMB or SM		3 times wkly† for 6 mos§		• Regimen should be directly observed. • Continue all four drugs for 6 mos.¶ • This regimen has been shown to be effective for INH-resistant TB.

TABLE S2–2.—REGIMEN OPTIONS FOR THE TREATMENT OF TUBERCULOSIS (TB) IN CHILDREN AND ADULTS—Continued

Option	Indication	Total duration of therapy	Initial treatment phase		Continuation treatment phase		Comments
			Drugs*	Interval and duration	Drugs*	Interval and duration	
4	Smear- and culture-negative pulmonary TB in adults.	4 mos	INH ..... RIF PZA EMB or SM	Follow option 1, 2, or 3 for 8 wks.	INH ..... RIF PZA EMB or SM	Daily or two or three times wkly† for 8 wks.	• Continue all four drugs for 4 mos. • If drug resistance is unlikely (primary INH resistance <4% and patient has no individual risk factors for drug resistance), EMB or SM may not be necessary and PZA may be discontinued after 2 mos.
¶	Pulmonary and extrapulmonary TB in adults and children when PZA is contraindicated.	9 mos	INH ..... RIF EMB or SM**	Daily for 8 wks.	INH ..... RIF	Daily or two times wkly† for 24 wks§.	• EMB or SM should be continued until susceptibility to INH and RIF is demonstrated. • In areas where primary INH resistance is <4%, EMB or SM may not be necessary for patients with no individual risk factors for drug resistance.

*EMB=ethambutol; INH=isoniazid; PZA=pyrazinamide; RIF=rifampin; SM=streptomycin.
† All regimens administered intermittently should be directly observed.
§ For infants and children with miliary TB, bone and joint TB, or TB meningitis, treatment should last at least 12 months. For adults with these forms of extrapulmonary TB, response to therapy should be monitored closely. If response is slow or suboptimal, treatment may be prolonged on a case-by-case basis.
¶ Some evidence suggests that SM may be discontinued after 4 months if the isolate is susceptible to all drugs.
** Avoid treating pregnant women with SM because of the risk of ototoxicity to the fetus.

Note: For all patients, if drug-susceptibility results show resistance to any of the first-line drugs, or if the patient remains symptomatic or smear- or culture-positive after 3 months, consult a TB medical expert.

TABLE S2–3.—DOSAGE RECOMMENDATIONS FOR THE INITIAL TREATMENT OF TUBERCULOSIS IN CHILDREN* AND ADULTS

Drug	Dosage schedule					
	Daily dose (maximum dose)		Two doses per week (maximum dose)		Three doses per week (maximum dose)	
	Children	Adults	Children	Adults	Children	Adults
Isoniazid	10–20 mg/kg (300 mg).	5 mg/kg (300 mg)	20–40 mg/kg (900 mg).	15 mg/kg (900 mg).	20–40 mg/kg (900 mg).	15 mg/kg) (900 mg)
Rifampin	10–20 mg/kg (600 mg).	10 mg/kg (600 mg).	10–20 mg/kg (600 mg).	10 mg/kg (600 mg).	10–20 mg/kg (600 mg).	10 mg/kg (600 mg)
Pyrazinamide	15–30 mg/kg (2 gm).	15–30 mg/kg (2 gm).	50–70 mg/kg (4 gm).	50–70 mg/kg (4 gm).	50–70 mg/kg (3 gm).	50–70 mg/kg (3 gm)
Ethambutol	15–25 mg/kg	15–25 mg/kg	50 mg/kg	50 mg/kg	25–40 mg/kg	25–30 mg/kg
Streptomycin	20–40 mg/kg (1 gm).	15 mg/kg (1 gm) ..	20–40 mg/kg (1.5 gm).	20–40 mg/kg (1.5 gm).	20–40 mg/kg (1.5 gm).	20–40 mg/kg (1.5 gm)

*Persons ≤12 years of age.

Supplement 3: Engineering Controls

I. Introduction

This supplement provides information regarding the use of ventilation (Section II) and UVGI (Section III) for preventing the transmission of *M. tuberculosis* in health-care facilities. The information provided is primarily conceptual and is intended to educate staff in the health-care facility concerning engineering controls and how these controls can be used as part of the TB infection-control program. This supplement should not be used in place of consultation with experts, who can assume responsibility for advising on ventilation system design and selection, installation, and maintenance of equipment.

The recommendations for engineering controls include (a) local exhaust ventilation (i.e., source control), (b) general ventilation, and (c) air cleaning. General ventilation considerations include (a) dilution and removal of contaminants, (b) airflow patterns within rooms, (c) airflow direction in facilities, (d) negative pressure in rooms, and (e) TB isolation rooms. Air cleaning

or disinfection can be accomplished by filtration of air (e.g., through HEPA filters) or by UVGI.

II. Ventilation

Ventilation systems for health-care facilities should be designed, and modified when necessary, by ventilation engineers in collaboration with infection-control and occupational health staff. Recommendations for designing and operating ventilation systems have been published by ASHRAE (*47*), AIA (*48*), and the American Conference of Governmental Industrial Hygienists, Inc. (*98*).

As part of the TB infection-control plan, health-care facility personnel should determine the number of TB isolation rooms, treatment rooms, and local exhaust devices (i.e., for cough-inducing or aerosol-generating procedures) that the facility needs. The locations of these rooms and devices will depend on where in the facility the ventilation conditions recommended in this document can be achieved. Grouping isolation rooms together in one area of the facility may facilitate the care of TB patients and the installation and maintenance of optimal engineering controls (particularly ventilation).

Periodic evaluations of the ventilation system should review the number of TB isolation rooms, treatment rooms, and local exhaust devices needed and the regular maintenance and monitoring of the local and general exhaust systems (including HEPA filtration systems if they are used).

The various types and conditions of ventilation systems in health-care facilities and the individual needs of these facilities preclude the ability to provide specific instructions regarding the implementation of these recommendations. Engineering control methods must be tailored to each facility on the basis of need and the feasibility of using the ventilation and air-cleaning concepts discussed in this supplement.

A. Local Exhaust Ventilation

Purpose: To capture airborne contaminants at or near their source (i.e., the source control method) and remove these contaminants without exposing persons in the area to infectious agents (*98*).

Source control techniques can prevent or reduce the spread of infectious droplet nuclei into the general air circulation by entrapping infectious droplet nuclei as they are being emitted by the patient (i.e., the source). These techniques are especially important when performing procedures likely to generate aerosols containing infectious particles and when infectious TB patients are coughing or sneezing.

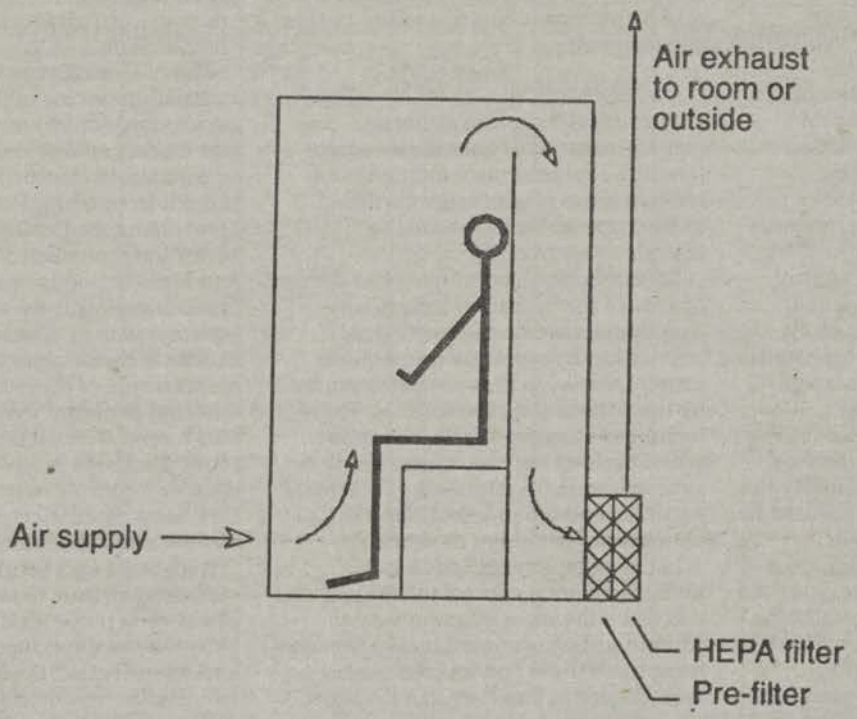
Local exhaust ventilation is a preferred source control technique, and it is often the most efficient way to contain airborne contaminants because it captures these contaminants near their source before they can disperse. Therefore, the technique should be used, if feasible, wherever aerosol-generating procedures are performed. Two basic types of local exhaust devices use hoods: (a) The enclosing type, in which the hood either partially or fully encloses the infectious source; and (b) the exterior type, in which the infectious source is near but outside the hood. Fully enclosed hoods, booths, or tents are always preferable to exterior types because of their superior ability to prevent contaminants from escaping into the HCW's breathing zone. Descriptions of both enclosing and exterior devices have been published previously (*98*).

1. Enclosing Devices

The enclosing type of local exhaust ventilation device includes laboratory hoods used for processing specimens that could contain viable infectious organisms, booths used for sputum induction or administration of aerosolized medications (e.g., aerosolized pentamidine) (Figure S3–1), and tents or hoods made of vinyl or other materials used to enclose and isolate a patient. These devices are available in various configurations. The most simple of these latter devices is a tent that is placed over the patient; the tent has an exhaust connection to the room discharge exhaust system. The most complex device is an enclosure that has a sophisticated self-contained airflow and recirculation system.

Both tents and booths should have sufficient airflow to remove at least 99% of airborne particles during the interval between the departure of one patient and the arrival of the next (*99*). The time required for removing a given percentage of airborne particles from an enclosed space depends on several factors. These factors include the number of ACH, which is determined by the number of cubic feet of air in the room or booth and the rate at which air is entering the room or booth at the intake source; the location of the ventilation inlet and outlet; and the physical configuration of the room or booth (Table S3–1).

FIGURE S3-1. An enclosing booth designed to sweep air past a patient who has active tuberculosis and entrap the infectious droplet nuclei in a high-efficiency particulate air (HEPA) filter



*Passage of air directly from the air supply to the exhaust (i.e., short-circuiting of air) is prevented by the structure on which patients sit and the wall on which patients rest their backs.

2. Exterior Devices

The exterior type of local exhaust ventilation device is usually a hood very near, but not enclosing, the infectious patient. The airflow produced by these devices should be sufficient to prevent cross-currents of air near the patient's face from causing escape of droplet nuclei. Whenever possible, the patient should face directly into the hood opening so that any coughing or sneezing is directed into the hood, where the droplet nuclei are captured. The device should maintain an air velocity of ≥ 200 feet per minute at the patient's breathing zone to ensure capture of droplet nuclei.

3. Discharge Exhaust From Booths, Tents, and Hoods

Air from booths, tents, and hoods may be discharged into the room in which the device is located or it may be exhausted to the outside. If the air is discharged into the room, a HEPA filter should be incorporated at the discharge duct or vent of the device. The exhaust fan should be located on the discharge side of the HEPA filter to ensure that the air pressure in the filter housing and booth is negative with respect to adjacent areas. Uncontaminated air from the room will flow into the booth through all openings, thus preventing infectious droplet nuclei in the booth from escaping into the room. Most commercially available booths, tents, and hoods are fitted with HEPA filters, in which case additional HEPA filtration is not needed.

If the device does not incorporate a HEPA filter, the air from the device should be exhausted to the outside in accordance with recommendations for isolation room exhaust (Suppl. 3, Section II.B.5). (See Supplement 3, Section II.C, for information regarding recirculation of exhaust air.)

TABLE S3–1.—AIR CHANGES PER HOUR (ACH) AND TIME IN MINUTES REQUIRED FOR REMOVAL EFFICIENCIES OF 90%, 99%, and 99.9% OF AIRBORNE CONTAMINANTS*

ACH	Minutes required for a removal efficiency of:		
	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

*This table has been adapted from the formula for the rate of purging airborne contaminants (*99*). Values have been derived from the formula $t_1 = [\ln C_2 + C_1) + (Q + V)] \times 60$, with $T_1 = 0$ and $C_2 + C_1 -$ (removal efficiency + 100), and where:

t_1 = initial timepoint
C_1 = initial concentration of contaminant
C_2 = final concentration of contaminants
Q = air flow rate (cubic feet per hour)
V = room volume (cubic feet)
Q + V = ACH

The times given assume perfect mixing of the air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor (*98*). The required time is derived by multiplying the appropriate time from the table by the mixing factor that has been determined for the booth or room. The factor and required time should be included in the operating instructions provided by the manufacturer of the booth or enclosure, and these instructions should be followed.

B. General Ventilation

General ventilation can be used for several purposes, including diluting and removing contaminated air, controlling airflow patterns within rooms, and controlling the direction of airflow throughout a facility. Information on these topics is contained in the following sections.

1. Dilution and Removal

Purpose: To reduce the concentration of contaminants in the air.

General ventilation maintains air quality by two processes: dilution and removal of airborne contaminants. Uncontaminated supply (i.e., incoming) air mixes with the contaminated room air (i.e., dilution), which is subsequently removed from the room by the exhaust system (i.e., removal). These processes reduce the concentration of droplet nuclei in the room air.

a. Types of general ventilation systems.

Two types of general ventilation systems can be used for dilution and removal of contaminated air: the single-pass system and the recirculating system. In a single-pass system, the supply air is either outside air that has been appropriately heated and cooled or air from a central system that supplies a number of areas. After air passes through the room (or area), 100% of that air is exhausted to the outside. The single-pass system is the preferred choice in areas where infectious airborne droplet nuclei are known to be present (e.g., TB isolation rooms or treatment rooms) because it prevents contaminated air from being recirculated to other areas of the facility.

In a recirculating system, a small portion of the exhaust air is discharged to the outside and is replaced with fresh outside air, which mixes with the portion of exhaust air that was not discharged to the outside. The resulting mixture, which can contain a large proportion of contaminated air, is then recirculated to the areas serviced by the system. This air mixture could be recirculated into the general ventilation, in which case contaminants may be carried from contaminated areas to uncontaminated areas. Alternatively, the air mixture could also be recirculated within a specific room or area, in which case other areas of the facility will not be affected (Suppl. 3, Section II.C.3).

b. Ventilation rates.

Recommended general ventilation rates for health-care facilities are usually expressed in number of ACH. This number is the ratio of the volume of air entering the room per hour to the room volume and is equal to the exhaust airflow (Q [cubic feet per minute]) divided by the room volume (V [cubic feet]) multiplied by 60 (i.e., ACH = Q ÷ V × 60).

The feasibility of achieving specific ventilation rates depends on the construction and operational requirements of the ventilation system (e.g., the energy requirements to move and to heat or cool the air). The feasibility of achieving specific ventilation rates may also be different for retrofitted facilities and newly constructed facilities. The expense and effort of achieving specific higher ventilation rates for new construction may be reasonable, whereas retrofitting an existing facility to achieve similar ventilation rates may be more difficult. However, achieving higher ventilation rates by using auxiliary methods (e.g.,

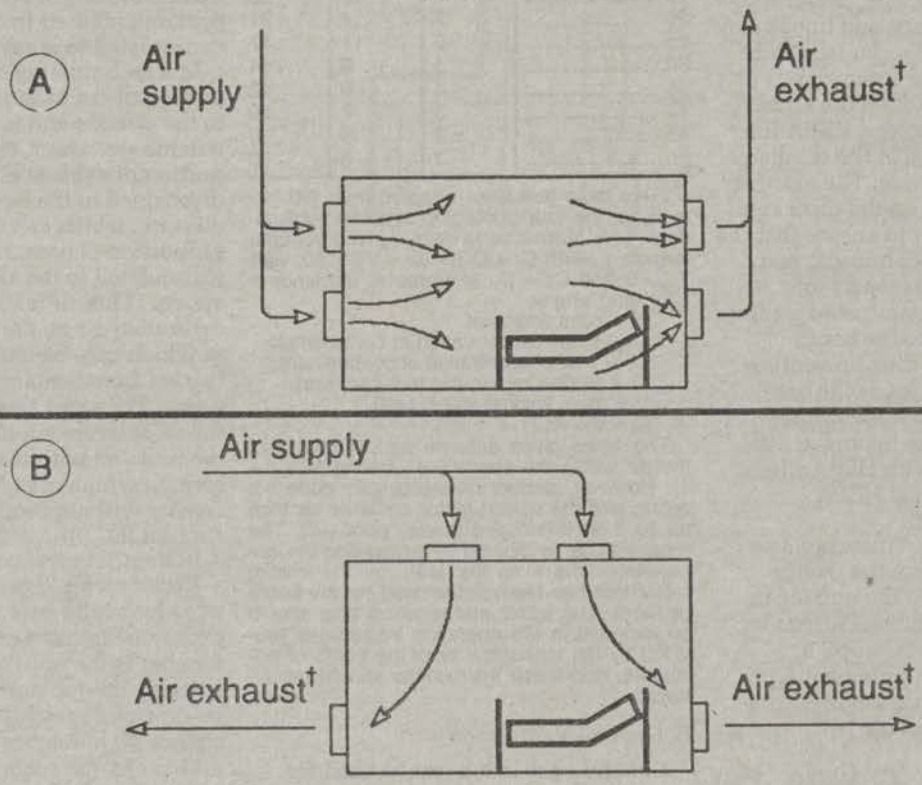
room-air recirculation) in addition to exhaust ventilation may be feasible in existing facilities (Suppl. 3, Section II.C).

2. Airflow Patterns Within Rooms (Air Mixing)

Purpose: To provide optimum airflow patterns and prevent both stagnation and short-circuiting of air.

General ventilation systems should be designed to provide optimal patterns of airflow within rooms and prevent air stagnation or short-circuiting of air from the supply to the exhaust (i.e., passage of air directly from the air supply to the air exhaust). To provide optimal airflow patterns, the air supply and exhaust should be located such that clean air first flows to parts of the room where HCWs are likely to work, and then flows across the infectious source and into the exhaust. In this way, the HCW is not positioned between the infectious source and the exhaust location. Although this configuration may not always be possible, it should be used whenever feasible. One way to achieve this airflow pattern is to supply air at the side of the room opposite the patient and exhaust it from the side where the patient is located. Another method, which is most effective when the supply air is cooler than the room air, is to supply air near the ceiling and exhaust it near the floor (Figure S3–2). Airflow patterns are affected by large air temperature differentials, the precise location of the supply and exhausts, the location of furniture, the movement of HCWs and patients, and the physical configuration of the space. Smoke tubes can be used to visualize airflow patterns in a manner similar to that described for estimating room air mixing.

FIGURE S3-2. Room airflow patterns designed to provide mixing of air and prevent passage of air directly from the air supply to the exhaust*



*Short-circuiting of air.
†Air should be exhausted to the outside (or through high-efficiency particulate air [HEPA] filters, if recirculated).

Adequate air mixing, which requires that an adequate number of ACH be provided to a room (Suppl. 3, Section II.B.1), must be ensured to prevent air stagnation within the room. However, the air will not usually be changed the calculated number of times per hour because the airflow patterns in the room may not permit complete mixing of the supply and room air in all parts of the room. This results in an "effective" airflow rate in which the supplied airflow may be less than required for proper ventilation. To account for this variation, a mixing factor (which ranges from 1 for perfect mixing to 10 for poor mixing) is applied as a multiplier to determine the actual supply airflow (i.e., the recommended ACH multiplied by the mixing factor equals the actual required ACH) (*51,98*). The room air supply and exhaust system should be designed to achieve the lowest mixing factor possible. The mixing factor is determined most accurately by experimentally testing each space configuration, but this procedure is complex and time-consuming. A reasonably good qualitative measure of mixing can be estimated by an experienced ventilation engineer who releases smoke from smoke tubes at a number of locations in the room and observes the movement of the smoke. Smoke movement in all areas of the

room indicates good mixing. Stagnation of air in some areas of the room indicates poor mixing, and movement of the supply and exhaust openings or redirection of the supply air is necessary.

3. Airflow Direction in the Facility

Purpose: To contain contaminated air in localized areas in a facility and prevent its spread to uncontaminated areas.

a. Directional airflow.

The general ventilation system should be designed and balanced so that air flows from less contaminated (i.e., more clean) to more contaminated (less clean) areas (*47,48*). For example, air should flow from corridors (cleaner areas) into TB isolation rooms (less clean areas) to prevent spread of contaminants to other areas. In some special treatment rooms in which operative and invasive procedures are performed, the direction of airflow is from the room to the hallway to provide cleaner air during these procedures. Cough-inducing or aerosol-generating procedures (e.g., bronchoscopy and irrigation of tuberculous abscesses) should not be performed in rooms with this type of airflow on patients who may have infectious TB.

b. Negative pressure for achieving directional airflow.

The direction of airflow is controlled by creating a lower (negative) pressure in the area into which the flow of air is desired. For air to flow from one area to another, the air pressure in the two areas must be different. Air will flow from a higher pressure area to a lower pressure area. The lower pressure area is described as being at negative* pressure relative to the higher pressure area. Negative pressure is attained by exhausting air from an area at a higher rate than air is being supplied. The level of negative pressure necessary to achieve the desired airflow will depend on the physical configuration of the ventilation system and area, including the airflow path and flow openings, and should be determined on an individual basis by an experienced ventilation engineer.

4. Achieving Negative Pressure in a Room

Purpose: To control the direction of airflow between the room and adjacent areas, thereby preventing contaminated air from escaping from the room into other areas of the facility.

a. Pressure differential.

The minimum pressure difference necessary to achieve and maintain negative pressure that will result in airflow into the room is very small (0.001 inch of water). Higher pressures (≥ 0.001 inch of water) are satisfactory; however, these higher pressures may be difficult to achieve. The actual level of negative pressure achieved will depend on the difference in the ventilation exhaust and supply flows and the physical configuration of the room, including the airflow path and flow openings. If the room is well sealed, negative pressures greater than the minimum of 0.001 inch of water may be readily achieved. However, if rooms are not well sealed, as may be the case in many facilities (especially older facilities), achieving higher negative pressures may require exhaust/supply flow differentials beyond the capability of the ventilation system.

To establish negative pressure in a room that has a normally functioning ventilation system, the room supply and exhaust airflows are first balanced to achieve an exhaust flow of either 10% or 50 cubic feet per minute (cfm) greater than the supply (whichever is the greater). In most situations, this specification should achieve a negative pressure of at least 0.001 inch of water. If the minimum 0.001 inch of water is not achieved and cannot be achieved by increasing the flow differential (within the limits of the ventilation system), the room should be inspected for leakage (e.g., through doors, windows, plumbing, and equipment wall penetrations), and corrective action should be taken to seal the leaks.

Negative pressure in a room can be altered by changing the ventilation system operation or by the opening and closing of the room's doors, corridor doors, or windows. When an operating configuration has been established, it is essential that all doors and windows remain properly closed in the isolation room and other areas (e.g., doors in corridors that affect air pressure) except when persons need to enter or leave the room or area.

b. Alternate methods for achieving negative pressure.

Although an anteroom is not a substitute for negative pressure in a room, it may be used to reduce escape of droplet nuclei during opening and closing of the isolation room door. Some anterooms have their own air supply duct, but others do not. The TB isolation room should have negative pressure relative to the anteroom, but the air pressure in the anteroom relative to the corridor may vary depending on the building design. This should be determined, in accordance with applicable regulations, by a qualified ventilation engineer.

If the existing ventilation system is incapable of achieving the desired negative pressure because the room lacks a separate ventilation system or the room's system cannot provide the proper airflow, steps should be taken to provide a means to discharge air from the room. The amount of air to be exhausted will be the same as discussed previously (Suppl. 3, Section II.B.4.a).

Fixed room-air recirculation systems (i.e., systems that recirculate the air in an entire room) may be designed to achieve negative pressure by discharging air outside the room (Suppl. 3, Section II.C.3).

Some portable room-air recirculation units (Suppl. 3, Section II.C.3.b.) are designed to discharge air to the outside to achieve negative pressure. Air cleaners that can accomplish this must be designed specifically for this purpose.

A small centrifugal blower (i.e., exhaust fan) can be used to exhaust air to the outside through a window or outside wall. This approach may be used as an interim measure to achieve negative pressure, but it provides no fresh air and suboptimal dilution.

Another approach to achieving the required pressure difference is to pressurize the corridor. Using this method, the corridor's general ventilation system is balanced to create a higher air pressure in the corridor than in the isolation room; the type of balancing necessary depends on the configuration of the ventilation system. Ideally, the corridor air supply rate should be increased while the corridor exhaust rate is not increased. If this is not possible, the exhaust rate should be decreased by resetting appropriate exhaust dampers. Caution should be exercised, however, to ensure that the exhaust rate is not reduced below acceptable levels. This approach requires that all settings used to achieve the pressure balance, including doors, be maintained. This method may not be desirable if the corridor being pressurized has rooms in which negative pressure is not desired. In many situations, this system is difficult to achieve, and it should be considered only after careful review by ventilation personnel.

c. Monitoring negative pressure.

The negative pressure in a room can be monitored by visually observing the direction of airflow (e.g., using smoke tubes) or by measuring the differential pressure between the room and its surrounding area.

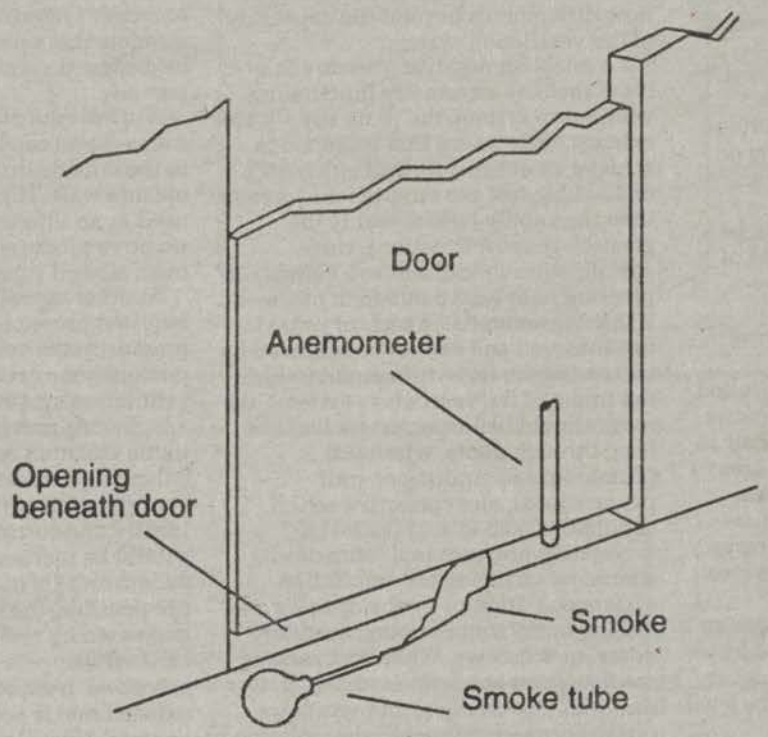
Smoke from a smoke tube can be used to observe airflow between areas or

*Negative is defined relative to the air pressure in the area from which air is to flow.

airflow patterns within an area. To check the negative pressure in a room by using a smoke tube, hold the smoke tube near the bottom of the door and approximately 2 inches in front of the door, or at the face of a grille or other opening if the door has such a feature, and generate a small amount of smoke by gently squeezing the bulb (Figure S3–3). The smoke tube should be held parallel to the door, and the smoke should be issued from the tube slowly to ensure the velocity of the smoke from the tube does not overpower the air velocity. The smoke will travel in the direction of airflow. If the room is at negative pressure, the smoke will travel under the door and into the room (e.g., from higher to lower pressure). If the room is not at negative pressure, the smoke will be blown outward or will stay stationary. This test must be performed while the door is closed. If room air cleaners are being used in the room, they should be running. The smoke is irritating if inhaled, and care should be taken not to inhale it directly from the smoke tube. However, the quantity of smoke issued from the tube is minimal and is not detectable at short distances from the tube.

Differential pressure-sensing devices also can be used to monitor negative pressure; they can provide either periodic (noncontinuous) pressure measurements or continuous pressure monitoring. The continuous monitoring component may simply be a visible and/or audible warning signal that air pressure is low. In addition, it may also provide a pressure readout signal, which can be recorded for later verification or used to automatically adjust the facility's ventilation control system.

FIGURE S3-3. Smoke-tube testing and anemometer placement to determine the direction of airflow into and out of a room*

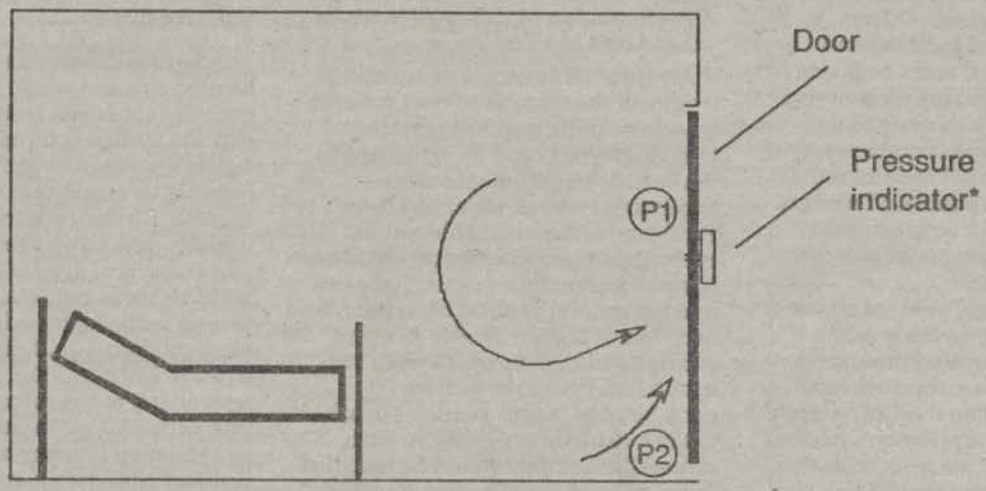


*Smoke flowing into the room indicates the room is at negative pressure relative to the corridor, and smoke flowing out of the room indicates the room is at positive pressure relative to the corridor. The anemometer, if used, is placed with the sensor in the airflow path at the bottom of the door.

Pressure-measuring devices should sense the room pressure just inside the airflow path into the room (e.g., at the bottom of the door). Unusual airflow patterns within the room can cause pressure variations; for example, the air can be at negative pressure at the middle of a door and at positive pressure at the bottom of the same door (Figure S3–4). If the pressure-sensing ports of the device cannot be located directly across the airflow path, it will be necessary to validate that the negative pressure at the sensing point is and remains the same as the negative pressure across the flow path.

Pressure-sensing devices should incorporate an audible warning with a time delay to indicate that a door is open. When the door to the room is opened, the negative pressure will decrease. The time-delayed signal should allow sufficient time for persons to enter or leave the room without activating the audible warning.

FIGURE S3-4. Cross-sectional view of a room showing the location of negative pressure measurement



Airflow pressure at Position 1 may differ from Position 2.

Measure pressure at Position 2 to correctly identify negative pressure.

*Located on door frame.

A potential problem with using pressure-sensing devices is that the pressure differentials used to achieve the low negative pressure necessitate the use of very sensitive mechanical devices, electronic devices, or pressure gauges to ensure accurate measurements. Use of devices that cannot measure these low pressures (i.e., pressures as low as 0.001 inch of water) will require setting higher negative pressures that may be difficult and, in some instances, impractical to achieve (Suppl. 3, Section II.B.4).

Periodic checks are required to ensure that the desired negative pressure is present and that the continuous monitoring devices, if used, are operating properly. If smoke tubes or other visual checks are used, TB isolation rooms and treatment rooms should be checked frequently for negative pressure. Rooms undergoing changes to the ventilation system should be checked daily. TB isolation rooms should be checked daily for negative pressure while being used for TB isolation. If these rooms are not being used for patients who have suspected or confirmed TB but potentially could be used for such patients, the negative pressure in the rooms should be checked monthly. If pressure-sensing devices are used, negative pressure should be verified at least once a month by using smoke tubes or taking pressure measurements.

C. HEPA Filtration

Purpose: To remove contaminants from the air.

HEPA filtration can be used as a method of air cleaning that supplements other recommended ventilation measures. For the purposes of these guidelines, HEPA filters are defined as air-cleaning devices that have a demonstrated and documented minimum removal efficiency of 99.97% of particles greater than or equal to 0.3 μm in diameter. HEPA filters have been shown to be effective in reducing the concentration of *Aspergillus* spores (which range in size from 1.5 μm to 6 μm) to below measurable levels (100–102). The ability of HEPA filters to remove tubercle bacilli from the air has not been studied, but *M. tuberculosis* droplet nuclei probably range from 1 μm to 5 μm in diameter (i.e., approximately the same size as *Aspergillus* spores). Therefore, HEPA filters can be expected to remove infectious droplet nuclei from contaminated air. HEPA filters can be used to clean air before it is exhausted to the outside, recirculated to other areas of a facility, or recirculated within a room. If the device is not completely passive (e.g., it utilizes techniques such as electrostatics) and the failure of the electrostatic components permits loss of filtration efficiency to less than 99.97%, the device should not be used in systems that recirculate air back into the general facility ventilation system from TB isolation rooms and treatment rooms in which procedures are performed on patients who may have infectious TB (Suppl. 3, Section II.C.2).

HEPA filters can be used in a number of ways to reduce or eliminate infectious droplet nuclei from room air or exhaust. These methods include placement of HEPA filters (a) in exhaust ducts to remove droplet nuclei from air being discharged to the outside, either directly or through ventilation equipment; (b) in ducts discharging room air into the general ventilation system; and (c) in fixed or portable room-air cleaners. The effectiveness of portable HEPA room-air cleaning units has not been evaluated adequately, and there is probably considerable variation in their effectiveness. HEPA filters can also be used in exhaust ducts or vents that discharge air from booths or enclosures into the surrounding room (Suppl. 3, Section II.A.3). In any application, HEPA filters should be installed carefully and maintained meticulously to ensure adequate function.

Manufacturers of room-air cleaning equipment should provide documentation of the HEPA filter efficiency and the efficiency of the installed device in lowering room-air contaminant levels.

1. Use of HEPA Filtration When Exhausting Air to the Outside

HEPA filters can be used as an added safety measure to clean air from isolation rooms and local exhaust devices (i.e., booths, tents, or hoods used for cough-inducing procedures) before exhausting it directly to the outside, but such use is unnecessary if the exhaust air cannot re-enter the ventilation system supply. The use of HEPA filters should be considered wherever exhaust air could possibly reenter the system.

In many instances, exhaust air is not discharged directly to the outside; rather, the air is directed through heat-recovery devices (e.g., heat wheels). Heat wheels are often used to reduce the costs of operating ventilation systems (*103*). If such units are used with the system, a HEPA filter should also be used. As the wheel rotates, energy is transferred into or removed from the supply inlet air stream. The HEPA filter should be placed upstream from the heat wheel because of the potential for leakage across the seals separating the inlet and exhaust chambers and the theoretical possibility that droplet nuclei could be impacted on the wheel by the exhaust air and subsequently stripped off into the supply air.

2. Recirculation of HEPA-Filtered Air to Other Areas of a Facility

Air from TB isolation rooms and treatment rooms used to treat patients who have confirmed or suspected infectious TB should be exhausted to the outside in accordance with applicable Federal, state, and local regulations. The air should not be recirculated into the general ventilation. In some instances, recirculation of air into the general ventilation system from such rooms is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust to the outside impossible). In such cases, HEPA filters should be installed in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before it is returned to the general ventilation system (Section II.F; Suppl. 3). Air from TB isolation rooms and treatment rooms in new or renovated facilities should not be recirculated into the general ventilation system.

3. Recirculation of HEPA-Filtered Air Within a Room

Individual room-air recirculation can be used in areas where there is no general ventilation system, where an existing system is incapable of providing adequate airflow, or where an increase in ventilation is desired without affecting the fresh air supply or negative pressure system already in place. Recirculation of HEPA-filtered air within a room can be achieved in several ways: (a) by exhausting air from the room into a duct, filtering it through a HEPA filter installed in the duct, and returning it to the room (Figure S3–5); (b) by filtering air through HEPA recirculation systems mounted on the wall or ceiling of the room (Figure S3–6); or (c) by filtering air through portable HEPA recirculation systems. In this document, the first two of these approaches are referred to as fixed room-air recirculation systems, because the HEPA filter devices are fixed in place and are not easily movable.

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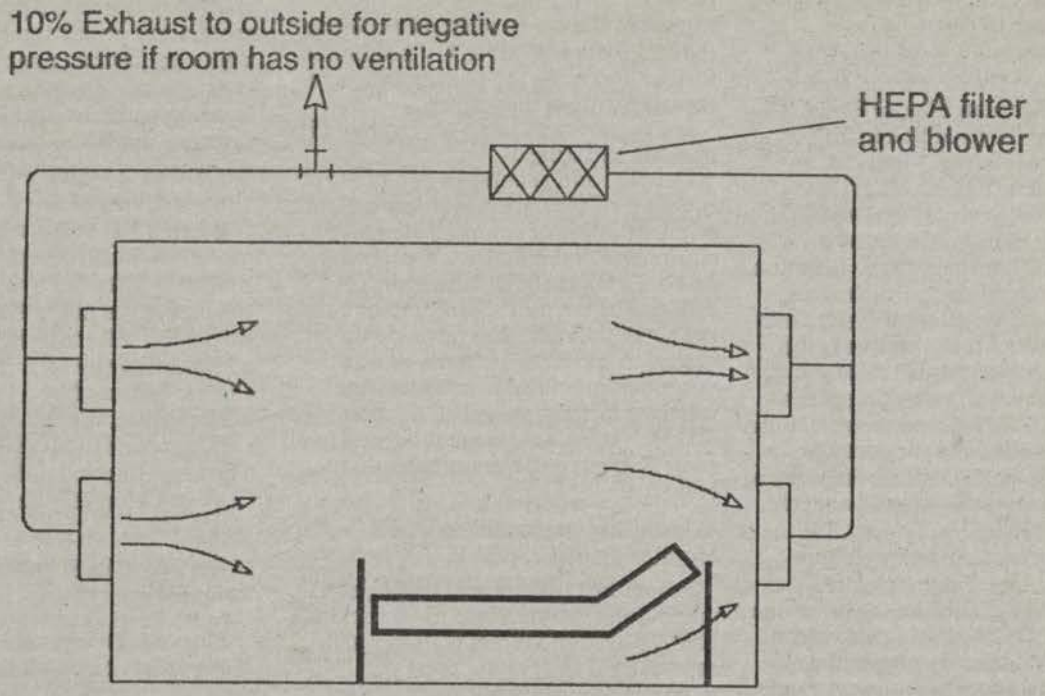
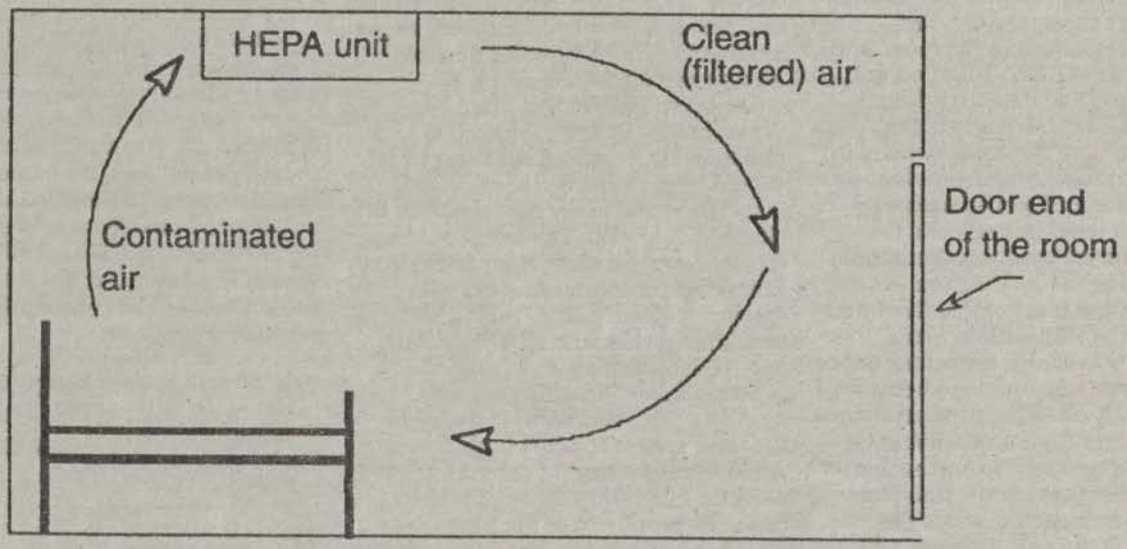
FIGURE S3-5. Fixed, ducted room-air recirculation system using a high-efficiency particulate air (HEPA) filter inside an air duct*



*Such a system can be used to increase the room ventilation rate.

FIGURE S3-6. Fixed ceiling-mounted room-air recirculation system using a high-efficiency particulate air (HEPA) filter*



*Such a system can be used to increase the room ventilation rate. Position the HEPA unit one third of the room's length from the patient's end of the room.

a. Fixed room-air recirculation systems.

The preferred method of recirculating HEPA-filtered air within a room is a built-in system, in which air is exhausted from the room into a duct, filtered through a HEPA filter, and returned to the room (Figure S3–5). This technique may be used to add air changes in areas where there is a recommended minimum ACH that is difficult to meet with general ventilation alone. The air does not have to be conditioned, other than by the filtration, and this permits higher airflow rates than the general ventilation system can usually achieve. An alternative is the use of HEPA filtration units that are mounted on the wall or ceiling of the room (Figure S3–7). Fixed recirculation systems are preferred over portable (free-standing) units because they can be installed and maintained with a greater degree of reliability.

b. Portable room-air recirculation units.

Portable HEPA filtration units may be considered for recirculating air within rooms in which there is no general ventilation system, where the system is incapable of providing adequate airflow, or where increased effectiveness in room airflow is desired. Effectiveness depends on circulating as much of the air in the room as possible through the HEPA filter, which may be difficult to achieve and evaluate. The effectiveness of a particular unit can vary depending on the room's configuration, the furniture and persons in the room, and placement of the HEPA filtration unit and the supply and exhaust grilles. Therefore, the effectiveness of the portable unit may vary considerably in rooms with different configurations or in the same room if moved from one location to another in the room. If portable units are used, caution should be exercised to ensure they can recirculate all or nearly all of the room air through the HEPA filter. Some commercially available units may not be able to meet this requirement because of design limitations or insufficient airflow capacity. In addition, units should be designed and operated to ensure that persons in the room cannot interfere with or otherwise compromise the functioning of the unit. Portable HEPA filtration units have not been evaluated adequately to determine their role in TB infection-control programs.

Portable HEPA filtration units should be designed to achieve the equivalent of ≥12 ACH. They should also be designed to ensure adequate air mixing in all areas of the hospital rooms in which they are used, and they should not interfere with the current ventilation system.

Some HEPA filtration units employ UVGI for disinfecting air after HEPA filtration. However, whether exposing the HEPA-filtered air to UV irradiation further decreases the concentration of contaminants is not known.

c. Evaluation of room-air recirculation systems and units.

Detailed and accurate evaluations of room-air recirculation systems and units require the use of sophisticated test equipment and lengthy test procedures that are not practical. However, an estimate of the unit's ability to circulate the air in the room can be made by visualizing airflow patterns as was described previously for estimating room air mixing (Suppl. 3, Section II.B.1). If the air movement is good in all areas of the room, the unit should be effective.

4. Installing, Maintaining, and Monitoring HEPA Filters

Proper installation and testing and meticulous maintenance are critical if a HEPA filtration system is used (*104*), especially if the system used recirculates air to other parts of the facility. Improper design, installation, or maintenance could allow infectious particles to circumvent filtration and escape into the general ventilation system (*47*). HEPA filters should be installed to prevent leakage between filter segments and between the filter bed and its frame. A regularly scheduled maintenance program is required to monitor the HEPA filter for possible leakage and for filter loading. A quantitative leakage and filter performance test (e.g., the dioctal phthalate [DOP] penetration test [*105*]) should be performed at the initial installation and every time the filter is changed or moved. The test should be repeated every 6 months for filters in general-use areas and in areas with systems that exhaust air that is likely to be contaminated with *M. tuberculosis* (e.g, TB isolation rooms).

A manometer or other pressure-sensing device should be installed in the filter system to provide an accurate and objective means of determining the need for filter replacement. Pressure drop characteristics of the filter are supplied by the manufacturer of the filter. Installation of the filter should allow for maintenance that will not contaminate the delivery system or the area served. For general infection-control purposes, special care should be taken to not jar or drop the filter element during or after removal.

The scheduled maintenance program should include procedures for installation, removal, and disposal of filter elements. HEPA filter maintenance should be performed only by adequately trained personnel. Appropriate respiratory protection should be worn while performing maintenance and testing procedures. In addition, filter housing and ducts leading to the housing should be labelled clearly with the words "Contaminated Air" (or a similar warning).

When a HEPA filter is used, one or more lower efficiency disposable prefilters installed upstream will extend the useful life of the HEPA filter. A disposable filter can increase the life of a HEPA filter by 25%. If the disposable filter is followed by a 90% extended surface filter, the life of the HEPA filter can be extended almost 900% (*98*). These prefilters should be handled and disposed of in the same manner as the HEPA filter.

D. TB Isolation Rooms and Treatment Rooms

Purpose: To separate patients who are likely to have infectious TB from other persons, to provide an environment that will allow reduction of the concentration of droplet nuclei through various engineering methods, and to prevent the escape of droplet nuclei from such rooms into the corridor and other areas of the facility using directional airflow.

A hierarchy of ventilation methods used to achieve a reduction in the concentration of droplet nuclei and to achieve directional airflow using negative pressure has been developed (Table S3–2). The methods are listed in order from the most desirable to the least desirable. The method selected will depend on the configuration of the isolation room and the ventilation system in the facility; the determination should be made in consultation with a ventilation engineer.

TABLE S3–2.—HIERARCHY OF VENTILATION METHODS FOR TUBERCULOSIS (TB) ISOLATION ROOMS AND TREATMENT ROOMS

Reducing concentration of airborne tubercle bacilli*	Achieving directional airflow using negative pressure†
1. Facility heating, ventilation, and air-conditioning (HVAC) system.	1. Facility HVAC system.
2. Fixed room-air high-efficiency particulate air (HEPA) recirculation system.	2. Bleed air§ from fixed room-air HEPA recirculation system.

TABLE S3–2.—HIERARCHY OF VENTILATION METHODS FOR TUBERCULOSIS (TB) ISOLATION ROOMS AND TREATMENT ROOMS—Continued

Reducing concentration of airborne tubercle bacilli*	Achieving directional airflow using negative pressure†
3. Wall- or ceiling-mounted room-air HEPA recirculation system.	3. Bleed air from wall- or ceiling-mounted room-air HEPA recirculation system.
4. Portable room-air HEPA recirculation unit¶.	4. Bleed air from portable room-air HEPA recirculation unit.¶
	5. Exhaust air from room through window-mounted fan.**

*Ventilation methods are used to reduce the concentration of airborne tubercle bacilli. If the facility HVAC system cannot achieve the recommended ventilation rate, auxiliary room-air recirculation methods may be used. These methods are listed in order from the most desirable to the least desirable. Ultraviolet germicidal irradiation may be used as a supplement to any of the ventilation methods for air cleaning.

†Directional airflow using negative pressure can be achieved with the facility HVAC system and/or the auxiliary air-recirculation-cleaning systems. These methods are listed in order from the most desirable to the least desirable.

§To remove the amount of return air necessary to achieve negative pressure.

¶The effectiveness of portable room-air HEPA recirculation units can vary depending on the room's configuration, the furniture and persons in the room, the placement of the unit, the supply and exhaust grilles, and the achievable ventilation rates and air mixing. Units should be designed and operated to ensure that persons in the room cannot interfere with or otherwise compromise the function of the unit. Fixed recirculating systems are preferred over portable units in TB isolation rooms of facilities in which services are provided regularly to TB patients.

**This method simply achieves negative pressure and should be used only as a temporary measure.

1. Preventing the Escape of Droplet Nuclei From the Room

Rooms used for TB isolation should be single-patient rooms with negative pressure relative to the corridor or other areas connected to the room. Doors between the isolation room and other areas should remain closed except for entry into or exit from the room. The room's openings (e.g., windows and electrical and plumbing entries) should be sealed as much as possible. However, a small gap of ⅛ to ½ inch should be at the bottom of the door to provide a controlled airflow path. Proper use of negative pressure will prevent contaminated air from escaping the room.

2. Reducing the Concentration of Droplet Nuclei in the Room

ASHRAE (*47*), AIA (*48*), and the Health Resources and Services Administration (*49*) recommend a minimum of 6 ACH for TB isolation rooms and treatment rooms. This ventilation rate is based on comfort- and odor-control considerations. The effectiveness of this level of airflow in reducing the concentration of droplet nuclei in the room, thus reducing the transmission of airborne pathogens, has not been evaluated directly or adequately.

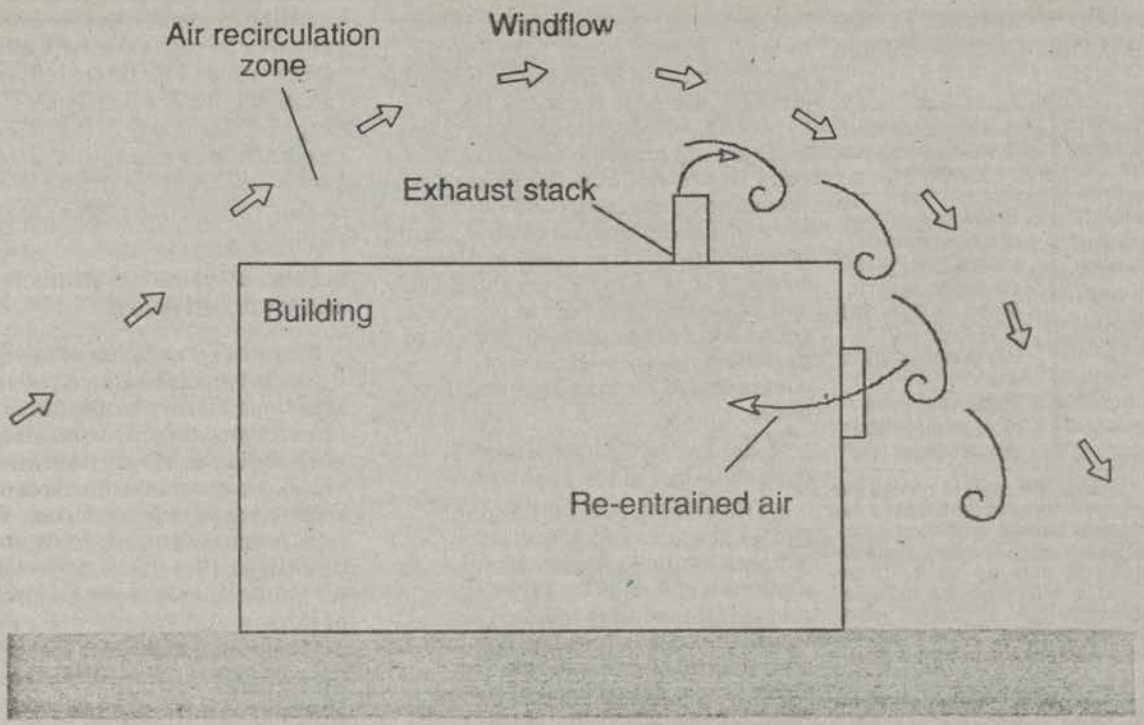
Ventilation rates >6 ACH are likely to produce an incrementally greater reduction in the concentration of bacteria in a room than are lower rates (*50–52*). However, accurate quantitation of decreases in risk that would result from specific increases in general ventilation levels has not been performed and may not be possible.

To reduce the concentration of droplet nuclei, TB isolation rooms and treatment rooms in existing health-care facilities should have an airflow of ≥6 ACH. Where feasible, this airflow rate should be increased to ≥12 ACH by adjusting or modifying the ventilation system or by using auxiliary means (e.g., recirculation of air through fixed HEPA filtration units or portable air cleaners) (Suppl. 3, Section II.C) (*53*). New construction or renovation of existing health-care facilities should be designed so that TB isolation rooms achieve an airflow of ≥12 ACH.

3. Exhaust From TB Isolation Rooms and Treatment Rooms

Air from TB isolation rooms and treatment rooms in which patients with infectious TB may be examined should be exhausted directly to the outside of the building and away from air-intake vents, persons, and animals in accordance with federal, state, and local regulations concerning environmental discharges. (See Suppl. 3, Section II.C, for information regarding recirculation of exhaust air.) Exhaust ducts should not be located near areas that may be populated (e.g., near sidewalks or windows that could be opened). Ventilation system exhaust discharges and inlets should be designed to prevent reentry of exhausted air. Wind blowing over a building creates a highly turbulent recirculation zone, which can cause exhausted air to reenter the building (Figure S3–7). Exhaust flow should be discharged above this zone (Suppl. 3, Section II.C.1). Design guidelines for proper placement of exhaust ducts can be found in the 1989 *ASHRAE Fundamentals Handbook* (*106*). If recirculation of air from such rooms into the general ventilation system is unavoidable, the air should be passed through a HEPA filter before recirculation (Suppl. 3, Section II.C.2).

FIGURE S3-7. Air recirculation zone* created by wind blowing over a building



*Height of air recirculation zone may be variable. Air should be exhausted above this zone to prevent re-entrainment.

4. Alternatives to TB Isolation Rooms

Isolation can also be achieved by use of negative-pressure enclosures (e.g, tents or booths) (Suppl. 3, Section II.A.1). These can be used to provide patient isolation in areas such as emergency rooms and medical testing and treatment areas and to supplement isolation in designated isolation rooms.

III. UVGI

Purpose: To kill or inactivate airborne tubercle bacilli.

Research has demonstrated that UVGI is effective in killing or inactivating tubercle bacilli under experimental conditions (*66,107–110*) and in reducing transmission of other infections in hospitals (*111*), military housing (*112*), and classrooms (*113–115*). Because of the results of numerous studies (*116–120*) and the experiences of TB clinicians and mycobacteriologists during the past several decades, the use of UVGI has been recommended as a supplement to other TB infection-control measures in settings where the need for killing or inactivating tubercle bacilli is important (*2,4,121–125*).

UV radiation is defined as that portion of the electromagnetic spectrum described by wavelengths from 100 to 400 nm. For convenience of classification, the UV spectrum has been separated into three different wavelength bands: UV–A (long wavelengths, range: 320–400 nm), UV–B (midrange wavelengths, range: 290–320 nm), and UV–C (short wavelengths, range: 100–290 nm) (*126*). Commercially available UV lamps used for germicidal purposes are low-pressure mercury vapor lamps (*127*) that emit radiant energy in the UV–C range, predominantly at a wavelength of 253.7 nm (*128*).

A. Applications

UVGI can be used as a method of air disinfection to supplement other engineering controls. Two systems of UVGI can be used for this purpose: duct irradiation and upper-room air irradiation.

1. Duct Irradiation

Purpose: To inactivate tubercle bacilli without exposing persons to UVGI.

In duct irradiation systems, UV lamps are placed inside ducts that remove air from rooms to disinfect the air before it is recirculated. When UVGI duct systems are properly designed, installed, and maintained, high levels of UV radiation may be produced in the duct work. The only potential for human exposure to this radiation occurs during maintenance operations.

Duct irradiation may be used:

- In a TB isolation room or treatment room to recirculate air from the room, through a duct containing UV lamps, and back into the room. This recirculation method can increase the overall room airflow but does not increase the supply of fresh outside air to the room.
- In other patients' rooms and in waiting rooms, emergency rooms, and other general-use areas of a facility where patients with undiagnosed TB could potentially contaminate the air, to recirculate air back into the general ventilation. Duct-irradiation systems are dependent on airflow patterns within a room that ensure that all or nearly all of the room air circulates through the duct.

2. Upper-Room Air Irradiation

Purpose: To inactivate tubercle bacilli in the upper part of the room, while minimizing radiation exposure to persons in the lower part of the room.

In upper-room air irradiation, UVGI lamps are suspended from the ceiling or mounted on the wall. The bottom of the lamp is shielded to direct the radiation upward but not downward. The system depends on air mixing to take irradiated

air from the upper to the lower part of the room, and nonirradiated air from the lower to the upper part. The irradiated air space is much larger than that in a duct system.

UVGI has been effective in killing bacteria under conditions where air mixing was accomplished mainly by convection. For example, BCG was atomized in a room that did not have supplemental ventilation (*120*), and in another study a surrogate bacteria, *Serratia marcesens*, was aerosolized in a room with a ventilation rate of 6 ACH (*129*). These reports estimated the effect of UVGI to be equivalent to 10 and 39 ACH, respectively, for the organisms tested, which are less resistant to UVGI than *M. tuberculosis* (*120*). The addition of fans or some heating/air conditioning arrangements may double the effectiveness of UVGI lamps (*130–132*). Greater rates of ventilation, however, may decrease the length of time the air is irradiated, thus decreasing the killing of bacteria (*117,129*). The optimal relationship between ventilation and UVGI is not known. Air irradiation lamps used in corridors have been effective in killing atomized *S. marcesens* (*133*). Use of UVGI lamps in an outpatient room has reduced culturable airborne bacteria by 14%–19%. However, the irradiation did not reduce the concentration of gram-positive, rod-shaped bacteria; although fast-growing mycobacteria were cultured, *M. tuberculosis* could not be recovered from the room's air samples because of fungal overgrowth of media plates (*134*).

Upper-room air UVGI irradiation may be used:

- In isolation or treatment rooms as a supplemental method of air cleaning.
- In other patients' rooms and in waiting rooms, emergency rooms, corridors, and other central areas of a facility where patients with undiagnosed TB could potentially contaminate the air. Determinants of UVGI effectiveness include room configuration, UV lamp placement, and the adequacy of airflow patterns in bringing contaminated air into contact with the irradiated upper-room space. Air mixing may be facilitated by supplying cool air near the ceiling in rooms where warmer air (or a heating device) is present below. The ceiling should be high enough for a large volume of upper-room air to be irradiated without HCWs and patients being overexposed to UV radiation.

B. Limitations

Because the clinical effectiveness of UV systems varies, and because of the risk for transmission of *M. tuberculosis* if a system malfunctions or is maintained improperly, UVGI is not recommended for the following specific applications:

1. Duct systems using UVGI are not recommended as a substitute for HEPA filters if air from isolation rooms must be recirculated to other areas of a facility.

2. UVGI alone is not recommended as a substitute for HEPA filtration or local exhaust of air to the outside from booths, tents, or hoods used for cough-inducing procedures.

3. UVGI is not a substitute for negative pressure.

The use of UV lamps and HEPA filtration in a single unit would not be expected to have any infection-control benefits not provided by use of the HEPA filter alone.

The effectiveness of UVGI in killing airborne tubercle bacilli depends on the intensity of UVGI, the duration of contact the organism has with the irradiation, and the relative humidity (*66,108,111*). Humidity can have an adverse effect on UVGI effectiveness at levels >70% relative humidity for *S. marcescens* (*135*). The interaction of these factors has not been fully defined, however, making precise recommendations for individual UVGI installations difficult to develop.

Old lamps or dust-covered UV lamps are less effective; therefore, regular maintenance of UVGI systems is crucial.

C. Safety Issues

Short-term overexposure to UV radiation can cause erythema and keratoconjunctivitis (*136,137*). Broad-spectrum UV radiation has been associated with increased risk for squamous and basal cell carcinomas of the skin (138). UV–C was recently classified by the International Agency for Research on Cancer as "probably carcinogenic to humans (Group 2A)" (*138*). This classification is based on studies suggesting that UV–C radiation can induce skin cancers in animals; DNA damage, chromosomal aberrations and sister chromatid exchange and transformation in human cells in vitro; and DNA damage in mammalian skin cells in vivo. In the animal studies, a contribution of UV–B to the tumor effects could not be excluded, but the effects were greater than expected for UV–B alone (*138*). Although some recent studies have demonstrated that UV radiation can activate HIV gene promoters (i.e., the genes in HIV that prompt replication of the virus) in laboratory samples of human cells (*139–144*), the implications of these in vitro findings for humans are unknown.

In 1972, the National Institute for Occupational Safety and Health (NIOSH) published a recommended exposure limit (REL) for occupational exposure to UV radiation (*136*). The REL is intended to protect workers from the acute effects of UV exposure (e.g., erythema and photokeratoconjunctivitis). However, photosensitive persons and those exposed concomitantly to photoactive chemicals may not be protected by the recommended standard. If proper procedures are not followed, HCWs performing maintenance on such fixtures are at risk for exposure to UV radiation. Because UV fixtures used for upper-room air irradiation are present in rooms, rather than hidden in ducts, safety may be much more difficult to achieve and maintain. Fixtures must be designed and installed to ensure that UV exposure to persons in the room (including HCWs and inpatients) are below current safe exposure levels. Recent health hazard evaluations conducted by CDC have noted problems with overexposure of HCWs to UVGI and with inadequate maintenance, training, labelling, and use of personal protective equipment (*145–147*).

The current number of persons who are properly trained in UVGI system design and installation is limited. CDC strongly recommends that a competent UVGI system designer be consulted to address safety considerations before such a system is procured and installed. Experts who might be consulted include industrial hygienists, engineers, and health physicists. Principles for the safe installation of UV lamp fixtures have been developed and can be used as guidelines (*148,149*).

If UV lamps are being used in a facility, the general TB education of HCWs should include:

1. The basic principles of UVGI systems (i.e., how they work and what their limitations are).

2. The potential hazardous effects of UVGI if overexposure occurs.

3. The potential for photosensitivity associated with certain medical conditions or use of some medications.

4. The importance of general maintenance procedures for UVGI fixtures.

Exposure to UV intensities above the REL should be avoided. Lightweight clothing made of tightly woven fabric and UV-absorbing sunscreens with solar-protection factors (SPFs) ≥15 may help protect photosensitive persons. HCWs should be advised that any eye or skin irritation that develops after UV exposure should be examined by occupational health staff.

D. Exposure Criteria for UV Radiation

The NIOSH REL for UV radiation is wavelength dependent because different wavelengths of UV radiation have different adverse effects on the skin and eyes (*136*). Relative spectral effectiveness (Sλ) is used to compare various UV sources with a source producing UV radiation at 270 nm, the wavelength of maximum ocular sensitivity. For example, the Sλ at 254 nm is 0.5; therefore, twice as much energy is required at 254 nm to produce an identical biologic effect at 270 nm (*136*). Thus, at 254 nm, the NIOSH REL is 0.006 joules per square centimeter (J/cm²); and at 270 nm, it is 0.003 J/cm².

For germicidal lamps that emit radiant energy predominantly at a wavelength of 254 nm, proper use of the REL requires that the measured irradiance level (E) in microwatts per square centimeter (μW/cm²) be multiplied by the relative spectral effectiveness at 254 nm (0.5) to obtain the effective irradiance (E_{eff}). The maximum permissible exposure time can then be determined for selected values of E_{eff} (Table S3–3), or it can be calculated (in seconds) by dividing 0.003 J/cm² (the NIOSH REL at 270 nm) by E_{eff} in μW/cm² (*136,150*).

To protect HCWs who are exposed to germicidal UV radiation for 8 hours per workday, the measured irradiance (E) should be ≤0.2 μW/cm². This is calculated by obtaining E_{eff} (0.1 μW/cm²) (Table S3–3) and then dividing this value by Sλ (0.5).

TABLE S3–3.—MAXIMUM PERMISSIBLE EXPOSURE TIMES* FOR SELECTED VALUES OF EFFECTIVE IRRADIANCE

Permissible exposure time per day	Effective irradiance (E_{eff})† (μW/cm²)
8 hrs	0.1
4 hrs	0.2
2 hrs	0.4
1 hr	0.8
30 min	1.7
15 min	3.3
10 min	5.0
5 min	10.0
1 min	50.0
30 sec	100.0

*Permissible exposure times are designed to prevent acute effects of irradiation to skin and eyes (*136*). These recommended limits are wavelength dependent because different wavelengths of ultraviolet (UV) radiation have different adverse effects on these organs

†Relative spectral effectiveness (Sλ) is used to compare various UV sources with a source producing UV radiation at 270 nm, the wavelength of maximum ocular sensitivity. For example, the relative spectral effectiveness at 254 nm is 0.5; therefore, twice as much energy is required at 254 nm to produce an identical biologic effect at 270 nm. At 254 nm, the NIOSH REL is 0.006 joules per square centimeter (J/cm²); and at 270 nm, it is 0.003 J/cm². For germicidal lamps that emit radiant energy predominantly at a wavelength of 254 nm, proper use of the REL requires that the measured irradiance level (E) in microwatts per square centimeter (μW/cm²) be multiplied by the relative spectral effectiveness at 254 nm (0.5) to obtain E_{eff}. The maximum permissible exposure time can be calculated (in seconds) by dividing 0.003 J/cm² (the NIOSH REL at 270 nm) by E_{eff} in μW/cm² (*136,150*). To protect health-care workers who are exposed to germicidal UV radiation for 8 hours per work day, the measured irradiance (E) should be ≤0.2 μW/cm², which is calculated by obtaining E_{eff} (0.1 μW/cm²), then dividing this value by Sλ (0.5).

E. Maintenance and Monitoring

1. Labelling and Posting

Warning signs should be posted on UV lamps and wherever high-intensity (i.e., UV exposure greater than the REL) germicidal UV irradiation is present (e.g., upper-room air space and accesses to ducts [if duct irradiation is used]) to alert maintenance staff or other HCWs of the hazard. Some examples are shown below:

CAUTION
ULTRAVIOLET ENERGY: TURN OFF LAMPS BEFORE ENTERING UPPER ROOM
CAUTION
ULTRAVIOLET ENERGY: PROTECT EYES & SKIN

2. Maintenance

Because the intensity of UV lamps fluctuates as they age, a schedule for replacing the lamps should be developed. The schedule can be determined from either a time/use log or a system based on cumulative time. The tube should be checked periodically for dust build-up, which lessens the output of UVGI. If the tube is dirty, it should be allowed to cool, then cleaned with a damp cloth. Tubes should be replaced if they stop glowing or if they flicker to an objectionable extent. Maintenance personnel must turn off all UV tubes before entering the upper part of the room or before accessing ducts for any purpose. Only a few seconds of direct exposure to the intense UV radiation in the upper-room air space or in ducts can cause burns. Protective equipment (e.g., gloves and goggles [and/or face shields]) should be worn if exposure greater than the recommended standard is anticipated.

Banks of UVGI tubes can be installed in ventilating ducts. Safety devices should be used on access doors to eliminate hazard to maintenance personnel. For duct irradiation systems, the access door for servicing the lamps should have an inspection window* through which the lamps are checked periodically for dust build-up and malfunctioning. The access door should have a warning sign written in languages appropriate for maintenance personnel to alert them to the health hazard of looking directly at bare tubes. The lock for this door should have an automatic electric switch or other device that turns off the lamps when the door is opened.

Two types of fixtures are used in upper-room air irradiation: wall-mounted fixtures that have louvers to block downward radiation and ceiling-mounted fixtures that have baffles to block radiation below the horizontal plane of the UV tube. The actual UV tube in either type of fixture must not be visible from any normal position in the room. Light switches that can be locked should be used, if possible, to prevent injury to personnel who might unintentionally turn the lamps on during maintenance procedures. In most applications, properly shielding the UV lamps to provide protection from most, if not all, of the direct UV radiation is not difficult. However, radiation reflected from glass, polished metal, and high-gloss ceramic paints can be harmful to persons in the room, particularly if more than one UV lamp is in use. Surfaces in irradiated rooms that can reflect UVGI into occupied areas of the room should be covered with non-UV reflecting material.

3. Monitoring

A regularly scheduled evaluation of the UV intensity to which HCWs, patients, and others are exposed should be conducted.

UV measurements should be made in various locations within a room using a detector designed to be most sensitive at 254 nm. Equipment used to measure germicidal UV radiation should be maintained and calibrated on a regular schedule.

A new UV installation must be carefully checked for hot spots (i.e., areas of the room where the REL is exceeded) by an industrial hygienist or other person knowledgeable in making UV measurements. UV radiation levels should not exceed those in the recommended guidelines.

*Ordinary glass (not quartz) is sufficient to filter out UV radiation.

Supplement 4: Respiratory Protection

I. Considerations for Selection of Respirators

Personal respiratory protection should be used by (a) persons entering rooms where patients with known or suspected infectious TB are being isolated, (b) persons present during cough-inducing or aerosol-generating procedures performed on such patients, and (c) persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei. These other settings should be identified on the basis of the facility's risk assessment.

Although data regarding the effectiveness of respiratory protection from many hazardous airborne materials have been collected, the precise level of effectiveness in protecting HCWs from *M. tuberculosis* transmission in health-care settings has not been determined. Information concerning the transmission of *M. tuberculosis* is incomplete. Neither the smallest infectious dose of *M. tuberculosis* nor the highest level of exposure to *M. tuberculosis* at which transmission will not occur has been defined conclusively (*59,151,152*). Furthermore, the size distribution of droplet nuclei and the number of particles containing viable *M. tuberculosis* that are expelled by infectious TB patients have not been defined adequately, and accurate methods of measuring the concentration of infectious droplet nuclei in a room have not been developed.

Nevertheless, in certain settings the administrative and engineering controls may not adequately protect HCWs from airborne droplet nuclei (e.g., in TB isolation rooms, treatment rooms in which cough-inducing or aerosol-generating procedures are performed, and ambulances during the transport of infectious TB patients). Respiratory protective devices used in these settings should have characteristics that are suitable for the organism they are protecting against and the settings in which they are used.

A. Performance Criteria for Personal Respirators for Protection Against Transmission of *M. tuberculosis*

Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following standard criteria. These criteria are based on currently available information, including (a) data on the effectiveness of respiratory protection against noninfectious hazardous materials in workplaces other than health-care settings and on an interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*; (b) data on the efficiency of respirator filters in filtering biological aerosols; (c) data on face-seal leakage; and (d) data on the characteristics of respirators that were used in conjunction with administrative and engineering controls in outbreak settings where transmission to HCWs and patients was terminated.

1. The ability to filter particles 1 um in size in the unloaded state with a filter efficiency of ≥95% (i.e., filter leakage of ≤5%), given flow rates of up to 50 L per minute.

Available data suggest that infectious droplet nuclei range in size from 1 μm to 5 μm; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particles in this range. Fifty liters per minute is a reasonable estimate of the highest airflow rate an HCW is likely to achieve during breathing, even while performing strenuous work activities.

2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of ≤10% (*54,55*).

3. The ability to fit the different facial sizes and characteristics of HCWs, which can usually be met by making the respirators available in at least three sizes.

4. The ability to be checked for facepiece fit, in accordance with OSHA standards and good industrial hygiene practice, by HCWs each time they put on their respirators (*54,55*).

In some settings, HCWs may be at risk for two types of exposure: (a) inhalation of *M. tuberculosis* and (b) mucous membrane exposure to fluids that may contain bloodborne pathogens. In these settings, protection against both types of exposure should be used.

When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW should serve two functions: (a) it should protect the surgical field from the respiratory secretions of the HCW and (b) it should protect the HCW from infectious droplet nuclei that may be expelled by the patient or generated by the procedure. Respirators with expiration valves and positive-pressure respirators do not protect the sterile field; therefore, a respirator that does not have a valve and that meets the criteria in Supplement 4, Section I.A, should be used.

B. Specific Respirators

The OSHA respiratory protection standard requires that all respiratory protective devices used in the workplace be certified by NIOSH.* NIOSH-approved HEPA respirators are the only currently available air-purifying respirators that meet or exceed the standard performance criteria stated above. However, the NIOSH certification procedures are currently being revised (*153*). Under the proposed revision, filter materials would be tested at a flow rate of 85 L/min for penetration by particles with a median aerodynamic diameter of 0.3 μm and, if certified, would be placed in one of the following categories: type A, which has ≥99.97% efficiency (similar to current HEPA filter media); type B, ≥99% efficiency; or type C, ≥95% efficiency. According to this proposed scheme, type C filter material would meet or exceed the standard performance criteria specified in this document.

The facility's risk assessment may identify a limited number of selected settings (e.g., bronchoscopy performed on patients suspected of having TB or autopsy performed on deceased persons suspected of having had active TB at the time of death) where the estimated risk for transmission of *M. tuberculosis* may be such that a level of respiratory protection exceeding the standard criteria is appropriate. In such circumstances, a level of respiratory protection exceeding the standard criteria and compatible with patient-care delivery (e.g., negative-pressure respirators that are more protective; powered air-purifying particulate respirators [PAPRs]; or positive-pressure airline, half-mask respirators) should be provided by employers to HCWs who are exposed to *M. tuberculosis*. Information on these and other respirators may be found in the *NIOSH Guide to Industrial Respiratory Protection (55)*.

C. The Effectiveness of Respiratory Protective Devices

The following information, which is based on experience with respiratory protection in the industrial setting, summarizes the available data about the effectiveness of respiratory protection against hazardous airborne materials. Data regarding protection against transmission of *M. tuberculosis* are not available.

The parameters used to determine the effectiveness of a respiratory protective device are face-seal efficacy and filter efficacy.

1. Face-Seal Leakage

Face-seal leakage compromises the ability of particulate respirators to protect HCWs from airborne materials

* 29 CFR 1910.134.

(*154–156*). A proper seal between the respirator's sealing surface and the face of the person wearing the respirator is essential for effective and reliable performance of any negative-pressure respirator. This seal is less critical, but still important, for positive-pressure respirators. Face-seal leakage can result from various factors, including incorrect facepiece size or shape, incorrect or defective facepiece sealing-lip, beard growth, perspiration or facial oils that can cause facepiece slippage, failure to use all the head straps, incorrect positioning of the facepiece on the face, incorrect head strap tension or position, improper respirator maintenance, and respirator damage.

Every time a person wearing a negative-pressure particulate respirator inhales, a negative pressure (relative to the workplace air) is created inside the facepiece. Because of this negative pressure, air containing contaminants can take a path of least resistance into the respirator—through leaks at the face-seal interface—thus avoiding the higher-resistance filter material. Currently available, cup-shaped, disposable particulate respirators have from 0 to 20% face-seal leakage (*55,154*). This face-seal leakage results from the variability of the human face and from limitations in the respirator's design, construction, and number of sizes available. The face-seal leakage is probably higher if the respirator is not fitted properly to the HCW's face, tested for an adequate fit by a qualified person, and then checked for fit by the HCW every time the respirator is put on. Face-seal leakage may be reduced to less than <10% with improvements in design, a greater variety in available sizes, and appropriate fit testing and fit checking.

In comparison with negative-pressure respirators, positive-pressure respirators produce a positive pressure inside the facepiece under most conditions of use. For example, in a PAPR, a blower forcibly draws ambient air through HEPA filters, then delivers the filtered air to the facepiece. This air is blown into the facepiece at flow rates that generally exceed the expected inhalation flow rates. The positive pressure inside the facepiece reduces face-seal leakage to low levels, particularly during the relatively low inhalation rates expected in health-care settings. PAPRs with a tight-fitting facepiece have <2% face-seal leakage under routine conditions (*55*). Powered-air respirators with loose-fitting facepieces, hoods, or helmets have <4% face-seal leakage under routine conditions (*55*). Thus, a PAPR may offer lower levels of face-seal leakage than nonpowered, half-mask respirators. Full facepiece, nonpowered respirators have the same leakage (i.e., <2%) as PAPRs.

Another factor contributing to face-seal leakage of cup-shaped, disposable respirators is that some of these respirators are available in only one size. A single size may produce higher leakage for persons who have smaller or difficult-to-fit faces (*157*). The facepieces used for some reusable (including HEPA and replaceable filter, negative-pressure) and all positive-pressure particulate air-purifying respirators are available in as many as three different sizes.

2. Filter Leakage

Aerosol leakage through respirator filters depends on at least five independent variables: (a) the filtration characteristics for each type of filter, (b) the size distribution of the droplets in the aerosol, (c) the linear velocity through the filtering material, (d) the filter loading (i.e., the amount of contaminant deposited on the filter), and (e) any electrostatic charges on the filter and on the droplets in the aerosol (*158*).

When HEPA filters are used in particulate air-purifying respirators, filter efficiency is so high (i.e., effectively 100%) that filter leakage is not a consideration. Therefore, for all HEPA-filter respirators, virtually all inward leakage of droplet nuclei occurs at the respirator's face seal.

3. Fit Testing

Fit testing is part of the respiratory protection program required by OSHA for all respiratory protective devices used in the workplace. A fit test determines whether a respiratory protective device adequately fits a particular HCW. The HCW may need to be fit tested with several devices to determine which device offers the best fit. However, fit tests can detect only the leakage that occurs at the time of the fit testing, and the tests cannot distinguish face-seal leakage from filter leakage.

Determination of facepiece fit can involve qualitative or quantitative tests (*55*). A qualitative test relies on the subjective response of the HCW being fit tested. A quantitative test uses detectors to measure inward leakage.

Disposable, negative-pressure particulate respirators can be qualitatively fit tested with aerosolized substances that can be tasted, although the results of this testing are limited because the tests depend on the subjective response of the HCW being tested. Quantitative fit testing of disposable negative-pressure particulate respirators can best be performed if the manufacturer provides a test respirator with a probe for this purpose.

Replaceable filter, negative-pressure particulate respirators and all positive-pressure particulate respirators can be fit tested reliably, both qualitatively and quantitatively, when fitted with HEPA filters.

4. Fit Checking

A fit check is a maneuver that an HCW performs before each use of the respiratory protective device to check the fit. The fit check can be performed according to the manufacturer's facepiece fitting instructions by using the applicable negative-pressure or positive-pressure test.

Some currently available cup-shaped, disposable negative-pressure particulate respirators cannot be fit checked reliably by persons wearing the devices because occluding the entire surface of the filter is difficult. Strategies for overcoming these limitations are being developed by respirator manufacturers.

5. Reuse of Respirators

Conscientious respirator maintenance should be an integral part of an overall respirator program. This maintenance applies both to respirators with replaceable filters and respirators that are classified as disposable but that are reused. Manufacturers' instructions for inspecting, cleaning, and maintaining respirators should be followed to ensure that the respirator continues to function properly (*55*).

When respirators are used for protection against noninfectious aerosols (e.g., wood dust), which may be present in the air in heavy concentrations, the filter material may become occluded with airborne material. This occlusion may result in an uncomfortable breathing resistance. In health-care settings where respirators are used for protection against biological aerosols, the concentration of infectious particles in the air is probably low; thus, the filter material in a respirator is very unlikely to become occluded with airborne material. In addition, there is no evidence that particles impacting on the filter material in a respirator are re-aerosolized easily. For these reasons, the filter material used in respirators in the health-care setting should remain functional for weeks to months. Respirators with replaceable filters are reusable, and a respirator classified as disposable may be reused by the same HCW as long as it remains functional.

Before each use, the outside of the filter material should be inspected. If the filter material is physically damaged or soiled, the filter should be changed (in the case of respirators with

replaceable filters) or the respirator discarded (in the case of disposable respirators). Infection-control personnel should develop standard operating procedures for storing, reusing, and disposing of respirators that have been designated as disposable and for disposing of replaceable filter elements.

II. Implementing a Personal Respiratory Protection Program

If personal respiratory protection is used in a health-care setting, OSHA requires that an effective personal respiratory protection program be developed, implemented, administered, and periodically reevaluated (*54,55*).

All HCWs who need to use respirators for protection against infection with *M. tuberculosis* should be included in the respiratory protection program. Visitors to TB patients should be given respirators to wear while in isolation rooms, and they should be given general instructions on how to use their respirators.

The number of HCWs included in the respiratory protection program in each facility will vary depending on (a) the number of potentially infectious TB patients, (b) the number of rooms or areas to which patients with suspected or confirmed infectious TB are admitted, and (c) the number of HCWs needed in these rooms or areas. Where respiratory protection programs are required, they should include enough HCWs to provide adequate care for a patient with known or suspected TB should such a patient be admitted to the facility. However, administrative measures should be used to limit the number of HCWs who need to enter these rooms or areas, thus limiting the number of HCWs who need to be included in the respiratory protection program.

Information regarding the development and management of a respiratory protection program is available in technical training courses that cover the basics of personal respiratory protection. Such courses are offered by various organizations, such as NIOSH, OSHA, and the American Industrial Hygiene Association. Similar courses are available from private contractors and universities.

To be effective and reliable, respiratory protection programs must contain at least the following elements (*55,154*):

1. *Assignment of responsibility.* Supervisory responsibility for the respiratory protection program should be assigned to designated persons who have expertise in issues relevant to the program, including infectious diseases and occupational health.

2. *Standard operating procedures.* Written standard operating procedures should contain information concerning all aspects of the respiratory protection program.

3. *Medical screening.* HCWs should not be assigned a task requiring use of respirators unless they are physically able to perform the task while wearing the respirator. HCWs should be screened for pertinent medical conditions at the time they are hired, then rescreened periodically (*55*). The screening could occur as infrequently as every 5 years. The screening process should begin with a general screening (e.g., a questionnaire) for pertinent medical conditions, and the results of the screening should then be used to identify HCWs who need further evaluation. Routine physical examination or testing with chest radiographs or spirometry is not necessary or required.

Few medical conditions preclude the use of most negative-pressure particulate respirators. HCWs who have mild pulmonary or cardiac conditions may report discomfort with breathing when wearing negative-pressure particulate respirators, but these respirators are unlikely to have adverse health effects on the HCWs. Those HCWs who have more severe cardiac or pulmonary conditions may have more difficulty than HCWs with similar but milder conditions if performing duties while wearing negative-pressure respirators. Furthermore, these HCWs may be unable to use some PAPRs because of the added weight of these respirators.

4. *Training.* HCWs who wear respirators and the persons who supervise them should be informed about the necessity for wearing respirators and the potential risks associated with not doing so. This training should also include at a minimum:

- The nature, extent, and specific hazards of *M. tuberculosis* transmission in their respective health-care facility.
- A description of specific risks for TB infection among persons exposed to *M. tuberculosis*, of any subsequent treatment with INH or other chemoprophylactic agents, and of the possibility of active TB disease.
- A description of engineering controls and work practices and the reasons why they do not eliminate the need for personal respiratory protection.
- An explanation for selecting a particular type of respirator, how the respirator is properly maintained and stored, and the operation, capabilities, and limitations of the respirator provided.
- Instruction in how the HCW wearing the respirator should inspect, put on, fit check, and correctly wear the provided respirator (i.e., achieve and maintain proper face-seal fit on the HCW's face).
- An opportunity to handle the provided respirator and learn how to put it on, wear it properly, and check the important parts.
- Instruction in how to recognize an inadequately functioning respirator.

5. *Face-seal fit testing and fit checking.* HCWs should undergo fit testing to identify a respirator that adequately fits each individual HCW. The HCW should receive fitting instructions that include demonstrations and practice in how the respirator should be worn, how it should be adjusted, and how to determine if it fits properly. The HCW should be taught to check the facepiece fit before each use.

6. *Respirator inspection, cleaning, maintenance, and storage.* Conscientious respirator maintenance should be an integral part of an overall respirator program. This maintenance applies both to respirators with replaceable filters and respirators that are classified as disposable but that are reused. Manufacturers' instructions for inspecting, cleaning, and maintaining respirators should be followed to ensure that the respirator continues to function properly (*55*).

7. *Periodic evaluation of the personal respiratory protection program.* The program should be evaluated completely at least once a year, and both the written operating procedures and program administration should be revised as necessary based on the results of the evaluation. Elements of the program that should be evaluated include work practices and employee acceptance of respirator use (i.e., subjective comments made by employees concerning comfort during use and interference with duties).

Supplement 5: Decontamination—Cleaning, Disinfecting, and Sterilizing of Patient-Care Equipment

Equipment used on patients who have TB is usually not involved in the transmission of *M. tuberculosis*, although transmission by contaminated bronchoscopes has been demonstrated (*159,160*). Guidelines for cleaning, disinfecting, and sterilizing equipment have been published (*161,162*). The rationale for cleaning, disinfecting, or sterilizing patient-care equipment can be understood more readily if medical devices, equipment, and surgical materials are divided into three general categories. These categories—critical,

semicritical, and noncritical items—are defined by the potential risk for infection associated with their use (*163,164*).

Critical items are instruments that are introduced directly into the bloodstream or into other normally sterile areas of the body (e.g., needles, surgical instruments, cardiac catheters, and implants). These items should be sterile at the time of use.

Semicritical items are those that may come in contact with mucous membranes but do not ordinarily penetrate body surfaces (e.g., noninvasive flexible and rigid fiberoptic endoscopes or bronchoscopes, endotracheal tubes, and anesthesia breathing circuits). Although sterilization is preferred for these instruments, high-level disinfection that destroys vegetative microorganisms, most fungal spores, tubercle bacilli, and small nonlipid viruses may be used. Meticulous physical cleaning of such items before sterilization or high-level disinfection is essential.

Noncritical items are those that either do not ordinarily touch the patient or touch only the patient's intact skin (e.g., crutches, bedboards, blood pressure cuffs, and various other medical accessories). These items are not associated with direct transmission of *M. tuberculosis*, and washing them with detergent is usually sufficient.

Health-care facility policies should specify whether cleaning, disinfecting, or sterilizing an item is necessary to decrease the risk for infection. Decisions about decontamination processes should be based on the intended use of the item, not on the diagnosis of the patient for whom the item was used. Selection of chemical disinfectants depends on the intended use, the level of disinfection required, and the structure and material of the item to be disinfected.

Although microorganisms are ordinarily found on walls, floors, and other environmental surfaces, these surfaces are rarely associated with transmission of infections to patients or HCWs. This is particularly true with organisms such as *M. tuberculosis*, which generally require inhalation by the host for infection to occur. Therefore, extraordinary attempts to disinfect or sterilize environmental surfaces are not indicated. If a detergent germicide is used for routine cleaning, a hospital-grade, EPA-approved germicide/disinfectant that is not tuberculocidal can be used. The same routine daily cleaning procedures used in other rooms in the facility should be used to clean TB isolation rooms, and personnel should follow isolation practices while cleaning these rooms. For final cleaning of the isolation room after a patient has been discharged, personal protective equipment is not necessary if the room has been ventilated for the appropriate amount of time (Table S3–1).

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Glossary

This glossary contains many of the terms used in the guidelines, as well as others that are encountered frequently by persons who implement TB infection-control programs. The definitions given are not dictionary definitions but are those most applicable to usage relating to TB.

Acid-fast bacilli (AFB): Bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria. When AFB are seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis*.

Adherence: Refers to the behavior of patients when they follow all aspects of the treatment regimen as prescribed by the medical provider, and also refers to the behavior of HCWs and employers when they follow all guidelines pertaining to infection control.

Aerosol: The droplet nuclei that are expelled by an infectious person (e.g., by coughing or sneezing); these droplet nuclei can remain suspended in the air and can transmit *M. tuberculosis* to other persons.

AIA: The American Institute of Architects, a professional body that develops standards for building ventilation.

Air changes: The ratio of the volume of air flowing through a space in a certain period of time (i.e., the airflow rate) to the volume of that space (i.e., the room volume); this ratio is usually expressed as the number of air changes per hour (ACH).

Air mixing: The degree to which air supplied to a room mixes with the air already in the room, usually expressed as a *mixing* factor. This factor varies from 1 (for perfect mixing) to 10 (for poor mixing), and it is used as a multiplier to determine the actual airflow required (i.e., the recommended ACH multiplied by the mixing factor equals the actual ACH required).

Alveoli: The small air sacs in the lungs that lie at the end of the bronchial tree; the site where carbon dioxide in the blood is replaced by oxygen from the lungs and where TB infection usually begins.

Anergy; The inability of a person to react to skin-test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

Anteroom: A small room leading from a corridor into an isolation room; this room can act as an airlock, preventing the escape of contaminants from the isolation room into the corridor.

Area: A structural unit (e.g., a hospital ward or laboratory) or functional unit (e.g., an internal medicine service) in which HCWs provide services to and share air with a specific patient population or work with clinical specimens that may contain viable *M tuberculosis* organisms. The risk for exposure to *M tuberculosis* in a given area depends on the prevalence of TB in the population served and the characteristics of the environment.

ASHRAE: The American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc., a professional body that develops standards for building ventilation.

Asymptomatic: Without symptoms, or producing no symptoms.

Bacillus of Calmette and Guérin (BCG) vaccine: A TB vaccine used in many parts of the world.

BACTEC®: One of the most often used radiometric methods for detecting the early growth of mycobacteria in culture. It provides rapid growth (in 7–14 days) and rapid drug-susceptibility testing (in 5–6 days). When BACTEC® is used with rapid species identification methods, *M. tuberculosis* can be identified within 10–14 days of specimen collection.

Booster phenomenon: A phenomenon in which some persons (especially older adults) who are skin tested many years after infection with *M. tuberculosis* have a negative reaction to an initial skin test, followed by a positive reaction to a subsequent skin test. The second (i.e., positive) reaction is caused by a boosted immune response. Two-step testing is used to distinguish new infections from boosted reactions (see Two-step testing).

Bronchoscopy: A procedure for examining the respiratory tract that requires inserting an instrument (a bronchoscope) through the mouth or nose and into the trachea. The procedure can be used to obtain diagnostic specimens.

Capreomycin: An injectable, second-line anti-TB drug used primarily for the treatment of drug-resistant TB.

Cavity: A hole in the lung resulting from the destruction of pulmonary tissue by TB or other pulmonary infections or conditions. TB patients who have cavities in their lungs are referred to as having cavitary disease, and they are often more infectious than TB patients without cavitary disease.

Chemotherapy: Treatment of an infection or disease by means of oral or injectable drugs.

Cluster: Two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational (nosocomial) transmission.

Contact: A person who has shared the same air with a person who has infectious TB for a sufficient amount of time to allow possible transmission of *M. tuberculosis*.

Conversion, PPD: See PPD test conversion.

Culture: The process of growing bacteria in the laboratory so that organisms can be identified.

Cycloserine: A second-line, oral anti-TB drug used primarily for treating drug-resistant TB.

Directly observed therapy (DOT): An adherence-enhancing strategy in which an HCW or other designated person watches the patient swallow each does of medication.

DNA probe: A technique that allows rapid and precise identification of mycobacteria (e.g., *M. tuberculosis* and *M. bovis*) that are grown in culture. The identification can often be completed in 2 hours.

Droplet nuclei: Microscopic particles (i.e., 1–5 μm in diameter) produced when a person coughs, sneezes, shouts, or sings. The droplets produced by an infectious TB patient can carry tubercle bacilli and can remain suspended in the air for prolonged periods of time and be carried on normal air currents in the room.

Drug resistance, acquired: A resistance to one or more anti-TB drugs that develops while a patient is receiving therapy and which usually results from the patient's nonadherence to therapy or the prescription of an inadequate regimen by a health-care provider.

Drug resistance, primary: A resistance to one or more anti-TB drugs the exists before a patient is treated with the drug(s). Primary resistance occurs in persons exposed to and infected with a drug-resistant strain of *M. tuberculosis*.

Drug-susceptibility pattern: The anti-TB drugs to which the tubercle bacilli cultured from a TB patient are susceptible or resistant based on drug-susceptibility tests.

Drug-susceptibility tests: Laboratory tests that determine whether tubercle bacilli cultured from a patient are susceptible or resistant to various anti-TB drugs.

Ethambutol: A first-line, oral anti-TB drug sometimes used concomitantly with INH, rifampin, and pyrazinamide.

Ethionamide: A second-line, oral anti-TB drug used primarily for treating drug-resistant TB.

Exposure: The condition of being subjected to something (e.g., infectious agents) that could have a harmful effect. A person exposed to *M. tuberculosis* does not necessarily become infected (see Transmission).

First-line drugs: The most often used anti-TB drugs (i.e., INH, rifampin, pyrazinamide, ethambutol, and streptomycin).

Fixed room-air HEPA recirculation systems: Nonmobile devices or systems that remove airborne contaminants by recirculating air through a HEPA filter. These may be built into the room and permanently ducted or may be mounted to the wall or ceiling within the room. In either situation, they are fixed in place and are not easily movable.

Fluorochrome stain: A technique for staining a clinical specimen with fluorescent dyes to perform a microscopic examination (smear) for mycobacteria. This technique is preferable to other staining techniques because the mycobacteria can be seen easily and the slides can be read quickly.

Fomites: Linens, books, dishes, or other objects used or touched by a patient. These objects are not involved in the transmission of *M. tuberculosis*.

Gastric aspirate: A procedure sometimes used to obtain a specimen for culture when a patient cannot cough up adequate sputum. A tube is inserted through the mouth or nose and into the stomach to recover sputum that was coughed into the throat and then swallowed. This procedure is particularly useful for diagnosis in children, who are often unable to cough up sputum.

High-efficiency particulate air (HEPA) filter: A specialized filter that is capable of removing 99.97% of particles ≥0.3 μm in diameter and that may assist in controlling the transmission of *M. tuberculosis*. Filters may be used in ventilation systems to remove particles from the air or in personal respirators to filter air before it is inhaled by the person wearing the respirator. The use of HEPA filters in ventilation systems requires expertise in installation and maintenance.

Human immunodeficiency virus (HIV) infection: Infection with the virus that causes acquired immunodeficiency syndrome (AIDS). HIV infection is the most important risk factor for the progression of latent TB infection to active TB.

Immunosuppressed: A condition in which the immune system is not functioning normally (e.g., severe cellular immunosuppression resulting from HIV infection or immunosuppressive therapy). Immunosuppressed persons are at greatly increased risk for developing active TB after they have been infected with *M. tuberculosis*. No data are available regarding whether these persons are also at increased risk for infection with *M. tuberculosis* after they have been exposed to the organism.

Induration: An area of swelling produced by an immune response to an antigen. In tuberculin skin testing or anergy testing, the diameter of the indurated area is measured 48–72 hours after the injection, and the result is recorded in millimeters.

Infection: The condition in which organisms capable of causing disease (e.g., *M. tuberculosis*) enter the body and elicit a response from the host's immune defenses. TB infection may or may not lead to clinical disease.

Infectious: Capable of transmitting infection. When persons who have clinically active pulmonary or laryngeal TB disease cough or sneeze, they can expel droplets containing *M. tuberculosis* into the air. Persons whose sputum smears are positive for AFB are probably infectious.

Injectable: A medication that is usually administered by injection into the muscle (intramuscular [IM]) or the bloodstream (intravenous [IV]).

Intermittent therapy: Therapy administered either two or three times per week, rather than daily. Intermittent therapy should be administered only under the direct supervision of an HCW or other designated person (see Directly observed therapy [DOT]).

Intradermal: Within the layers of the skin.

Isoniazid (INH): A first-line, oral drug used either done as preventive therapy or in combination with several other drugs to treat TB disease.

Kanamycin: An injectable, second-line anti-TB drug used primarily for treatment of drug-resistant TB.

Latent TB infection: Infection with *M. tuberculosis*, usually detected by a positive PPD skin-test result, in a person who has no symptoms of active TB and who is not infectious.

Mantoux test: A method of skin testing that is performed by injecting 0.1 mL of PPD-tuberculin containing 5 tuberculin units into the dermis (i.e., the second layer of skin) of the forearm with a needle and syringe. This test is the most reliable and standardized technique for tuberculin testing (see Tuberculin skin test and Purified protein derivative [PPD]-tuberculin test).

Multidrug-resistant tuberculosis (MDR-TB): Active TB caused by *M. tuberculosis* organisms that are resistant to more than one anti-TB drug; in practice, often refers to organisms that are resistant to both INH and rifampin with or without resistance to other drugs (see Drug resistance, acquired and Drug resistance, primary).

M. tuberculosis complex: A group of closely related mycobacterial species that can cause active TB (e.g., *M. tuberculosis, M. bovis*, and *M. africanum*); most TB in the United States is caused by *M. tuberculosis*.

Negative pressure: The relative air pressure difference between two areas in a healthcare facility. A room that is at negative pressure has a lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas.

Nosocomial: An occurrence, usually an infection, that is acquired in a hospital or as a result of medical care.

Para-aminosalicylic acid: A second-line, oral anti-TB drug used for treating drug-resistant TB.

Pathogenesis: The pathologic, physiologic, or biochemical process by which a disease develops.

Pathogenicity: The quality of producing or the ability to produce pathologic changes or disease. Some nontuberculous mycobacteria are pathogenic (e.g., *Mycobacterium kansasii*), and others are not (.e.g., *Mycobacterium phlei*).

Portable room-air HEPA recirculation units: Free-standing portable devices that remove airborne contaminants by recirculating air through a HEPA filter.

Positive PPD reaction: A reaction to the purified protein derivative (PPD)-tuberculin skin test that suggests the person tested is infected with *M. tuberculosis*. The person interpreting the skin-test reaction determines whether it is positive on the basis of the size of the induration and the medical history and risk factors of the person being tested.

Preventive therapy: Treatment of latent TB infection used to prevent the progression of latent infection to clinically active disease.

Purified protein derivative (PPD)-tuberculin: A purified tuberculin preparation that was developed in the 1930s and that was derived from old tuberculin. The standard Mantoux test uses 0.1 mL of PPD standardized to 5 tuberculin units.

Purified protein derivative (PPD)-tuberculin test: A method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. A small dose of tuberculin (PPD) is injected just beneath the surface of the skin, and the area is examined 48–72 hours after the injection. A reaction is measured according to the size of the induration. The classification of a reaction as positive or negative depends on the patient's medical history and various risk factors (see Mantoux test).

Purified protein derivative (PPD)-tuberculin test conversion: A change in PPD test results from negative to positive. A conversion within a 2-year period is usually interpreted as new *M. tuberculosis* infection, which carries an increased risk for progression to active disease. A booster reaction may be misinterpreted as a new infection (see Booster phenomenon and Two-step testing).

Pyrazinamide: A first-line, oral anti-TB drug used in treatment regimens.

Radiography: A method of viewing the respiratory system by using radiation to transmit an image of the respiratory system to film. A chest radiograph is taken to view the respiratory system of a person who is being evaluated for pulmonary TB. Abnormalities (e.g., lesions or cavities in the lungs and enlarged lymph nodes) may indicate the presence of TB.

Radiometric method: A method for culturing a specimen that allows for rapid detection of bacterial growth by measuring production of CO_2 by viable organisms; also a method of rapidly performing susceptibility testing of *M. tuberculosis*.

Recirculation: Ventilation in which all or most of the air that is exhausted from an area is returned to the same area or other areas of the facility.

Regimen: Any particular TB treatment plan that specifies which drugs are used, in what doses, according to what schedule, and for how long.

Registry: A record-keeping method for collecting clinical, laboratory, and radiographic data concerning TB patients so that the data can be organized and made available for epidemiologic study.

Resistance: The ability of some strains of bacteria, including *M. tuberculosis*, to grow and multiply in the presence of certain drugs that ordinarily kill them; such strains are referred to as drug-resistant strains.

Rifampin: A first-line, oral anti-TB drug that, when used concomitantly with INH and pyrazinamide, provides the basis for short-course therapy.

Room-air HEPA recirculation systems and units: Devices (either fixed or portable) that remove airborne contaminants by recirculating air through a HEPA filter.

Second-line drugs: Anti-TB drugs used when the first-line drugs cannot be use (e.g., for drug-resistant TB or because of adverse reactions to the first-line drugs). Examples are cycloserine, ethionamide, and capreomycin.

Single-pass ventilation: Ventilation in which 100% of the air supplied to an area is exhausted to the outside.

Smear (AFB smear): A laboratory technique for visualizing mycobacteria. The specimen is smeared onto a slide and stained, then examined using a microscope. Smear results should be available within 24 hours. In TB, a large number of mycobacteria seen on an AFB smear usually indicates infectiousness. However, a positive result is not diagnostic of TB because organisms other than *M. tuberculosis* may be seen

on an AFB smear (e.g., nontuberculous mycobacteria).

Source case: A case of TB in an infectious person who has transmitted *M. tuberculosis* to another person or persons.

Source control: Controlling a contaminant at the source of its generation, which prevents the spread of the contaminant to the general work space.

Specimen: Any body fluid, secretion, or tissue sent to a laboratory where smears and cultures for *M. tuberculosis* will be performed (e.g., sputum, urine, spinal fluid, and material obtained at biopsy).

Sputum: Phlegm coughed up from deep within the lungs. If a patient has pulmonary disease, an examination of the sputum by smear and culture can be helpful in evaluating the organism responsible for the infection. Sputum should not be confused with saliva or nasal secretions.

Sputum induction: A method used to obtain sputum from a patient who is unable to cough up a specimen spontaneously. The patient inhales a saline mist, which stimulates a cough from deep within the lungs.

Sputum smear, positive: AFB are visible on the sputum smear when viewed under a microscope. Persons with a sputum smear positive for AFB are considered more infectious than those with smear-negative sputum.

Streptomycin: A first-line, injectable anti-TB drug.

Symptomatic: Having symptoms that may indicate the presence of TB or another disease (see Asymptomatic).

TB case: A particular episode of clinically active TB. This term should be used only to refer to the disease itself, not the patient with the disease. By law, cases of TB must be reported to the local health department.

TB infection: A condition in which living tubercle bacilli are present in the body but the disease is not clinically active. Infected persons usually have positive tuberculin reactions, but they have no symptoms related to the infection and are not infectious. However, infected persons remain at lifelong risk for developing disease unless preventive therapy is given.

Transmission: The spread of an infectious agent from one person to another. The likelihood of transmission is directly related to the duration and intensity of exposure to *M. tuberculosis* (see Exposure).

Treatment failures: TB disease in patients who do not respond to chemotherapy and in patients whose disease worsens after having improved initially.

Tubercle bacilli: *M. tuberculosis* organisms.

Tuberculin skin test: A method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. A small dose of PPD-tuberculin is injected just beneath the surface of the skin, and the area is examined 48–72 hours after the injection. A reaction is measured according to the size of the induration. The classification of a reaction as positive or negative depends on the patient's medical history and various risk factors (see Mantoux test, PPD test).

Tuberculosis (TB): A clinically active, symptomatic disease caused by an organism in the *M. tuberculosis* complex (usually *M. tuberculosis* or, rarely, *M. bovis* or *M. africanum*).

Two-step testing: A procedure used for the baseline testing of persons who will periodically receive tuberculin skin tests (e.g., HCWs) to reduce the likelihood of mistaking a boosted reaction for a new infection. If the initial tuberculin-test result is classified as negative, a second test is repeated 1–3 weeks later. If the reaction to the second test is positive, it probably represents a boosted reaction. If the second test result is also negative, the person is classified as not infected. A positive reaction to a subsequent test would indicate new infection (i.e., a skin-test conversion) in such a person.

Ultraviolet germicidal irradiation (UVGI): The use of ultraviolet radiation to kill or inactivate microorganisms.

Ultraviolet germicidal irradiation (UVGI) lamps: Lamps that kill or inactivate microorganisms by emitting ultraviolet germicidal radiation, predominantly at a wavelength of 254 nm (intermediate light waves between visible light and X-rays). UVGI lamps can be used in ceiling or wall fixtures or within air ducts of ventilation systems.

Ventilation, dilution: An engineering control technique to dilute and remove airborne contaminants by the flow of air into and out of an area. Air that contains droplet nuclei is removed and replaced by contaminant-free air. If the flow is sufficient, droplet nuclei become dispersed, and their concentration in the air is diminished.

Ventilation, local exhaust: Ventilation used to capture and remove airborne contaminants by enclosing the contaminant source (i.e., the patient) or by placing an exhaust hood close to the contaminant source.

Virulence: The degree of pathogenicity of a micoorganism as indicated by the severity of the disease produced and its ability to invade the tissues of a host. *M. tuberculosis* is a virulent organism.

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[FR Doc. 94–26598 Filed 10–27–94; 8:45 am]
BILLING CODE 4163–18–P

federal register

Friday
October 28, 1994

Part III

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 773, 778, 840, and 843
Applicant/Violator Computer System (AVS); Standards and Procedures for Ownership and Control Determinations; Final Rule

Office of Hearings and Appeals

43 CFR Part 4
Hearings and Appeals Procedures; Special Rules Applicable to Surface Coal Mining; Final Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 773, 778, 840, and 843

RIN 1029–AB34

Use of the Applicant/Violator Computer System (AVS) in Surface Coal Mining and Reclamation Permit Approval; Standards and Procedures for Ownership and Control Determinations

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) establishes new regulations to require regulatory authorities to use OSM's Applicant/Violator Computer System (AVS) and other information sources to identify ownership or control links between permit applicants and violators.

The regulations establish the procedures, standards, and type of proof required to challenge ownership or control links and to disprove violations.

OSM also amends a number of regulations affecting blocking of permits, abatement of notices of violation, improvidently issued permits, and permit application information.

The regulations reduce the possibility of violators receiving and retaining permits in violation of the permit approval provisions of SMCRA. Finally, the rules establish enhanced due process procedures for the regulated community.

EFFECTIVE DATE: November 28, 1994.

ADDRESSES: Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Russell Frum, Acting Chief, Applicant/Violator System Office, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1849 C Street NW., Washington, DC 20240. Telephone: 202–208–4655.

SUPPLEMENTARY INFORMATION:

I. Background

Section 510(c) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act) and 30 CFR part 773 establish certain requirements for permits and permit processing. These requirements include the identification of ownership or control links between permit applicants and individuals or entities who are responsible for unabated violations of certain Federal or State laws and rules. See 30 CFR 773.5; 30 CFR 773.15(b). The purpose of such inquiry is to determine whether a permit applicant is linked to unabated violations of the Act and related air and water quality requirements. See 30 CFR 773.15(b). In the event that a permit applicant is so linked, the regulatory authority may not issue a permit to the applicant unless the applicant submits proof that the violation has been or is in the process of being corrected to the satisfaction of the agency that has jurisdiction over the violation. In the alternative, the applicant may establish that the violation is the subject of a good faith, direct, administrative or judicial appeal which contests the validity of the violation. *Id.* In the event that a permit applicant is so linked and proof of the violation's correction or good faith appeal is not submitted, issuance of a permit to the applicant may constitute improvident issuance and may subject the permittee to certain remedial measures including suspension or rescission of the permit. See 30 CFR 773.20 and 30 CFR 773.21.

Under a court order in the case of *Save Our Cumberland Mountains, Inc. et al.* v. *Clark*, No. 81–2134 (D.D.C. January 31, 1985) (Parker, J.), the Secretary of the Interior was required to improve the enforcement and implementation of Section 510(c) of SMCRA, and to establish a computerized Applicant/Violator System ("AVS") to match permit applicants and their owners and controllers with current violators of SMCRA. OSM has developed such a computer system to enable OSM and State regulatory authorities to comply effectively with the responsibilities prescribed by Section 510(c) of SMCRA and 30 CFR part 773.

On January 24, 1990, OSM and DOI entered into a Settlement Agreement attempting to resolve litigation with Save Our Cumberland Mountains ("SOCM") and other plaintiffs. The Settlement Agreement was approved by the U.S. District Court on September 5, 1990, and became effective, by its own terms, on that date. See Memorandum of the Court, *Save Our Cumberland Mountains, Inc., et al.*, v. *Lujan*, No. 81–2134 (D.D.C. September 5, 1990). That Settlement Agreement contained provisions whereby OSM agreed to propose rules to implement Section 510(c) of SMCRA and the AVS. Accordingly, on September 6, 1991, OSM proposed rules whose purpose was:

> to require that, prior to issuing permits to applicants, regulatory authorities consider complete ownership and control information in conducting the analysis mandated by section 510(c) of SMCRA and 30 CFR 773.15(b). The proposed rules would mandate the use of AVS as a critical component of the ownership and control information consideration process.

See Proposed Rule, Use of the Applicant/Violator Computer System in Surface Coal Mining and Reclamation Permit Approval, 56 FR 45780, 45781 (September 6, 1991). While the proposal of the rules fulfilled certain provisions of OSM's Settlement Agreement with SOCM, OSM indicated that:

> it must be emphasized that OSM independently believes that the proposal and public consideration of such rules are important to assist OSM in implementing its duties under Section 510(c) of SMCRA and duties imposed by regulations such as 30 CFR 773.15. The proposed rules should be viewed as proposals that OSM would have made regardless of any litigation or settlement.

Id. Subsequently, on March 16, 1992, the U.S. Court of Appeals (D.C. Cir.) vacated the District Court's approval of the Settlement Agreement with SOCM. *Save Our Cumberland Mountains, Inc., et al.*, v. *Lujan*, No. 90–5374, Slip. Op. (U.S. Court of Appeals, D.C. Cir., May 22, 1992). In its decision, the Court noted that "nothing" in the Court's opinion precluded OSM's maintenance and improvement of the AVS as agency policy. *Id.*, at page 22.

As OSM indicated at the time of its proposal of September 1991, these rules are important and appropriate—independent of any litigation or settlement. OSM continues to be committed to the maintenance and improvement of the AVS as a matter of agency policy and believes that the publication of final rules is now necessary to the effective implementation of section 510(c) of the Act and the implementation of the AVS. OSM's commitment to AVS is in accord with the position recently expressed by the Senate Appropriations Committee:

> Regarding the AVS, the Committee joins the House in commending OSM for improvements made to the system. The Committee has consistently supported development and implementation of the AVS because the AVS is essential to effective enforcement of the Surface Mining Control and Reclamation Act of 1977 [SMCRA].

Report of the Senate Appropriations Committee, Senate Report No. 103–114, at page 47 (July 28, 1993). Accordingly, OSM has determined to go forward with the final rules published today without

regard to the course of litigation between OSM and SOCM or any other person. OSM has reviewed the proposed rules in light of the comments that have been made with a view towards serving the agency's commitment to protecting the environment, to implementing SMCRA, and ultimately, to serving the public interest.

These final rules incorporate the AVS into the Federal regulations and mandate the use of the system by State and Federal surface mining regulatory authorities. At the same time that these rules strengthen the enforcement of Section 510(c), they also establish a detailed set of procedural pathways to assure the protection of due process for the regulated community.

Public Participation

As indicated above, OSM published proposed rules on September 6, 1991. The proposed regulations were available for public comment until November 20, 1991. Comments were received from members of the regulated community, representatives of environmental advocacy groups, representatives of State regulatory authorities, and various citizens. While a total of 20 commenters submitted written comments, most comments can be grouped into three major categories which are captioned below. After the discussion of these three major issues, this preamble will then provide a section-by-section discussion of the final rules.

II. Rules Adopted and Responses to Public Comments

A. Summary of Rules Adopted

These final rules include the following provisions:

Part 701—Permanent Regulatory Program

Section 701.5 is amended to delete the definition of "Violation notice."

Part 773—Requirements for Permits and Permit Processing

The Table of Contents is amended to include new section numbers 773.22, verification of ownership or control application information; 773.23, review of ownership or control and violation information; 773.24, procedures for challenging ownership or control links shown in AVS; and 773.25, standards for challenging ownership or control links and the status of violations.

Section 773.5 is amended to include definitions of "Applicant/Violator System" or "AVS." The terms are defined to mean the computer system maintained by OSM to identify ownership or control links involving permit applicants, permittees, and persons cited in violation notices. The regulation is further amended to include definitions of "Federal violation notice," "Ownership or control link," "State violation notice," and "Violation notice."

A "Federal violation notice" is defined to include a violation notice issued by OSM or by another agency or instrumentality of the United States.

An "ownership or control link" is defined as any relationship included in the definition of "owned or controlled" or "owns or controls" in 30 CFR 773.5 or in the violations review provisions of 30 CFR 773.15(b). It includes any relationship presumed to constitute ownership or control under 30 CFR 773.5(b) unless such presumption has been successfully rebutted under sections 773.24 and 773.25 of this rule or under the provisions of 30 CFR part 775 and § 773.25 of this rule. It also includes an identity between persons, e.g., an applicant and a violator.

A "State violation notice" is defined as a violation notice issued by a State regulatory authority or by another agency or instrumentality of State government.

"Violation notice" is defined as any written notification from any governmental entity advising of violations of the Act or any other laws which would form the basis for a regulatory authority to deny issuance of a permit in accordance with the criteria contained in § 773.15(b) of the regulations. The type of written notification is broadly defined to include a letter, memorandum, legal or administrative pleading, or other written communication. Consistent with the provisions of § 773.15(b), the term includes notification of a violation of the Act, any Federal rule or regulation promulgated pursuant thereto, a State program, or any Federal or State law, rule, or regulation pertaining to air or water environmental protection in connection with a surface coal mining operation. It includes, but is not limited to, a notice of violation; an imminent harm cessation order; a failure-to-abate cessation order; a final order, bill, or demand letter pertaining to a delinquent civil penalty; a bill or demand letter pertaining to delinquent abandoned mine reclamation fees; and a notice of bond forfeiture, where one or more violations upon which the forfeiture was based have not been corrected.

Section 773.10 is revised to include the new sections of the AVS-related rules that result in information collection requirements. The revision provides an estimate of the average public reporting burden of four and one-half hours per response for the collection of information under part 773 as such part is revised by these final rules. The section also lists the addresses for OSM and OMB where comments on the information collection requirements may be sent.

Paragraph 773.15(b)(1) is amended to require the regulatory authority to review all reasonably available information concerning violation notices and ownership or control links involving the applicant. Such information would include that obtained pursuant to § 773.22 (verification of ownership or control application information); § 773.23 (review of ownership or control and violation information); § 778.13 (identification of interests); and § 778.14 (violation information).

The net effect of referencing such provisions in § 773.15(b)(1) is to assure that the regulatory authority makes a decision with respect to permit issuance or denial based upon complete information relating to ownership, control, and violations. Such complete information includes the mandated use of AVS.

Furthermore, in accordance with § 773.23, the regulatory authority will follow the procedures and standards set forth in §§ 773.24 and 773.25 in deciding whether to issue the permit under § 773.15(b).

OSM has also decided to amend 30 CFR 773.15(b)(1) to provide that, in the absence of a failure-to-abate cessation order (FTACO), a regulatory authority may presume that a notice of violation (NOV) is being corrected to the satisfaction of the agency with jurisdiction over the violation where the abatement period for such notice of violation has not yet expired and where the permit applicant has provided certification in his or her permit application that such violation is in the process of being abated to the satisfaction of the agency with jurisdiction over the violation. In addition, OSM has also amended 30 CFR 773.15(b)(2) to provide that any permits issued incident to such presumption and certification will be conditionally issued based upon successful completion of the necessary abatement.

Section 773.20 is amended by the insertion of a new paragraph (b)(2), which makes the provisions of proposed § 773.25, standards for challenging ownership or control links and the status of violations, applicable when a regulatory authority makes determinations with respect to improvidently issued permits. In this context, § 773.25 is applicable when a regulatory authority determines whether

a violation, penalty, or fee existed at the time that it was cited, remains unabated or delinquent, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, and whether any ownership or control link between the permittee and the person responsible for the violation, penalty, or fee existed, still exists, or has been severed.

The insertion of the language referring to § 773.25 has the effect of assuring that the standards, responsibilities, and procedures created by proposed § 773.25 are consistently applied to permit issuance and to determinations regarding improvident permit issuance. Such an approach enhances the fairness of the permitting process and the prospect for the uniform enforcement of nationwide minimum standards. In one respect, however, the improvident permit issuance process will differ from the permit issuance process. In the improvident permit issuance process, prior to permit suspension or rescission, the permittee will be able to challenge the existence of the violation at the time it was cited. In the permit issuance process, prior to permit denial, the applicant will not be able to challenge the existence of the violation at the time it was cited.

OSM has also renumbered certain provisions of the regulation at 30 CFR 773.20(c). Among such provisions, renumbered paragraph (c)(1)(iv), which authorizes the regulatory authority to use rescission as one of the remedial measures for improvident permit issuance, deletes a specific reference contained in the former 30 CFR 773.20(c)(4) to the rescission procedures of 30 CFR 773.21.

The reason for this deletion is that OSM today establishes a prior notice and a common appeal procedure for both permit suspensions and permit rescissions with respect to improvidently issued permits. The former regulation governing permit suspensions at 30 CFR 773.20(c)(3) did not impose any specific requirements for prior notice, opportunity to be heard, or right of appeal for the permittee whose permit is to be suspended. See 54 FR 18450 (1989). In contrast to this, regulations governing permit rescissions at 30 CFR 773.21 contained specific requirements for prior notice to a permittee and an explicit right of appeal. OSM has now provided for greater consistency in its procedures governing suspension and rescission of permits.

Accordingly, OSM amends 30 CFR 773.20 to add a new paragraph (c)(2) which requires that a regulatory authority which decides to suspend a permit must provide at least 30 days' prior written notice to the permittee. In the event that the regulatory authority decides to rescind a permit, it must provide notice in accordance with the provisions of 30 CFR 773.21. The amendment further provides that a permittee be given the opportunity to request administrative review of the notice under Office of Hearings and Appeals, (OHA) rule 43 CFR 4.1370 *et seq.*, where OSM is the regulatory authority, or under the State program equivalent, where the State is the regulatory authority.

The regulation further allows for enhanced due process protection and fairness by providing that temporary relief from the regulatory authority's decision is available in accordance with the provisions of OHA rule 43 CFR 4.1376 or the State program equivalent. In the absence of such temporary relief, the regulatory authority's decision remains in effect during the pendency of appeal.

OSM has retained the language in paragraph 773.20 which addresses the situation which occurs when a permit is issued in reliance upon the presumption that an NOV is being abated in the absence of a cessation order and a cessation order is, in fact, issued with respect to the violation. In such an event, a regulatory authority is required to find that the permit has been improvidently issued.

OSM amends paragraph (a) of 30 CFR 773.21 to make the provisions of § 773.25, standards for challenging ownership or control links and the status of violations, applicable when a regulatory authority invokes the automatic suspension and rescission procedures of 30 CFR 773.21. The rationale for such amendment is the same as that discussed above with respect to similar language contained in § 773.20.

Further, OSM deletes former paragraph (c) of 30 CFR 773.21 which provides for appeals of rescission notices. As discussed above, rescission appeal procedures are incorporated in 30 CFR 773.20.

Section 773.22 is a new section and mandates an inquiry whose focus is to assure that the regulatory authority develops complete and accurate information as to the identification of the applicant and all owners or controllers of the applicant prior to making a determination on a permit application and enters such information promptly into the AVS. Accordingly, this section focuses on verification of ownership or control application information. Such accurate and complete information enables the regulatory authority to make an informed decision as to whether the applicant is linked to a surface coal mining and reclamation operation in violation of the Act or other any other environmental law within the terms of 30 CFR 773.15(b)(1).

Paragraph (a) of § 773.22 imposes a duty upon a regulatory authority to review the information provided in the permit application, pursuant to 30 CFR 778.13(c) and 778.13(d), to determine whether the information provided, including the identification of the operator and all owners and controllers of the operator, is complete and accurate. In making such determination, the regulatory authority is required to compare information provided in the application with information contained in manual and automated data sources. Manual sources for review include the regulatory authority's own enforcement and inspection records and State corporation commission or tax records, to the extent they contain information concerning ownership or control links. Automated data sources include the regulatory authority's own computer systems, if any, and the AVS.

Paragraph (b) of § 773.22 provides that, if it appears from information provided in the application pursuant to paragraphs (c) and (d) of § 778.13 that none of the persons identified in the application has had any previous mining experience, the regulatory authority has to inquire of the applicant and investigate whether anyone other than those persons identified in the application will own or control the mining operation as either an operator or as another type of owner or controller.

Paragraph (c) of § 773.22 provides that if, after conducting the information review described above, the regulatory authority identifies any potential omission, inaccuracy, or inconsistency in the ownership or control information provided in the application, it must contact the applicant prior to making a final determination with respect to the application. The applicant is then required to resolve the potential omission, inaccuracy, or inconsistency through submission of an amendment to the application or a satisfactory explanation which includes credible information sufficient to demonstrate that no actual omission, inaccuracy, or inconsistency exists. The regulation also contains a reference to required action by the regulatory authority in accordance with § 843.23, sanctions for knowing omissions or inaccuracies in ownership or control and violation information, or the State program equivalent, where appropriate. As will

be described more fully below, OSM is deferring action at this time with respect to proposed § 843.23. Such proposed section will be considered as part of a subsequent rulemaking. OSM has, however, retained the reference to proposed § 843.23 in final § 773.22 in the event that proposed § 843.23 is ultimately adopted. Nevertheless, OSM has made no decision with respect to the adoption of proposed § 843.23 and the retention of such reference does not mean that OSM will ultimately adopt proposed § 843.23 as a final rule.

Paragraph (d) of § 773.22 requires that, upon completion of the information review mandated by § 773.22, the regulatory authority promptly enter into or update all ownership or control information on AVS.

Section 773.23 is a new section which delineates the regulatory authority's review obligations with respect to a permit application after the regulatory authority has completed the process of verifying ownership or control application information as described in proposed § 773.22.

Paragraph (a) of § 773.23 requires the regulatory authority to review all reasonably available information concerning violation notices and ownership or control links involving the applicant to determine whether the application can be approved under the provisions of 30 CFR 773.15(b). With respect to ownership or control links involving the applicant, such information includes all information obtained under proposed § 773.22 and 30 CFR 778.13. With respect to violation notices, such information includes all information obtained under § 778.14, information obtained from OSM, including information shown in the AVS, and information obtained from the regulatory authority's own records concerning violation notices.

In substance, the regulation assures that the regulatory authority considers complete ownership, control, and violation information in making the decision required by 30 CFR 773.15(b)(1) with respect to a permit application.

Paragraph (b) of § 773.23 provides the course of action which a regulatory authority is required to take if the review conducted pursuant to paragraph (a) of the section discloses any ownership or control link between the applicant and any person cited in a violation notice.

Thus, paragraph (b)(1) of § 773.23 requires that the regulatory authority notify the applicant of such link and refer the applicant to the agency with jurisdiction over the violation notice.

Paragraph (b)(2) of § 773.23 requires that the regulatory authority not approve the permit application unless and until it determines that all ownership or control links between the applicant and any person cited in a violation notice are erroneous or have been rebutted, or the regulatory authority determines that the violation to which the applicant has been linked has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, within the meaning of 30 CFR 773.15(b)(1) or the State program equivalent. The determinations to be made by the regulatory authority under paragraph (b)(2) of the regulation are made in accordance with the provisions of § 773.24, procedures for challenging ownership or control links shown in AVS, and § 773.25, standards for challenging ownership or control links and the status of violations, or their State program equivalents.

Paragraph (c) of § 773.23 requires that, following the regulatory authority's decision on the application or following the applicant's withdrawal of the application, the regulatory authority is required to promptly enter all relevant information related to the decision or withdrawal into AVS. The regulatory authority's decision could include unconditional issuance, conditional issuance, or denial of the permit. The requirement that all relevant information be promptly entered into AVS is intended to insure that AVS is continually updated to reflect the most current information available with respect to permit applicants. A critical source of such information is the regulatory authority.

Section 773.24 is a new section that establishes the procedures to be followed if a person wishes to challenge an ownership or control link between a person and any other person shown on AVS. The procedures to be followed by both OSM and the challenger are included. The section provides procedures for direct appeals of such links to OSM by persons who have been so linked. The section also provides for challenges concerning the status of violations to which persons shown on AVS have been linked. The section further provides the opportunity for those persons making a challenge to obtain a temporary relief from any adverse use of the challenged link or violation information during the pendency of such challenge.

Paragraph (a)(1) of § 773.24 provides that an applicant or anyone else shown in AVS is an ownership or control link to any person could challenge such a link in accordance with the provisions of paragraphs (b) through (d) of § 773.24 and in accordance with the provisions of § 773.25. Paragraph (a)(1) of § 773.24 provides, however, that such challenge is not available if the challenger is bound by a prior administrative or judicial decision with respect to the link.

Paragraph (a)(1) of § 773.24 provides that challenges of ownership or control links shown on AVS are made before OSM.

Paragraph (a)(2) of § 773.24 provides that an applicant or anyone else shown in AVS in an ownership or control link to a person cited in a Federal violation notice seeking to challenge the status of such violation may do so in accordance with the provisions of paragraphs (b) through (d) of § 773.24 and in accordance with the provisions of § 773.25, which are discussed in detail below. The procedures applicable are similar to those described in paragraph (a)(1) of § 773.24.

The "status of the violation" means whether the violation remains outstanding, has been corrected, is in the process of being corrected, or is the subject of a good faith, direct administrative or judicial appeal to contest the validity of the violation. See 30 CFR 773.15(b)(1)(i)–(ii). This usage is carried forward into paragraphs (b) and (c) of § 773.24 and into the provisions of paragraph (b)(1)(iv) of § 773.25. The process for challenging the status of a Federal violation is a Federal process and such challenges will be made before OSM.

In challenging the current status of a violation under § 773.24 or 773.25, a person will not be able to challenge the existence of the violation at the time it was cited unless the challenge is made by a permittee within the context of the improvidently issued permit process or by an applicant after permit denial. In general, the existence of the violation will have been established by prior administrative or judicial proceedings involving the person cited in the violation notice, or by such person's failure to exhaust its available remedies in a timely manner.

Paragraph (a)(2) of § 773.24 provides, in language similar to that contained in paragraph (a)(1) of the regulation, that the opportunity to challenge the status of a violation is not available to any person who "is bound by a prior administrative or judicial determination concerning the status of the violation."

Paragraph (a)(3) of § 773.24 provides that any applicant or person shown in AVS to be linked by ownership or control to a person cited in a State violation notice may challenge the status of the violation before the State that issued the violation notice. The

challenge must be made in accordance with the State's program equivalents to paragraphs (b) through (d) of § 773.24 and § 773.25. Again, the challenge may not involve the existence of the violation at the time it was cited, and is not available if the challenger is bound by a prior administrative or judicial determination with respect to status of the violation.

Paragraph (b) of § 773.24 requires that any applicant or other person seeking to challenge ownership or control links shown in AVS or the status of Federal violations must submit to OSM a written explanation of the basis for his or her challenge and provide relevant evidentiary materials and supporting documents. The information must be submitted to the Chief of OSM's AVS Office in Washington, DC.

Paragraph (c) of § 773.24 provides that, in response to a challenge made under paragraph (b) of that section, OSM must make a written decision with respect to the ownership or control link and/or with respect to the status of the violation.

Paragraph (d)(1) of § 773.24 provides that, if OSM has determined that the ownership or control link has been shown to be erroneous or has been rebutted and/or that the violation covered by the violation notice has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, OSM is required to provide notice of its determination to the permit applicant or other person challenging the link or the status of the violation. If an application is pending, OSM must also notify the regulatory authority before whom the application is pending. Further, OSM is required to correct information contained in AVS to reflect the determination which has been made.

Paragraph (d)(2) of § 773.24 provides that, if OSM has determined that the challenged ownership or control link has not been shown to be erroneous and has not been rebutted, and that the violation remains outstanding, OSM must provide notice of its determination to the permit applicant or other person challenging the link or the status of the violation. If an application is pending, OSM must also notify the regulatory authority before whom the application is pending. Further, OSM is required to update information contained in AVS, if necessary, to reflect OSM's determinations.

Paragraph (d)(2)(i) of § 773.24 provides that OSM must serve a copy of its decision with respect to a challenge upon the applicant or other challenger by certified mail, or by any other means consistent with the rules governing service of a summons and complaint under Rule 4 of the Federal Rules of Civil Procedure. The regulation provides that service is complete upon tender of the notice or of the mail and is not deemed incomplete by virtue of a challenger's refusal to accept the notice or mail.

Paragraph (d)(2)(ii) of § 773.24 provides that the applicant or other challenger can appeal OSM's decision to the Department of the Interior's Office of Hearings and Appeals (OHA) within 30 days of such decision in accordance with OHA regulations at 43 CFR 4.1380 *et seq.* Paragraph (d)(2)(ii) further provides that OSM's decision remains in effect unless temporary relief was granted in accordance with OHA regulations at 43 CFR 4.1386. The filing of an appeal will not automatically suspend the use of the information in AVS during the pendency of such appeal. The challenger must explicitly seek such relief in appeal proceeding before OHA.

Section 773.25 is a new section which establishes standards for challenges to ownership or control links and for challenges to the status of violations. The section allocates responsibilities between OSM and State regulatory authorities for resolving issues related to ownership and control and provides the standards for evidence to resolve such issues.

Paragraph (a) of § 773.25 provides that provisions of § 773.25 are applicable to any challenge concerning an ownership or control link to any person or the status of any violation covered by a violation notice when such challenge is made under the provisions of 30 CFR 773.20 and 30 CFR 773.21 (improvidently issued permits); §§ 773.23 (the regulatory authority's review of ownership or control and violation information), and 773.24 (procedures for challenging ownership or control links shown in AVS); or 30 CFR part 775 (administrative and judicial review of permitting decisions).

Paragraph (b) of § 773.25 provides the basic allocation of responsibility among regulatory authorities to make decisions with respect to ownership or control and with respect to the status of violations.

Paragraph (b)(1)(i) of § 773.25 provides that the regulatory authority before which an application is pending has responsibility for making decisions with respect to the ownership or control relationships of the application.

Paragraph (b)(1)(ii) of § 773.25 provides that the regulatory authority that issued a permit has responsibility for making decisions with respect to the ownership or control relationships of the permit.

Paragraph (b)(1)(iii) of § 773.25 provides that the State regulatory authority that issued a State violation notice has responsibility for making decisions with respect to the ownership or control relationships of the violation.

Paragraph (b)(1)(iv) of § 773.25 provides that the regulatory authority that issued a violation notice, whether State or Federal, has responsibility for making decisions concerning the status of the violation covered by the notice.

The "status" of the violation means whether the violation remains outstanding, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, within the meaning of 30 CFR 773.15(b)(1).

Paragraph (b)(2) of § 773.25 provides that OSM has responsibility for making decisions with respect to the ownership or control relationships of a Federal violation notice.

Paragraph (b)(3)(i) of § 773.25 provides that with respect to information shown on AVS, the responsibilities of State regulatory authorities to make decisions with respect to ownership or control links are subject to the plenary authority of OSM.

Paragraph (b)(3)(ii) of § 773.25 provides that with respect to information shown on AVS relating to the status of a violation and with respect to ownership or control information which has not been entered into AVS by a State, the authority of a State regulatory authority is subject to OSM's oversight authority under 30 CFR parts 773, 842, and 843.

Paragraph (c) of § 773.25 establishes evidentiary standards applicable to the formal and informal review of ownership or control links and the status of violations.

Paragraph (c)(1) of § 773.25 provides that in any formal or informal review of an ownership or control link or of the status of a violation covered by a violation notice, the agency responsible for making a decision is required to first make a prima facie determination or showing that the link exists, existed during the relevant period, and/or that the violation remains outstanding. A prima facie determination is made when the agency is reviewing the evidence itself, in an informal process; a prima facie showing is made when the agency's determination is the subject of a formal administrative or judicial review process. When the agency makes such a determination or showing, the person seeking to challenge the link or the status of the violation then has the burden of proving the necessary elements of his or her challenge to the

link or to the status of the violation by a preponderance of the evidence.

Under paragraph (c) of § 773.25, a challenger of a link has to prove at least one of three proposed conclusions by a preponderance of the evidence to succeed in his or her challenge.

First, under paragraph (c)(1)(i) of § 773.25, a challenger could prove that the facts relied upon by the responsible agency to establish ownership or control under the definition of "owned or controlled" or "owns or controls" in 30 CFR 773.5 do not or did not exist or that the facts relied upon to establish a presumption of ownership or control under the definition of "owned or controlled" or "owns or controls" in 30 CFR 773.5 do not or did not exist.

Paragraph (c)(1)(ii) of § 773.25 provides that a person subject to a presumption of ownership or control under the definition of "owned or controlled" or "owns or controls" in 30 CFR 773.5 could rebut such presumption by demonstrating that he or she does not or did not in fact have the authority directly or indirectly to determine the manner in which surface coal mining operations are or were conducted.

Paragraph (c)(1)(iii) of § 773.25 provides that a challenger could prove that the violation covered by a violation notice did not exist, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal within the meaning of 30 CFR 773.15(b)(1). Paragraph (c)(1)(iii) further provides, however, that a person challenging the status of a violation would not be able to challenge the existence of the violation at the time it was cited under the provisions of § 773.24 unless such challenger is a permittee acting within the context of §§ 773.20–773.21 of this part. In any circumstance, a person who had failed to take timely advantage of a prior opportunity to challenge the violation notice or who was bound by a previous administrative or judicial determination concerning the existence of the violation would also be precluded from making a challenge to the existence of the violation at the time it was cited in any proceeding.

Paragraph (c)(2) of § 773.25 describes the type of evidence that a person challenging an ownership or control link or the status of a violation has to present to meet the burden of proof by a preponderance of the evidence. The regulation provides that the evidence presented be probative, reliable, and substantial. See 5 U.S.C. 556(d).

Paragraph (c)(2) of § 773.25 provides a list of examples of such evidence for proceedings before the "responsible agency" (the agency with responsibility for making a decision with respect to a challenge) and for proceedings before administrative or judicial tribunals reviewing the decisions of the responsible agency. The list of the types of acceptable evidence is intended to be illustrative, not exhaustive. It is expected that regulatory authorities will add to this list as they develop experience in making determinations under the regulation.

Paragraph (c)(2)(i) of § 773.25 focuses upon proceedings before the responsible agency. The list of examples includes documents which are likely to be truthful and which have certain indicators of reliability which go beyond the mere assertions of the individual presenting the evidence.

Paragraph (c)(2)(i)(A) of the section provides that a challenger may submit affidavits setting forth specific facts concerning the scope of responsibility of the various owners or controllers of an applicant, a permittee, or any person cited in a violation notice; the duties actually performed by such owners or controllers; the beginning and ending dates of such owners' or controllers' affiliation with the applicant, permittee, or person cited in a violation notice; and the nature and details of any transaction creating or serving an ownership or control link; or specific facts concerning the status of the violation.

Paragraphs (c)(2)(i)(B) and (c)(2)(i)(C) of section 773.25 each look to official certification as the basis for the reliability of a submitted document. Paragraph (c)(2)(i)(B) allows for the submission of copies of certain types of documents if they are certified. Such documents include copies of corporate minutes, stock ledgers, contracts, purchase and sale agreements, leases, correspondence or other relevant company records. Paragraph (c)(2)(i)(C) allows for submission of certified copies of documents filed with or issued by any State, municipal, or Federal governmental agency.

Paragraph (c)(2)(i)(D) of final § 773.25 provides for a challenger's submission of an opinion of counsel in support of his or her position. Such opinion would be appropriate for submission when it is supported by evidentiary materials; when it is rendered by an attorney who certifies that he or she is qualified to render an opinion of law; and when counsel states that he or she has personally and diligently investigated the facts of the matter or where counsel states that such opinion is based upon information which has been supplied to counsel and which is assumed to be true.

Paragraph (c)(2)(ii) of § 773.25 provides that, when the decision of the responsible agency is reviewed by an administrative or judicial tribunal, the challenger could present any evidence to such tribunal which is admissible under the rules of the tribunal. Under the regulation, however, the evidence submitted still has to be probative, credible, and substantial.

Paragraph (d) of § 773.25 provides for the review and revision of information in AVS to reflect determinations made by regulatory authorities in response to challenges of ownership or control links or the status of violations. Paragraph (d) provides that, following any determination by a State regulatory authority or other State agency, or following any decision by an administrative or judicial tribunal reviewing such determination, the State regulatory authority shall review the information in AVS to determine if the information in AVS is consistent with the determination or decision. If it is not consistent, the State regulatory authority is required to promptly inform OSM and request that the AVS information be revised to reflect the determination or decision.

Part 778—Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information

Paragraph (c) of 30 CFR 778.14 is amended to require a permit applicant to disclose "all violation notices" received by the applicant within the preceding three years. In addition, the introductory language of the provision is amended to require the disclosure of all outstanding violation notices for any surface coal mining operation that is deemed or presumed to be owned or controlled by either the applicant or by any person who is deemed or presumed to own or control the applicant under definitions of "owned or controlled" or "owns or controls" under 30 CFR 773.5.

The regulation previously required the applicant to disclose violations of a number of various laws listed in 30 CFR 778.14(c). Use of the amended definition of "violation notice" adopted today as part of 30 CFR 773.5 obviates the need for listing each of these violations in 30 CFR 778.14.

The regulation also previously required that the applicant provide only a list of unabated cessation orders and unabated air and water quality violation notices received prior to the date of the application by any surface coal mining and reclamation operation owned or controlled by either the applicant or by any person who owns or controls the applicant. With respect to this list, the

previous regulation did not require that an applicant list notices of violation received or unpaid penalties or fees incurred by any surface coal mining operation owned or controlled by the applicant or by any person who owns or controls the applicant.

Paragraph (c) of § 778.14 is now amended to require an applicant to disclose all outstanding violation notices received by any surface coal mining operation that is deemed or presumed to own or control the applicant.

In addition, OSM has amended paragraph (c) of § 778.14 to provide that for each notice of violation issued pursuant to 30 CFR 843.12 or under a Federal or State program for which the abatement period has not expired, the applicant must certify that such notice of violation is in the process of being abated to the satisfaction of the agency with jurisdiction over the violation.

Part 840—State Regulatory Authority: Inspection and Enforcement

Paragraph (b) of 30 CFR 840.13 is amended to include a reference to § 843.23, a proposed rule. As has been explained previously, OSM has deferred action on adopting proposed § 843.23 at this time. The reference, however, to that section has been placed in § 840.13 in the event that proposed § 843.23 is adopted. The use of such reference does not mean, however, that OSM will ultimately adopt proposed § 843.23.

Part 843—Federal Enforcement

OSM amends the Table of Contents of 30 CFR part 843 to add § 843.24, oversight of State permitting decisions with respect to ownership or control of the status of violations.

Former § 843.10 is deleted since part 843 did not contain any information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507. The references to §§ 843.14(c) and 843.16 formerly in § 843.10 did not represent information collection requirements. The requirement in § 843.14(c) for OSM to furnish copies of notices and orders to the State regulatory authority and to any person having an interest did not require OMB approval because the obligation to provide the information is imposed upon OSM and not upon the State or upon a member of the public. Section 843.16 merely informs the public of the right to file an application for review and request a hearing under 43 CFR part 4.

Section 843.24 is a new section which provides standards for OSM's oversight of State permitting decisions with respect to ownership or control or the status of violations.

Paragraph (a) of § 843.24 establishes the bases which require OSM to take action under the provisions of paragraphs (b) and (c) of proposed § 843.24. Paragraph (a) provides that OSM is required to take action whenever it determines, through its oversight of the implementation of State programs, that a State has issued a permit without complying with the State program equivalents of proposed §§ 773.22 (verification of ownership or control application information), 773.23 (review of ownership or control and violation information), 773.24 (procedures for challenging ownership or control links shown in AVS), 773.25 (standards for challenging ownership or control links and the status of violations), and § 843.23. As has been explained previously, OSM has deferred action on adopting proposed § 843.23 at this time. The reference, however, to that proposed rule has been placed in § 843.24 in the event that § 843.23 is adopted. The use of such reference does not mean, however, that OSM will ultimately adopt proposed § 843.23.

If, as a result of determination made under paragraph (a) of § 843.24, OSM has reason to believe that the State has issued a permit improvidently within the meaning of 30 CFR 773.20, paragraph (b) of § 843.24 requires OSM to initiate action under 30 CFR 843.21.

Paragraph (c) of § 843.24 provides for remedial actions by OSM against a State which knowingly fails to comply with the regulations relating to ownership or control and violation information during the permit application process.

B. General Comments

Numerous comments were made which addressed various issues with respect to the overall rulemaking. While such comments also invoked particular sections of the proposed rules, these comments asserted several central themes which went beyond particular sections of the rulemaking even through specific sections of the proposed rulemaking were referenced as areas of concern by the commenters. Accordingly, OSM has decided to address these central issues in this portion of the preamble. Within the context of such discussion, particular sections of the proposed and final rules will be referred to as necessary. Nevertheless, in these responses, OSM focuses upon central issues which appear to be of overarching concern to the commenters.

Due Process

Industry commenters asserted that the proposed rules violated due process and the underlying principles of the Act. These commenters further argued that OSM's proposed rules violated due process principles because they did not allow for a permit conditioned upon the outcome of an appeal of an ownership or control link, upon the challenge of the status of the violation, or upon the challenge of the existence of the violation at the time it was cited. They also asserted that because OSM did not allow for de novo challenges of the existence of violations by owners or controllers, the proposed rules violated due process principles.

OSM disagrees with these commenters' characterizations. The proposed rules and the rules which have been adopted today provide detailed procedures to assure that those wishing to contest ownership or control links and the status of violations may do so. Further, the proposed and final rules provide that decisions on these matters are made based upon credible evidence and fair processes. Those seeking to challenge the existence of violations have the opportunity to do so, incident to permit denial, in accordance with currently existing rules which predate this rulemaking. See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38885 ("Due Process Provided.") (October 3, 1988). In addition, today's final rules clarify that permittees may make such challenges within the context of the improvidently issued permit process. The procedures provided in today's final rules supplement current rules contained at 30 CFR part 773 to provide more than sufficient due process to protect the limited property interest a permit applicant has in the expectancy of a permit to engage in surface coal mining operations.

OSM does not believe that principles of due process mandate, as a necessary condition precedent to the denial of a permit to an owner or controller of a violator, that the agency provide a full, formal, de novo hearing on the merits of an ownership or control link, the existence of the violation at the time it was cited, and the status of the violation—followed by an exhaustive appeal on each of these matters to the court of last resort. Instead, the final rules adopted today provide due process commensurate with the limited interest of a permit applicant—the expectancy of permit issuance. OSM's position is consistent with the agency's earlier

statements relating to the sufficiency of due process and the protection of property rights provided by the ownership and control rules and the AVS. See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38885 (October 3, 1988).

Moreover, in the cases of *Pittston Co.* v. *Lujan*, No. 92–1606 (4th Cir.) and No. 91–0006–A (W.D. Va.), *National Wildlife Federation* v. *Lujan*, No. 88–3117 (D.D.C.), and *Save Our Cumberland Mountains, Inc.* v. *Lujan*, No 81–2134 (D.D.C.), coal industry interests advanced similar due process arguments attacking the agency's ownership and control rules published at 53 FR 38868 *et seq.* on October 3, 1988, and the agency's implementation of AVS and those rules. In the briefs submitted by the Department of the Interior in those cases, the Department analyzed relevant case law and carefully explained why the due process criticisms were not well taken. Copies of these briefs are being placed in the Administrative Record of this rulemaking. To the extent relevant, OSM incorporates the arguments advanced by the Department in those briefs herein by reference.

Further, OSM disagrees with the commenters' view that due process requires that conditional permits be made available during the tendency of the appeal of an ownership or control link as a condition precedent to permit block. The final rules published today provide ample protection for an owner or controller by providing the opportunity for an owner or controller to challenge an ownership or control link. Further, the final rules provide for the Department's Office of Hearings and Appeals (OHA) to grant temporary relief from a permit block, where, *inter alia*, the challenger has a substantial likelihood of prevailing on the merits of the appeal. OHA is contemporaneously publishing final rules establishing procedures for the granting of temporary relief. Under OSM's final rules published today and the OHA rules, the likelihood of the erroneous deprivation of a permit due to an erroneous link is minimal. An appellant with a meritorious claim can get relief. Conditional permits for all appellants, without regard to the merits of their claims, are unnecessary and unwarranted.

Moreover, the final rules published today provide a measure of protection commensurate with the very limited interest that a permit applicant has in his or her application for a permit. An applicant does not have a right to a permit to mine coal in the same way that he or she has title to real property or a leasehold interest in a mineral lease. A permit to mine coal is a privilege granted by the regulatory authority to those who have complied with the requirements of the Act and the applicable regulatory program, including the provisions of Section 510(c) of the Act and the provisions of 30 CFR part 773. Until an applicant has been found in compliance with the applicable provisions of the program; until the other provisions governing permit issuance have been satisfied; and until a permit has been issued, the applicant has, at most, an expectation which may or may not be reasonable, depending upon the circumstances, that he or she will qualify for permit issuance. Such an expectancy is highly speculative, continent, and limited. Investments based on an expectancy do not transform the expectancy into a presently vested property right. See generally *Jacobsen* v. *Hannifin*, 627 F.2d 177, 179–80 (9th Cir. 1980). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legislation claim of entitlement to it." See also *Board of Regents* v. *Roth*, 408 U.S. 564, 577 (1972).

In contrast to this, the agency's interest in and responsibility for implementing Section 510(c) of the Act is substantial and must be balanced against the limited property interest of the permit applicant. OSM's ability to implement the provisions of Section 510(c) of the Act is critical to the agency's enforcement of the Act. Those provisions of the Act prevent violators from receiving new permits and, thus, from injuring the environment at new surface coal mining operations. Those provisions of the Act encourage abatement of violations and deter operators and their owners or controllers from committing violations. Potential applicants fear permit denial in the future. Therefore, such applicants are motivated to prevent or abate violations in the present. Thus, OSM has a substantial interest in the successful, credible implementation of Section 510(c) of the Act.

If conditional permits were allowed during the pendency of a prolonged appellate process challenging an ownership or control link, the agency's ability to enforce the provisions of section 510(c) of the Act and the ownership and control rules would be severely compromised. Rather than abate the violations of their owned or controlled operations, it is possible that some applicants would routinely appeal ownership or control links without regard to the strength of the link as demonstrated by a full proceeding on the merits. Such applicants would appeal merely for the purpose of gaining conditional permits. Depending upon how long the appeals process ran, an operator with a conditional permit could extract a significant portion of the coal in a permitted mine and would have no incentive to abate the violations of the surface coal mining operation to which he had been linked. The Act does not contemplate such a result; nor does the Constitution require it.

Further, such a result would provide an unfair competitive advantage to an unscrupulous operator to the detriment of the interests of the other members of the coal industry, the majority of whom take responsibility for environmental reclamation and are responsible corporate citizens.

Nevertheless, industry commenters have asserted that there is little likelihood of operators making frivolous or bad faith ownership or control appeals because they have significant investments in their surface coal mining operations. While OSM recognizes that this is probably true for the majority of operators, including those who have provided comments on the proposed rules, experience has shown that a small minority of irresponsible operators can create harm disproportionate to their numbers. In the process, such irresponsible operators do harm not just to OSM's effective implementation of the Act, but also to the reputation of the industry as well.

For instance, a marginal operator's significant investment in coal extraction equipment may mask his/her plan to avoid spending resources on reclamation. Indeed, there could be a serious economic temptation for such an operator to protect a significant investment by appealing, if such appeal would support the continuation of operations. Accordingly, OSM considers the extent of an applicant's investment in a surface coal mining operation to be an unreliable indicator of an applicant's motive in initiating an appeal. Thus, OSM declines to develop a process requiring the evaluation of operators' good faith based upon their comparative investments in surface coal mining operations.

OSM does recognize, however, that a permittee has an interest in his permit deserving of a higher level of protection than that of an applicant with respect to an application. A valid permit represents more than the mere expectancy represented by an application. A current, valid permit

represents legal authorization to conduct surface coal mining operations in accordance with the terms of such permit. See section 506 of the Act. Further, a permit carries with it the right of successive renewal. See section 506(d)(1) of the Act; 30 CFR 774.15. Thus, a detailed process governing improvidently issued permits has been established which recognizes this interest. See 30 CFR 773.20; 773.21. In response to concerns asserted by industry with respect to due process, OSM has amended the regulations governing improvident permit issuance to provide that a permittee can challenge the existence of the violation at the time it was cited as part of the improvidently issued permit process. See 773.20(b)(2). OSM has done this in recognition of the more substantial interest that a permit represents in contrast to the limited interest represented by a permit application.

Industry commenters have further asserted that an owner or controller must be afforded the opportunity to challenge the validity of the existence of the violation at the time that it was cited as a condition precedent to the recommendation of a denial of a permit application for an owner or controller of the violation. These commenters argued that owners or controllers may not have had the opportunity to challenge the validity of the violation which forms the basis of the permit denial at the time it was cited. They argued that only the actual violators were cited at that time and that the owners or controllers would not have received notice in a timely manner to enable them to challenge the violation then. They further asserted that a right to contest the merits of a violation after permit denial is not sufficient to redress the harm caused by permit denial. Rather than face permit denial, they asserted that coal operators will be forced to pay the disputed fees or to reclaim land. Accordingly, they asserted that they should be allowed to challenge the violation prior to any permit denial.

OSM disagrees with those views. The rights of an owner or controller are well protected by the ability to challenge the link to the violation. If the ownership or control link is not well taken, then the violation is irrelevant as a basis for permit block. If the link is meritorious, the owner or controller would have been well-positioned to have had knowledge in fact of the citations, if he or she desired such knowledge, see, e.g., 30 CFR 843.15(d), and to have compelled the controlled surface coal mining operation to abate the violation or to challenge the violation in a timely manner. See, e.g., 30 CFR 843.16(a). Accordingly, if an ownership or control link is well taken, the owner or controller has already had an opportunity to challenge the violation or to abate the violation through the controlled entity. Under these circumstances, OSM does not believe that an owner or controller is entitled to an additional opportunity to challenge the existence of a violation before the regulatory authority can deny issuance of a permit.

Even so, the final rules promulgated today would not prohibit the challenge of the existence of the violation. Such a challenge, however, must be made at the time of permit denial, rather than before, by persons who are not bound by prior administrative or judicial proceedings with respect to the existence of the violation or who have not had a prior opportunity to challenge the existence of the violation. This is entirely consistent with OSM's position as expressed in the preamble to the ownership and control rules published in 1988. See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38885 (October 3, 1988).

Additionally, within the context of today's final provisions amending the regulations governing improvident permit issuance, OSM has made explicit that a permittee may challenge the existence of the violation at the time it was cited. A permittee may make such challenge if the challenge is not otherwise precluded by a permittee's previous failure to take advantage of a prior opportunity to challenge or by a prior administrative or judicial determination concerning the existence of the violation. See §§ 773.20 and 773.25.

Nevertheless, the industry commenters questioned whether the ability to challenge a violation after permit denial is illusory because OSM may attempt to argue that the owner or controller failed to take advantage of a prior opportunity to challenge the violation at the time that it was issued or that the challenger was bound by a prior administrative or judicial determination. This is not OSM's intent. Each specific case must be evaluated on its merits. In general, a challenge would be precluded only when the facts indicate that a potential challenger has already had the opportunity to challenge and has squandered it, or when the potential challenger is bound by a prior determination. The purpose of this portion of the proposed rules and the final rules as adopted is to eliminate multiple repetitive opportunities for challenge for those who have already had a substantive opportunity to challenge, either directly or through a controlled entity. It is not OSM's intention to assert these defenses to a challenge unless such defenses are supported by the facts of a particular case.

Industry commenters argued that a State's decision to deny a permit based upon violation information contained in AVS is also not subject to challenge. OSM disagrees. The existence of the violation at the time it was cited, along with any other bases for permit denial, may be challenged in a proceeding under 30 CFR part 775, or the equivalent State programs, subject to the defenses discussed above. To the extent that a regulatory authority has based its permit denial decision upon violation information contained in AVS, that information would be an integral part of the challenge proceeding. When administrative and judicial tribunals consider appeals of permit denials, it is probable that evidence related to violations which form the basis of a permit denial will be relevant to the tribunal. OSM will work with State regulatory authorities to provide supporting documentation if required for appeals of State permitting decisions. OSM anticipates that State regulatory authorities will similarly cooperate with OSM and with each other in making such evidence related to violation information available to administrative and judicial tribunals.

Industry commenters also asserted that the proposed rules, along with the ownership and control rules promulgated in 1988, deny due process in that they retroactively impose responsibilities for violations upon owners and controllers. Again, OSM must reject this characterization of the effect of the proposed rules and 1988 ownership and control rules. OSM must further reject this characterization with respect to the final regulations adopted today. The ownership and control rules published in 1988, the AVS-related proposed rules published in September, 1991, and the final rules published today subject the owners or controllers of violations to permit denial for currently outstanding violations, rather than past, abated violations. This obligation follows the clear mandate of section 510(c) of the Act which requires the denial of permits when "any surface coal mining operation owned or controlled by the applicant is currently in violation" of the Act or other laws cited.

Moreover, the presumptions of ownership and control provided by 30 CFR 773.5 and the final rules merely

reflect the reality that owners or controllers have the authority, by reason of their control at the time that the violations are committed or during any period when the violations remained outstanding, to be aware of violations, to compel their controlled entities to undertake timely challenges of violations, and to compel their controlled entities to abate violations of the Act. Under these circumstances, there is no retroactive application of responsibility.

Moreover, the clear provisions of section 507(b)(4) of the Act require, in substance, that permit applicants identify most of those people who are considered owners or controllers for purposes of section 510(c) of the Act and 30 CFR 773.15 and 773.5. As OSM observed in the preamble to the ownership and control rules published in 1988:

> The legislative history of section 507(b)(4) includes the statement that "[t]he information required by [section 507(b)(4)] is a key element of the operator's affirmative demonstration that the environmental protection provisions of the Act can be met as stipulated in Section 510 and includes: (1) Identification of all parties, corporations, and officials involved *to allow identification* of parties ultimately responsible * * *." H.R. Rep. No. 94–896, 94th Cong., 2nd Sess. 111 (1976). (Emphasis added.) See also S. Rep. No. 94–28, 94th Cong., 1st Sess. 206 (1975).

See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38875 (October 3, 1988).

With the ownership and control rules published in October of 1988 and with these final rules published today, OSM is simply implementing sections 510(c) and 507(b)(4) of the Act. None of these provisions impose retroactive responsibilities.

Finally, related to their due process concerns, industry commenters argued that the proposed rules also violate the Act by not providing conditional permits during the appeal of ownership or control links, the current status of the violation, or the existence of the violation at the time it was cited. They pointed to the provisions of current 30 CFR 773.15(b)(2) which allow for a permit to be conditioned upon a good faith, direct administrative or judicial appeal to contest the validity of the current violation as indicative of the agency's longstanding recognition that such an appeal is consistent with the Act.

OSM disagrees with the commenters' analysis and rejects the view that OSM's historic interpretation of the Act requires that owners or controllers be entitled to permits conditioned upon the appeals of ownership or control links, the status of the violation, or the existence of the violation at the time that it was cited.

OSM's regulation at 30 CFR 773.15(b)(2) does not constitute the agency's recognition that all appeals form the basis for conditional permits. Such a blanket interpretation would negate the clear mandate of the provisions of section 510(c) of the Act and of 30 CFR 773.15(b)(1) which require the denial of permits to applicants who own or control surface coal mining operations in current violation of the Act. As has been discussed previously in this preamble, the issuance of permits conditioned upon the appeal of ownership or control links thwarts the effective implementation of section 510(c) of the Act. OSM has never interpreted its regulations to allow for such a result.

Contrary to commenters' assertions, the regulation at 30 CFR 773.15(b)(2) only allows a limited exception for good faith, direct administrative or judicial appeals contesting the validity of the violation as the basis for conditional issuance. An appeal of an ownership or control link which tests a person's relationship to a violator or to a violation does not test the validity of the underlying violation. To the extent that the provisions of a State program allow for conditional issuance based upon the appeal of an ownership or control link, those provisions must be considered less effective than comparable Federal provisions. See 30 CFR parts 730 and 732.

Moreover, in many instances, the existence of ownership or control links in AVS may be readily discovered by the presumed controllers, and the accuracy of those links administratively challenged prior to the actual denial of a permit by a regulatory authority. An appeal challenging the current status of a violation does not constitute a direct challenge to the validity of the violation at the time that it was cited. Instead, it would test whether the violation is currently abated or not.

An appeal as to the existence of the violation at the time it was cited could constitute a challenge as to the validity of the violation. Nevertheless, there is nothing in the Act or OSM's regulations which requires that such an appeal, undertaken by an owner or controller of a violator after standard appeal times have run, be the basis for conditional issuance. Conditional issuance is particularly inappropriate when the controller's ability to compel the controlled entity to act is taken into account. A controller has the capacity to force the controlled entity to abate or to appeal and would have had such rights at the time that the violation was cited. Thus, a timely appeal of the violation, directly made through administrative or judicial tribunals, could have been made at that time.

One commenter argued that due process protection in the proposed rules should be enhanced. In substance, this commenter asserted that it is unfair to deny permits to applicants or to subject active permits to treatment as improvidently issued permits where the applicants or permittees are subjectively unaware of their ownership or control links to violators or of the import of such relationships. Accordingly, this commenter proposed that such persons should have extended opportunities for "corrections and questions" without the risk of permit denial or revocation.

OSM appreciates the commenter's suggestion, but does not believe that further proposed rules are needed or that amendments to the final rules should be made to reflect the commenter's proposal. The AVS Office will work with anyone at any time, including when there is no pending permitting action, to answer questions and make appropriate corrections to ownership and control information in the database. Data in the system is available on-line to any interested party, and the AVS Office will provide print-outs of AVS data on request. The AVS Office will also provide training to interested parties on the use of the system. The AVS Office routinely works with major companies to insure that their ownership and control information in the system is kept current. Given all these factors, there is no "risk of permit denial" necessarily involved in the resolution of an ownership and control link.

Furthermore, applicants and permittees are deemed to be aware of the law. The ownership and control rules were published in October, 1988. Since that time, applicants and permittees could reasonably be expected to be aware of the regulations and could have acted to cure any outstanding violations or to resolve any erroneous links in the AVS which would form the basis for a permit denial or revocation. Thus, any "unfair surprise" to applicants or permittees posited by the commenter is not an actual problem. Accordingly, it is entirely legitimate to deny permits to such applicants or permittees when they are linked to violations.

Further, permit applicants are required to provide full ownership and control information at the time of permit application. See 30 CFR 778.13; 778.14.

Permittees are required to update relevant ownership and control information in a timely manner. See 30 CFR 774.17. Thus, the proposed remedy offered by the commenter is already a requirement of the rules. Finally, in the unlikely event that a person has been unfairly subjected to permit denial by the process, that person could still seek temporary relief from OHA in accordance with procedures governing such relief provided by OHA's and OSM's regulations.

Primacy

Industry and State commenters asserted a number of concerns relating to the impact of the proposed rules upon the primacy of States.

In general, industry commenters argued that the proposed rules and the AVS itself impermissibly substitute Federal authority for State authority in the permitting process. They argued that, under the principle of State primacy, once a State's program has been approved by OSM, the State should have sole authority for making decisions with respect to permit issuance, including the determination of ownership and control matters. They asserted that requiring a State to query the AVS before making a permitting decision takes the decision out of the hands of the State and transfers substantive control of the decision to OSM which controls the content of the AVS. As evidence of this Federal control, industry commenters cited, with disapproval, provisions of the proposed rules which provide that challenges of ownership and control information on the AVS must be made to OSM.

OSM disagrees. First, in the cases of *National Wildlife Federation* v. *Lujan*, No. 88–3117 (D.D.C.), and *Save Our Cumberland Mountains, Inc.* v. *Lujan*, No. 81–2134 (D.D.C.), coal industry interests advanced similar primacy arguments attacking the agency's ownership and control rules published in 1988. OSM responded to those arguments in detail demonstrating that the ownership and control rules support State programs, rather than undermine them. Copies of these briefs are being placed in the Administrative Record of this rulemaking. OSM incorporates the arguments advanced by the Department in those briefs herein by reference.

Similarly, the purpose of AVS is to assist, rather than to undermine, the States in the exercise of their primary authority for the implementation of their approved programs. The provisions of section 510(c) of the Act require that the regulatory authority deny a permit to an applicant where "information available" to the regulatory authority indicates that any surface coal mining operation owned or controlled by the applicant is currently in violation" of the Act or certain other governmental laws. See section 510(c) of the Act. In a State which has an approved program to regulate surface coal mining operations pursuant to section 503 of the Act, neither OSM nor AVS decides whether or not to issue a permit to an applicant in that State. The State regulatory authority is the decisionmaker.

Contrary to the commenter's assertions, however, the Federal government has an ongoing role in this system of State primacy. The Act and Federal regulations require that OSM assist the States in the implementation of their programs under the Act and that OSM provide oversight of the State regulatory authorities' activities. See sections 102(g), 201(c), 503, 504, 505, and 521 of the Act; 30 CFR parts 732, 733, and 842.

Consistent with the State's role as primary decisionmaker, the AVS is a tool, developed by the Federal government in concert with the States, which provides information in a convenient mode, readily accessible to State regulatory authorities. It is a source of relevant "information available" of the type which the State regulatory authority is required by the Act to consider when the State regulatory authority decides whether to issue a permit to conduct surface coal mining operations. Absent AVS, a State regulatory authority would have to laboriously contact other State regulatory authorities for violation and ownership and control information or would have to simply reply upon the voluntary disclosure of information supplied by applicants or by public-spirited citizens. That OSM has taken the lead in developing the AVS and in proposing to require to use of AVS through rulemaking is consistent with the Federal government's role to assist and to oversee the State regulatory authorities. Even then, the content of AVS is the product of the efforts of both State regulatory authorities and OSM working together to incorporate into AVS ownership and control and violation information developed through their regulatory programs.

Accordingly, a State's authority to make a decision with respect to a permit application is primary and is unimpaired by anything in the proposed rules and by the State's use of AVS. To the extent that the rules support OSM's oversight of the State's decisions, such oversight is mandated by and consistent with the provisions of the Act and the regulations cited above.

To the extent that the proposed rules provide that challenges of information already on AVS be made to OSM, such provisions do not impair primacy. Instead, the rules recognize that the Federal government is uniquely situated to maintain the accuracy and integrity of a nationwide database that will be used by many States. To be sure, each of the State regulatory authorities has a valuable contribution to make to the quality of AVS information. Yet, the individual States may have differing perspectives on ownership and control issues. The potential for inconsistency is significant—particularly with respect to ownership and control decisions relating to multistate companies with complex organizational structures. Also, potential challengers of such information need, if possible, a single point at which they can challenge ownership or control information which will be used in many States and which, absent such a locus, could subject them to inconsistent outcomes. Such a role for OSM is consistent with the role for the agency envisioned by SMCRA. See sections 201(c)(9) and 201(c)(12) of SMCRA.

Further, it must be recognized that the decision to deny a permit because an operator is linked to a violation through ownership or control can be an unpopular one, subjecting a local economy to stress. An operator may claim that he "has been put out of business" by the State regulatory authority. This is one area where the Federal government can assist the States by accepting the responsibility of maintaining ownership and control information which may ultimately lead to permit denials in the various States. Federal acceptance of such a role helps to assure the integrity, consistency, and accuracy of ownership and control information on the AVS. It is also consistent with one of the purposes of the Act which is "to insure that competition in interstate commerce among sellers of coal produced in different States will not be used to undermine the ability of the several States to improve and maintain adequate standards of coal mining operations within their borders." See section 101(g) of the Act.

Finally, even with the State using information on AVS as part of its information gathering incident to making a determination with respect to a permit application, the State retains the authority, subject to Federal oversight, to decide whether to issue the permit or not. Appeals of such a decision are made to the appropriate

State reviewing tribunal, in accordance with the provisions of the State program. Also, the final rules published today make clear that the State regulatory authority which issues a permit has responsibility, subject to OSM's oversight, for determining the ownership or control relationships of the permit. See § 773.25(b)(1)(ii). Contrary to commenters' assertions, the State's use of AVS does not transmute the process into a Federal proceeding.

To the extent that a State denies a permit based upon information in AVS indicating that the applicant is linked through ownership or control to an outstanding violation of the Act, such denial is made based upon the mandate of section 510(c) as implemented by the applicable State program, rather than some extraordinary Federal intervention in the State's process. A State regulatory authority denying a permit based upon ownership or control information shown in AVS would be obligated under the Act to take the same action based upon a phone call, letter, or other communication from another regulatory authority advising of an applicant's ownership or control of a surface coal mining operation in current violation of the Act.

Further, it must be emphasized that the cooperation of all regulatory authorities, including the States and OSM, is necessary to facilitate the implementation of section 510(c) of the Act. Information on violations wherever they have occurred is needed by each regulatory authority considering a permit application to ensure true compliance with the provisions of section 510(c) of the Act. It is unreasonable, ineffective, and inefficient for each regulatory authority to attempt to develop such information by itself. It is both reasonable and prudent for OSM to fulfill this role. See sections 201(c)(9) and 201(c)(12) of SMCRA.

Industry commenters further asserted that the proposed rules will have the effect of "Balkanizing" (i.e., dispersing) regulatory authorities' permitting decisions. They were especially concerned about the provisions of § 773.26 of the proposed rules which allocated responsibility to particular regulatory authorities to make decisions with respect to ownership or control relationships.

Proposed § 773.26 allocated responsibility among the respective regulatory authorities such that the regulatory authority before which an application is pending would have had authority for making decisions with respect to the ownership or control relationships of the applicant; the regulatory authority that issued a permit would have had authority for making decisions with respect to the ownership or control relationships of the permittee; the State regulatory authority that issued a State violation notice would have had authority for making decisions with respect to the ownership or control relationships of persons cited in the violation; and the regulatory authority that issued a violation notice, whether State or Federal, would have had authority for making decisions concerning the status of the violation covered by the notice. The proposed rule provided that these allocations of authority were subject to OSM's oversight.

In substance, the industry commenters asserted that the provisions of this proposed section would impermissibly weaken the authority of the State regulatory authority before whom a permit application is pending. They asserted that the allocations of authority contained in the proposed rule would create confusion and delay in the permitting process.

OSM disagrees with these comments. The interaction between the Federal government and the States described above does not constitute a "balkanization" of the permit application process. Nor will such interaction lead to confusion in the permit application process. Such interaction is consistent with the mandate of SMCRA to implement section 510(c) within a context of State primacy supported by Federal oversight. The proposed rules and the final rules adopted today attempt to establish a road map which is consistent with SMCRA for the making of decisions with respect to ownership or control and for the development of information to be used in AVS.

First, the allocations of responsibility are consistent with the requirements of the Act. The provisions of section 510(c) of the Act mandate a separation of decisionmaking in the permit application process which commenters might characterize as "balkanization." The provisions of section 510(c) of the Act are very explicit in stating that permits shall be denied to applicants who own or control surface coal mining operations with outstanding violations of the Act "until the applicant submits proof that such violation has been corrected or is in the process of being corrected to the satisfaction of the regulatory authority, department, or agency which has jurisdiction over such violation."

Thus, the Act contemplates that the State regulatory authority before which an application is pending could require information from another State regulatory authority with respect to violations issued by the other State regulatory authority before issuing a permit.

Further, the Act is equally specific in establishing a mandated role for the Federal government to oversee the States in the implementation of their State regulatory programs. See sections 201(c)(1); 503; 504; 505; and 521 of the Act. Thus, to the extent that the proposed rules and the final rules adopted today envision the exercise of Federal oversight, such a role is responsive to the provisions of SMCRA.

Moreover, while the proposed rule and the final rule, modified and renumbered as § 773.25, will be compared and discussed in more detail below in this preamble, it is appropriate to offer some responses at this point since these critical comments refer to the issue of relationships between governments. These comments invoke issues of State primacy. Contrary to commenters' assertions, the rules in question allocate responsibility in a manner which is supportive of, and consistent with, State primacy.

For instance, the final rule provides that a State regulatory authority which issues a violation has responsibility, subject to OSM oversight, for identifying the ownership and control relationships of the violation. See 30 CFR 773.25(b)(1)(iii). The State regulatory authority which issues a violation has the greatest interest, among those regulatory authorities with an interest in the ownership and control relationships of that violation, in seeing that the persons responsible for the violation abate the violation. Such abatement directly improves the environmental quality of the State which issues the violation. Accordingly, the State which issued a violation should have the first opportunity, subject to Federal oversight, to identify the owners or controllers of the violation. Well before OSM made its proposals in September, 1991, which form the basis for today's final rules, both SMCRA and Federal regulations recognized that a violation had to be corrected to the satisfaction of the agency that has jurisdiction over the violation, before a permit could be issued by a regulatory authority. See section 510(c) of SMCRA; 30 CFR 773.15(b)(1)(i).

Moreover, today's final provisions further recognize the relative access to ownership and control information that the interested regulatory authorities have at each stage of the process. The regulatory authority which issued the violation is in the best position to investigate and to develop all of the

relevant facts about the violation, including the identification of those responsible for the violation. The violation was committed within the jurisdiction of the regulatory authority which issued the violation. That regulatory authority has access to the actors on the ground at the surface coal mining operation and would be able to question them to identify ownership and control information.

A similar analysis can be offered in support of affording the agency before which an application is pending responsibility for identifying the ownership and control of the application. This regulatory authority has the applicant before it and can inquire of the applicant directly with respect to any ownership and control information contained in the application. Thus, the regulatory authority before which an application is pending has responsibility, subject to Federal oversight, to decide the ownership and control relationships of the application. See 30 CFR 773.25(b)(1)(i).

A regulatory authority which has issued a permit has ongoing authority for the permittee's surface coal mining operations on the permitted site. Thus, this regulatory authority has responsibility, subject to Federal oversight, to decide the ownership and control relationships of the permit. See 30 CFR 773.25(b)(1)(ii).

Moreover, OSM recognizes that the industry commenters are deeply troubled by any use of the AVS in the permit application process and any application of OSM's ownership or control rules as contained at 30 CFR 773.5 and 773.15(b)(1). Nevertheless, OSM has accepted the mandate of Congress to develop and implement the AVS because "the AVS is essential to effective enforcement of the Surface Mining Control and Reclamation Act of 1977 [SMCRA]." See Report of the Senate Appropriations Committee, Senate Report No. 103–114, at page 47 (July 28, 1993). Thus, the allocation of responsibilities for the various regulatory authorities contained in the proposed rules and the final rules adopted today also attempt to reflect the pragmatic realities of implementing a national computer system.

Once a decision has been made to go forward with a national computer system to aid the enforcement of section 510(c) of SMCRA, certain pragmatic realities must be recognized. First, information will be coming to the computer system from many sources. As each State regulatory authority analyzes ownership and control information contained in permit applications and reports such information to AVS, such information is incorporated into AVS. A national computer system requires centralized management and maintenance to assure the accuracy and consistency of information. Centralized management provides a focus of responsibility when inaccuracies or technical problems are identified. Accordingly, the Federal government, acting through OSM, has responsibility for such system management. At the same time, the States are primary actors in the permit application process and critically important actors in the development and the support of AVS. With respect to AVS, the States play a critical role in using the computer system as an information resource in the permit application process and in supplying information to AVS gleaned from the permit application process and other research.

Consistent with the need for centralized management of the database, OSM has such a role with respect to the AVS and the information contained therein. As will be discussed below in the discussion of specific sections of the final rules, one of the changes made from the September, 1991, proposal was to place language in the final rule clarifying OSM's plenary role with respect to the content of ownership or control information in the AVS. See 30 CFR 773.25(b)(3)(i). OSM will also have sole responsibility over the ownership and control relationships incident to Federal violations. See 30 CFR 773.25(b)(2). Further, OSM will exercise oversight over State regulatory authorities' activities. See 30 CFR 773.25(b)(3)(ii). This role provided for OSM under the final rule, consistent with that proposed under the proposed rule, recognizes that, under the Act, while the States are subject to Federal oversight, OSM is not subject to the oversight of State regulatory authorities.

The industry commenters asserted that the proposed rules will create confusion and conflict among the States with the potential for conflicting decisions on ownership and control by multiple State regulatory authorities and OSM. Again, OSM disagrees with the commenters' characterization of the effect of the rules. As indicated above, the proposed rules and the final rules clearly allocate responsibility among the various regulatory agencies. The regulatory authority before which an application is pending decides whether or not to issue a permit.

OSM retains the authority to oversee the decision of the State. Indeed, OSM's role as controller of information already on AVS and as overseer of State ownership or control decisions will reduce, not create, confusion and conflict by establishing one final authority to make decisions in cases where disagreements among States might occur about information already on AVS.

Accordingly, the rules do not inappropriately disperse decisionmaking among State and Federal regulatory authorities with respect to ownership and control. Further, prior to the publication of these final rules, OSM's AVS Office and the States have worked well together to implement AVS and the ownership and control regulations promulgated in 1988. To the extent that there have been disagreements between OSM's AVS Office and the State regulatory counterparts, such disagreements have been addressed expeditiously and resolved in a collegial and cooperative manner.

Some commenters expressed concern that the proposed rules did not sufficiently address the issues of conflicts between the States and OSM and between the States themselves on matters of ownership and control. OSM believes that these issues will be addressed adequately by the provisions of 30 CFR 773.25. That section is based upon proposed § 773.26 and establishes the relative responsibilities of agencies responsible for making ownership and control decisions. As noted previously, this regulation is discussed in detail below. Within the framework of State primacy, OSM will exercise its oversight role to review State ownership or control decisions, in response to citizen complaints or as otherwise appropriate, to assure the integrity of the AVS. See 30 CFR 773.12; 842.11; and 843.21.

One commenter asserted, in substance, that the proposed rules did not go far enough in imposing Federal responsibility. This commenter proposed that all matters relating to ownership and control under section 510(c) of the Act should be OSM's responsibility. While OSM appreciates the commenter's suggestion, OSM must reject this proposal. As OSM indicated above, the Act establishes a system of State primacy with Federal oversight and assistance to the States. While it is understandable that some persons would prefer that the entire responsibility for permit decisionmaking be shouldered by the Federal government, such a system would require a significant restructuring of the statutory framework established by the Act. In contrast to this, today's final rules address the responsibilities established by section 510(c) of the Act in a manner more consistent with the statutory framework.

One commenter questioned whether OSM had given adequate consideration to the implications of the rules upon Federal and State relations. As the above discussion indicates, OSM has considered, in detail, the effect of AVS and these rules upon the relationship between OSM and the State regulatory authorities and believes that the rules are consistent with the framework for Federal and State relations established by the Act. Further, as indicated above, the working relationship between OSM's AVS Office and its State colleagues has been heretofore very productive and cooperative. OSM believes that State and Federal cooperation on AVS matters has been, overall, a significant success. Accordingly, OSM intends to continue to work closely and cooperatively with State regulatory authorities to resolve issues related to the implementation of AVS and section 510(c) of the Act.

Citizen Participation

Commenters representing environmental groups criticized the proposed rules as not containing sufficient provision for citizen participation. They asserted that citizens should be afforded the opportunity to add ownership and control links to AVS. They further argued that citizens should have appeal rights when the regulatory authority denies their requests to add ownership or control links and that citizens should have rights of intervention when decisions are made to sever links. They also urged that citizens should have explicit rights to request enforcement action with respect to improvidently issued permits, with respect to other provisions of the rules relating to ownership and control, and with respect to the imposition of sanctions.

OSM strongly supports citizen participation and agrees that opportunities for citizen participation need to be addressed in the rules governing ownership and control. OSM further agrees that the proposed rules did not sufficiently address these issues in the September, 1991, proposal. Under the Administrative Procedure Act, however, the agency has a responsibility to propose regulations for public comment, prior to finalizing such regulations. The changes proposed by commenters would represent significant modifications of the September, 1991, proposals.

Thus, OSM does not consider it appropriate to incorporate commenters' proposals into today's final rules without first providing opportunity for comment to the regulated community, the States, and the public generally. While OSM could delay finalization of today's rules to allow for such proposal and for opportunity for comment, OSM does not believe that the public interest would be served by such delay.

Nevertheless, suggestions made by the commenters are worthy of further consideration. Accordingly, at some future date, OSM may present proposals to respond to the concerns expressed by the commenters. Until such proposals are made, however, the interests of concerned citizens should be asserted pursuant to the provisions of 30 CFR 773.13, 842.11, 842.12, 843.21 and other regulations providing for citizen participation, as appropriate. In this respect, if citizens disagree with a decision of OSM finding that an ownership or control link does not exist, citizens can challenge such decision by demanding a Federal inspection of relevant permits affected by such decision in accordance with the current provisions of 30 CFR 842.12. If OSM rejects their demand to conduct an inspection, citizens can seek review of such rejection and the issues related thereto pursuant to 30 CFR 842.15 to the Director or his designee and, if necessary, to OHA in accordance with 43 CFR part 4.

Further, OSM's AVS Office will receive and consider ownership or control information from concerned citizens as part of OSM's ongoing research activities to incorporate ownership or control and violation information into the AVS database. Such information is relevant and will be used by the agency in the making of ownership or control determinations and for inclusion, upon verification by the agency, into AVS. OSM strongly encourages concerned citizens, environmental advocates, and members of the industry to come forward with information relevant to ownership or control matters. It is in everyone's interest for the AVS to contain the most complete, comprehensive, and accurate information possible.

C. Discussion of Final Rules

The following text, which describes the final rules and responds to the specific public comments that OSM received on the proposed rules, is organized by the part and section number of the affected provisions. Grammatical or stylistic changes that do not affect the substance of the final rules are generally not discussed.

1. Part 701—Permanent Regulatory Program

Section 701.5—Definitions. In the proposed rule, OSM deleted the definition of "violation notice" previously contained in the regulations and transferred such definition in expanded form to § 773.5. The final rule is identical to the proposed rule. As described below, the definition of "violation notice" refers to the types of violations of the Act or other laws which will form the basis for a regulatory authority to deny a permit application under the provisions of § 773.15(b).

2. Part 773—Requirements for Permits and Permit Processing

Part 773—The Table of Contents. In the proposed rule, OSM had included an amendment to the Table of Contents to provide for a proposed rule governing procedures for the challenge of ownership or control links prior to entry in AVS. Since OSM has determined not to go forward with that portion of the proposal, that reference is not included in the final Table of Contents adopted today. Also, since OSM has deferred action with respect to the adoption of proposed § 773.27 to a subsequent rulemaking, that reference has also been deleted. The final Table of Contents is adopted as described in Summary of Rules Adopted.

Section 773.5—Definitions. The proposed rule added certain definitions to § 773.5. Such definitions included the terms "Applicant/Violator System or AVS," "Federal violation notice," "Ownership or control link," "State violation notice," and "Violation notice." Such definitions were necessary to an understanding of the proposed comprehensive regulations relating to the implementation of AVS.

Industry commenters objected that the proposed definition of "violation notice" contained in the regulation was too broad. They argued that the proposed definition, insofar as it applies to a "Federal violation notice" should be explicitly limited to violations of environmental laws. Further, they asserted that the definition inappropriately included written communications and demand letters as "violations."

OSM disagrees with the commenters' concern over the need for an explicit limitation for violations of environmental laws in the definition of a "Federal violation notice." Commenters conceded that such a limitation is already contained in the proposed definition of "violation notice." The definition of a Federal violation notice is modified by any limitations contained in the definition of a violation notice. Accordingly, there is no need for an explicit additional limitation to address commenters' concerns. It is already clear that it is

limited to violations of environmental laws. Thus, OSM has adopted the proposed definition of "Federal violation notice" as a final definition without modification.

Further, commenters asserted that the proposed rule inappropriately expanded the definition of violation notice to include various written communications and demand letters. They asserted that a demand letter could somehow preclude a permit applicant from pursuing a good faith appeal and that a person's ability to challenge the debt would depend on whether the agency attempted to collect the debt. In substance, commenters took exception to the prospect of a demand letter being the basis for a permit denial when the demand letter contains notice of a delinquent civil penalty and the applicable statute of limitations has expired precluding further action to collect the debt. They asserted that the proposed rule impermissibly expands the types of violations for which a person could be subject to permit block without affording the person a right of timely challenge.

Again, OSM disagrees with commenters' analysis. First, it must be emphasized that the type of document is less significant than the violation of which it provides notice. The document is merely a vehicle for communicating notice of the substantive violation. The documents listed in the proposed definition merely recount the possible types of documents providing notice and do not substantively expand the universe of violations which would be the basis for permit denial under section 510(c) of the Act and the provisions of 30 CFR 773.15(b). The substantive violation, rather than the type of document, forms the basis for a permit denial under the provisions of section 510(c) of the Act and 30 CFR 773.15(b)(1). Pursuant to those provisions, a regulatory authority is required to refuse permit issuance where available information indicates that any surface coal mining operation owned or controlled by an applicant is currently in violation of the Act or other indicated laws. Delinquent fees or penalties which have ripened to the level for which a demand letter is indicated constitute available information for which an applicant will be held accountable and which a regulatory authority must take into account in any permit decision. Contrary to commenters' assertions, the filing of a suit to collect delinquent reclamation fees or civil penalties is not a condition precedent to such debts being valid violations or a condition precedent to such debts being considered the bases for permit denial.

With respect to the commenters' concerns about rights of challenge incident to demand letters, OSM believes that current quality control procedures will prevent the entry of unripe violations into the system. Furthermore, with this final rule and with OHA's rule which is being contemporaneously published, OSM and OHA have acted to provide a means for applicants to obtain temporary relief from permit blocks where they are likely to prevail on the merits. Thus, if a violation has not actually ripened into the basis for a permit block, temporary relief could be sought. The discussion of these provisions of the final rule are contained at the discussion of 30 CFR 773.25 below in this preamble.

Industry commenters also objected to the prospect that a demand letter or other notice could contain notice of a delinquent civil penalty the collection of which is barred by the applicable statute of limitations. In substance, they argued that such a notice should not be the basis for a permit denial. OSM disagrees. In 1988, OSM addressed similar concerns expressed by commenters with respect to the ownership and control rules. OSM stated, in relevant part, as follows:

Effect of Statute of Limitations on Collection Actions

A commenter asserted that permit blocking cannot occur for any civil penalty which has not been reduced to judgment within the applicable statute of limitations in 28 U.S.C. 2462 (barring an action, suit or proceeding for enforcement of any civil fine, penalty unless commenced within five years).

OSMRE disagree[s] with the commenter's position. Although the statute of limitations may provide a defense to suit for collection of money filed five years following the entry of a final order, it does not invalidate the final order or cancel the underlying debt, which will continue to be listed in the Applicant Violator System and will result in blocking the issuance of a permit.

See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38884 (October 3, 1988). The agency considers this position to be sound and has no intention of changing course. Accordingly, this criticism of the proposed definition is rejected.

A number of commenters representing industry interests asserted that the definition of violation contained in the rule was overbroad in that it potentially included violations of laws other than SMCRA as the basis for permit denial. These commenters proposed that the rule incorporate explicit limitations to the effect that only violations relevant to SMCRA or consistent with the environmental protection standards of SMCRA be the basis for permit denial.

OSM rejects the commenters' proposals as unnecessary. To the extent that the final definition of "violation notice" describes the type of violation for which the listed types of notice will be provided, the final rule is intended to track the language of section 510(c) of the Act. That provision of the Act states that the basis for permit denial includes violations of the Act "and any law, rule or regulation of the United States, or of any department or agency in the United States pertaining to air or water environmental protection *incurred by the applicant in connection with any surface coal mining operation * * *" (Emphasis added.)*

Commenters' concerns are already addressed by the Act and the proposed and final definitions of "violation notice" which incorporate the above-emphasized language of the Act. This language requires that violations which support permit denial must be those pertaining to air or water environmental protection *incurred in connection with any surface coal mining operation.* Any air or water environmental protection violations incurred in connection with a surface coal mining operation would be of a type "relevant to SMCRA." If the violations are committed not in connection with a surface coal mining operation, they would not be a basis for the denial of a permit under section 510(c) of the Act. Thus, OSM does not believe that a change in the proposed rule language to reflect commenters' concern is needed.

A commenter representing certain State regulatory authorities also criticized the proposed definition of "violation notice" as being too broad and was concerned that such definition, when read with the provisions of 30 CFR 778.14(c), would lead to "nationwide gridlock" or undue delay in State regulatory authorities' processing of permit applications.

The proposed definition of "violation notice" is designed to incorporate the full range of violations which would form the basis for permit denial under section 510(c) of SMCRA. The definition is intended to implement the statutory definition, not expand such definition. A more limited definition would be an impermissible constraint upon the broad language of the Act. Accordingly, OSM rejects the view that the proposed definition is overbroad.

OSM further disagrees with commenter's view that applicants' reporting of such violation notices in accordance with the provisions of 30

CFR 778.14(c) will lead to undue delay in the processing of permit applications. Applicants must supply complete information with respect to outstanding violations to enable regulatory authorities to make informed decisions as to permit issuance as mandated by section 510(c) of the Act and 30 CFR 773.15(b)(1). The reporting of such information by an applicant may, indeed, lead to permit denial. That, however, constitutes with the mandates of the Act, not inappropriate delay or stalemate. OSM is confident that OSM and Sate regulatory authorities can evaluate and use the information provided by applicants with respect to outstanding violations in accordance with the definitions of "violation" and "violation notice" along with information contained in AVS to meet the requirements of the Act in a timely fashion.

The same commenter additionally urged that OSM retain the limited definition of "violation notice" previously contained in 30 CFR 701.5 because such definition is more "realistic" in its scope and because there is a need for such a definition across OSM's regulations, not just those contained in 30 CFR part 773.

Again, OSM disagrees with commenter's views. The definition of "violation notice" previously contained in the regulations did not identify the types of violations of the Act or other laws which would form the basis for a regulatory authority to deny a permit under 30 CFR 773.15(b)(1). A fuller definition of the term which would encompass these types of violations as mandated by section 510(c) of the Act was necessary for incorporation by reference into a proposed amended version of 30 CFR 773.15(b)(1). While commenter has asserted that there is a need for a general definition of the term "violation notice" across OSM's regulations, commenter has identified no urgent need for a universal definition of the term that would outweigh the need to clarify the provisions of 30 CFR part 773. Further, in the event that it becomes apparent that the implementation of other regulations have been somehow significantly compromised by the deletion of the general definition of "violation notice" contained in 30 CFR 701.5, OSM can address these issues as necessary. Accordingly, OSM must reject the commenter's position.

Further, a commenter urged that any violations be in a final, unappealable posture before they can be the basis for permit denial. OSM disagrees with the commenter's characterization of the current state of the law and with what the commenter believes ought to prevail.

First, Federal regulations which predate the proposed rules and today's final rules already provide that permits may be conditionally issued based upon a good faith, direct administrative or judicial appeal testing the validity of the underlying violation. See 30 CFR 773.15(b)(1)(ii)–(b)(2). Thus, contrary to commenter's implication, permits are not necessarily denied while violations are under appeal. The burden, however, is on a violator to assert appeal rights in good faith and in a timely manner. There is no legitimate reason to afford additional appeal rights to people who have squandered their opportunity to appeal. In the absence of a timely appeal, a violation should be the basis for denial of a permit, in accordance with the provisions of section 510(c). In this preamble under the topic captioned "Due Process," OSM has responded in detail to commenters who have asserted that permits should be conditioned upon the appeals of ownership or control links or upon the appeals of the existence of the violation asserted by owners or controllers of violations after standard appeal times for the violations have run. As stated in this preamble, OSM rejects these assertions.

To the extent that the commenter implied that permits should be issued unconditionally during the pendency of an appeal of a violation, OSM also rejects this proposal. Under this proposal, a violator could commit a violation at his or her surface coal mining operation; take a timely appeal; and then be approved unconditionally for permit issuance at another site. Following the failure of his or her appeal, he or she could continue to mine on the new site with no interruption or termination of his or her rights on the new site. This course of events violates the provisions of section 510(c) of the Act which mandate that regulatory authorities deny permits when applicants have current violations of the Act or other laws. Also, the commenter's proposal is inconsistent with the provisions of 30 CFR 773.15(b)(1)(ii)–(b)(2) cited above which allow only conditional issuance, rather than unconditional issuance, for permits issued to applicants who have appealed outstanding violations

In that final rule, OSM has adopted the definitions of "Federal violation notice" and "violation notice" as proposed and without any of the changes requested by commenters.

In the proposed rule, the definition of "ownership or control link" included references to ownership or control "under paragraph (b)" of 30 CFR 773.5. Since the publication date of that proposal, OSM has proposed changes in the definitions of "owned or controlled" or "owns or controls" contained at 30 CFR 773.5. See Proposed Rule, Definitions and Procedures for Transfer, Assignment and Sale of Permit Rights; Definition of Ownership and Control, 58 FR 34652 *et seq.* (June 28, 1993). If some of those proposed changes are ultimately adopted, the reference to ownership or control as defined by "paragraph (b)" contained in the proposed definition of "ownership or control link" would be inappropriate.

Accordingly, to assure flexibility, OSM has deleted the reference to "paragraph (b)" of 30 CFR 773.5 from the final definition of "ownership or control link."

Also, the proposed definition of "ownership or control link" indicated that a link included presumptive ownership or control relationships which had not "been successfully rebutted under the provisions of §§ 773.24 and 773.26 or §§ 773.25 and 773.26 or under the provisions of part 775 of this chapter and § 773.26 of this part." As is discussed below in this preamble, OSM has deleted proposed section 773.25, procedures for challenging ownership or control links prior to entry in AVS and has renumbered proposed § 773.26 as final § 773.25, standards for challenging ownership or control links and the status of violations. The final definition of "ownership or control link" has been amended to reflect these changes.

The final rules are adopted containing the provisions described in this preamble above at *Summary of Rules Adopted.*

Section 773.10—Information Collection. The proposed rule would have revised § 773.10 which contained a list of the existing information collection requirements in part 773 and also the OMB clearance number indicating OMB approval of the information collection requirements. The proposed rule revision would have updated § 773.10 by including the proposed AVS-related rules containing information collection requirements. The proposed revision provided an estimate of the average public reporting burden per response of three hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The proposed section also listed the addresses for OSM and the Office of Management and Budget (OMB) where comments on the information collection requirements may be sent.

Industry commenters asserted that the estimate of three hours to prepare an average response for the collection of information required was unrealistically low.

OSM disagrees with commenters' assertion. The three hours estimated burden was an estimated average, rather than a predicted figure for the burden of a single, typical response. The calculation of an "average" response means that there are some responses which may require larger amounts of time to prepare and that there are also some responses which may require significantly lesser amounts of time. It is entirely reasonable to expect that the reporting and information collection burden of these regulations may vary among entities depending upon the entities' size and structural complexity.

Further, once companies have researched and compiled their particular ownership or control information, they have done the basic research which can be used for future compliance. This basic ownership or control research will then be readily available to the company and the company only needs to update such research to reflect changes in ownership or control for future applications. Once entities and regulatory authorities develop experience in complying with the regulations, they will also develop experience in collecting, storing, retrieving, and reporting the necessary compliance information. A number of large companies have told OSM that they have already collected and stored their ownership or control information in a computerized database or are in the process of doing so. Once such information has been so stored, it would be readily accessible and easily retrieved for compliance purposes. Thus, the amount of time required to prepare a typical response under these regulations should diminish over time.

Nevertheless, in the final rule adopted today, OSM has recalculated the estimated time for compliance in accordance with standard procedures required by the OMB. OSM has concluded that the public reporting burden for the collection of information required by part 773 as amended by these final regulations is four and one half hours per response, rather than three hours. The final rule also has been modified to delete specific references to the particular sections of part 773 which are relevant for information collection purposes. Instead, OSM has provided a reference to the collection of information required by 30 CFR part 773, since this part encompasses all sections of part 773, including the final rules adopted today, which generate an information collection obligation.

Section 773.15—Review of permit applications. In the proposed rule. OSM proposed to amend 30 CFR 773.15(b)(1) to refer to relevant amended definitions and AVS-related rules as the basis for a regulatory authority's analysis when reviewing a permit application.

The proposed regulation required the regulatory authority to review all reasonably available information concerning violation notices and ownership or control links involving the applicant.

Such information would include that obtained pursuant to § 773.22 (verification of ownership or control application information); § 773.23 (review of ownership or control and violation information); amended § 778.13 (identification of interests); and amended § 778.14 (violation information).

While those regulations will be discussed in detail later in this preamble, the net effect of referencing such provisions in § 773.15(b)(1) was to assure that the regulatory authority makes a decision with respect to permit issuance or denial based upon complete information relating to ownership, control, and violations. Such compete information includes the mandated use of AVS.

The proposed rule would have further added a paragraph (b)(4) to 30 CFR 773.15. This provision would have provided that delinquent civil penalties for violations cited prior to October 3, 1988, not form the basis for a permit block against persons linked through ownership or control to such violations, where reclamation had been completed in accordance with the provisions of the applicable regulatory program and where, with respect to each cessation order for which a delinquent civil penalty exists, such persons had paid $750 of the amount of such penalty to the regulatory authority which issued such cessation order. In substance, this regulation proposed a "safe harbor" with respect to owners or controllers of delinquent civil penalties cited prior to October 3, 1988.

In addition, the proposed amendments to 30 CFR 773.15(b)(1) would also have deleted the presumption contained in the then current version of that rule that allows a regulatory authority, in evaluating whether a surface coal mining operation owned or controlled by a permit applicant is currently in violation of the law, to presume, in the absence of a failure to abate cessation order (FTACO), that a notice of violation (NOV) has been or is being corrected, except where evidence to the contrary is set forth in the permit application, or where the notice of violation is issued for non-payment of abandoned mine reclamation fees or civil penalties.

Further, the proposed amendment to 30 CFR 773.15(b)(1) would have incorporated by reference the amended definition of "violation notice" and the proposed definition of "ownership or control link" contained in proposed § 773.5 by requiring a regulatory authority to review "all reasonably available information concerning violation notices and ownership or control links involving the applicant." This proposed change would have eliminated the need for the detailed list contained in 30 CFR 773.15(b)(1) of the types of violation information which a regulatory authority must review as part of the application review process provided by 30 CFR 773.15(b)(1).

The two issues which generated the most significant comments were the proposed deletion of the presumption of NOV abatement and the proposed safe harbor for owners or controllers of surface coal mining operations with delinquent civil penalties for violations issued prior to October 3, 1988.

The first of these issues to be addressed is the proposed deletion of the presumption of NOV abatement. Commenters representing a number of State regulatory authorities strongly objected to the deletion of the presumption. They asserted that the elimination of the presumption would lead to "nationwide gridlock." They asserted that such a rule provision would lead to automatic appeals of all NOV's; that State regulatory authorities would have to expend significant resources tracking the course of NOV's and NOV appeals; that companies operating before multiple State regulatory authorities would never be able to definitively prove that NOV's were being abated such that they could be issued permits; and that such efforts would be a significant waste of State and Federal resources. They asserted that 80%–85% of all NOV's are resolved and never ripen into CO's in any event.

Also, commenters representing industry interests strongly criticized the proposed deletion of the NOV presumption as both impractical and counterproductive. They asserted that the proposed deletion of the presumption would be especially burdensome on large multi-state corporations. They questioned whether such entities would be able to keep track of the abatement status of the NOV's of their many operating subsidiaries and contract miners. They further asserted that most NOV's are

routinely and timely abated. They argued that eliminating the NOV presumption would lead to information overload in the permit application process; to increased costs and delays in permit processing; and to increased errors in data collection. They argued that the deletion of the presumption would require the reallocation of personnel from enforcement to document processing.

In contrast to the positions of State regulatory authorities and the industry, one commenter representing environmental advocacy groups supported the deletion of the NOV presumption, asserting that the deletion of the presumption would lead to better tracking of the status of violations and to faster remediation of violations. Another commenter did concede, however, that it would be difficult for the OSM to keep AVS accurate and current with respect to violation information if the presumption of NOV abatement in the absence of an FTACO was eliminated.

OSM considers the arguments raised by the State regulatory authorities and by the industry to be persuasive. OSM must give particular consideration to the concerns expressed by the State regulatory authorities on this issue. These agencies have the responsibility of implementing the ownership and control process. If the State regulatory authorities believe that the complete elimination of the presumption of NOV abatement will impose a significantly increased burden upon them for limited environmental return, this position cannot be discounted. OSM recognizes that there may be a potential benefit in having multiple jurisdictions tracking the course of NOV's for purposes of permit issuance. Such multiple supervision could theoretically encourage prompt abatement. Nevertheless, the mechanics of implementing such a process through AVS and other means would be sufficiently complex so as to create significant uncertainty among permit applicants and regulatory authorities. Such uncertainty outweighs the benefits of the complete elimination of the presumption of NOV abatement.

In response to the environmentalists' arguments, OSM recognizes that there is a theoretical, potential benefit in multiple regulatory authorities tracking the course of an NOV for purposes of permit issuance. Under this scenario, a State would deny a permit to an applicant based upon his or her being linked through ownership or control to an NOV in another State even though the abatement period for the NOV had not expired. The threat of permit denial could enhance the prospect for prompt abatement of that NOV.

Nevertheless, the mechanics of implementing this process with respect to AVS would be complex and would create such uncertainty as to outweigh the benefits. Assuming that NOV's whose abatement period had not yet expired and which had not yet generated FTACO's were loaded onto AVS, OSM would have to check the status of such NOV's and continually update such information on AVS. It is unclear whether OSM would be able to keep up with the changing status of NOV's and incorporate such information in a timely manner into AVS. This would add an additional element of uncertainty with respect to the currency of violation information in AVS. OSM believes it is more desirable to have information in AVS which is both current and reliable, so that State regulatory authorities may depend on the system during the permit application review process.

Further, OSM believes that the decision to retain at least a limited presumption of NOV abatement is consistent with positions taken by the Department of the Interior in previous litigation. In litigation relating to § 773.15(b)(1) and related matters before the U.S. District Court of the District of Columbia, the Secretary advised the court that he had decided to reconsider the issue of whether, in the absence of an FTACO, the regulatory authority may presume that an NOV has been or is being corrected. The Secretary further advised the court that he would, if appropriate, engage in further rulemaking on the subject as expeditiously as possible. See *National Wildlife Fed'n* v. *Lujan*, No. 88–3117–AER (D.D.C.), Memorandum of Points and Authorities in Support of the Federal Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment, at pages 89–90.

As indicated in the preamble to the proposed rule, the proposed amendment to delete the presumption of NOV abatement represented the "further rulemaking" of which the court was advised. However, the Secretary committed only to reconsider the presumption of NOV abatement. The Secretary never committed to finalize any proposed rule. After receiving the States' and industry's comments cited above, OSM has determined that the complete deletion of the presumption would impose a significant burden upon the States and provide little enforcement benefit.

As indicated in the preamble to the September, 1991 proposed rule, it was, in fact, never OSM's intention to load NOV's (other than delinquent NOV civil penalties) into the AVS database, given the large volume of data entry that would be required to keep such violation information up to date. *Id.* Thus, even if OSM had completely deleted the presumption of NOV abatement by adopting the proposed modification to 30 CFR 773.15(b)(1), there would have been no immediate, direct impact upon the AVS database. If OSM had eliminated the presumption, there would have been, however, a significant indirect impact upon AVS. The States would have been required to spend scarce resources tracking other States' NOV's, including those whose abatement periods had not yet expired, for permit application purposes. The States would have had fewer resources available to focus upon the other information that AVS believes is more critical to the effective implementation of section 510(c) of the Act, including the development of complete information with respect to entities' ownership and control. Further, OSM is committed to making its best effort to provide, through the AVS, a complete list of violations which are required to be used as the basis for a permit block.

Accordingly, OSM has determined to retain a presumption of NOV abatement in 30 CFR 773.15(b)(1). The focus of State regulatory authorities' concern appears to be the uncertainty incident to NOV's with abatement periods which have not yet expired. In substance, where an NOV has been issued and the abatement period has not yet expired, it is uncertain whether the violation will be ultimately abated or will ripen into the basis for the issuance of a failure to abate cessation order. The State regulatory authorities and the coal industry argue that such uncertainty justifies unconditional permit issuance. The environmentalists argue that such uncertainty demands permit denial. While OSM recognizes the needs of the State regulatory authorities, OSM believes that environmental advocates have also asserted legitimate concerns about the consequences of a blanket presumption of abatement for all NOV's. OSM has therefore chosen a middle ground which will serve to reduce the uncertainty while balancing the concerns of the various interests.

In response to the comments made to its proposal, OSM has amended 30 CFR 773.15(b)(1) to provide that, in the absence of a failure-to-abate cessation order, a regulatory authority may presume that a notice of violation is being corrected to the satisfaction of the agency with jurisdiction over the violation where the abatement period

for such notice of violation has not yet expired and where the permit applicant has provided certification in his or her permit application that such violation is in the process of being corrected to the satisfaction of the agency with jurisdiction over the violation. Where OSM is regulatory authority, OSM will incorporate such certification into the statement of verification currently required in OSM's permit applications. Any permits issued incident to such certification will be conditionally issued based upon successful completion of the necessary abatement.

The above approach balances the concerns of the commenters. A blanket presumption of abatement for all NOV's—including those whose abatement period has expired—is inappropriate. It is entirely possible that there are NOV's with expired abatement periods for which cessation orders have not yet been written. To presume that such NOV's are abated is unjustified. At the same time, today's final rule recognizes that, until the abatement period has expired, diligent operators should have the opportunity to correct their NOV's in a timely manner without being subjected to permit denial during the period of abatement if they certify that such violations are in the process of abatement. State regulatory authorities can conserve limited resources by having the benefit of a reasonable presumption of NOV abatement which applies to those NOV's which are in a true state of uncertainty with respect to abatement. In considering whether a particular NOV should be the basis for permit denial, State regulatory authorities will also have the comfort of certification by the applicant and the protection of conditional issuance to assure that any representations made with respect to NOV abatement are actually fulfilled.

OSM recognizes that some large companies may not be aware of all NOV's whose abatement periods have not expired where such NOV's are cited against one or more of their many subsidiaries. Nevertheless, OSM expects that companies will make a good faith effort to track their NOV's and report such NOV's as part of permit applications. Where a company has developed a good faith NOV tracking procedure and, in the diligent exercise of such procedure, has inadvertently failed to report an NOV whose abatement period has not yet expired, such failure would not constitute willful nondisclosure by the company. On the other hand, where a company fails to set up a tracking procedure or where a company sets up a tracking procedure or corporate structure designed or intended to shield it from knowledge of NOV's or the ability to track NOV's this will not excuse a company's failure to accurately report NOV's in permit applications. Further, OSM expects that any certifications of ongoing correction provided with respect to NOV's be based upon truthful information and be submitted in good faith. To the extent that a company asserts that it cannot certify because it is not certain whether all violations have been identified, the presumption of NOV abatement would not apply. OSM recognizes that companies may assert this argument, but OSM considers the certification necessary to assure that violations are in the process of being corrected.

As indicated above, the second issue in the proposed rule which generated significant comments was the proposed safe harbor for the owners or controllers of delinquent civil penalties for violations issued prior to October 3, 1988.

Commenters from the coal industry and the States criticized the safe harbor proposal because it required, as a condition precedent for safe harbor treatment, that reclamation be completed within 120 days after the effective date of the rule. These commenters asserted that this proposed condition limiting the availability of safe harbor protection was inadequate and insufficiently flexible. They argued that the proposal did not take into account the time required to perform reclamation and the potential for reclamation to be effected by changing events and environmental conditions.

Moreover, commenters representing the environmental community also criticized the safe harbor provision. These commenters criticized the proposed $750 settlement amount as arbitrarily and artificially low. Commenters representing the State regulatory authorities asserted that the proposed penalty amount provided insufficient flexibility and that a State regulatory authority should be able to demand a greater penalty if the circumstances warrant.

While the industry and the States focused upon the limited window of time available to perform abatement and the environmentalists and the States questioned the limited penalty amount, all of these commenters seemed to share the view, subject to their particular and differing perspectives, that the proposed safe harbor provision was artificial and unnecessarily rigid.

Upon consideration of the comments, OSM agrees that the proposal was unnecessarily rigid and has, therefore, not finalized the safe harbor proposal. Accordingly, regulatory authorities will have the discretion to review the totality of the facts on a case by case basis to determine whether a person who is linked, through ownership or control, to delinquent civil penalties may avoid permit block through payment of a portion of such penalties. OSM will review the adequacy of such settlements within the context of OSM's routine oversight of the State regulatory authorities under 30 CFR parts 732 and 733 and of case specific complaints and investigations under 30 CFR part 842.

Whether a settlement is adequate will be a function of the entire context of a particular case. Factors to be considered include, but are not limited to, whether the settling owner or controller has performed required reclamation to abate the violations other than the delinquent civil penalties in a timely manner. The regulatory authority should also consider the degree to which the facts indicate that the owner or controller had the authority to exercise control of the violator. If the owner or controller had such authority, whether it chose to exercise such authority or not, it is less credible for the owner or controller to argue that it was unaware of the activities and violations such that a significant discount in civil penalty amount is warranted for the owner or controller. In substance, with such authority, the owner or controller would have had the ability to be informed of violations in a timely manner if he or she had wanted to be so informed. The regulatory authority should also consider the size and solvency of the owner or controller and the impact that the payment of a reduced amount of the civil penalty will have upon the activities of that company and other companies similarly situated. Further, the regulatory authority should consider the impact of the settlement upon the integrity of the regulatory authority's enforcement program. In other words, will the proposed settlement encourage companies to conclude that there is an economic benefit in ignoring the civil penalties and violations of their owned or controlled entities until such companies are required to settle by regulatory authorities?

In accordance with the above discussion, OSM has not adopted the provisions of the proposed rule which would have deleted the presumption that NOV abatement currently contained in 30 CFR 773.15(b)(1) and which would have created a safe harbor for owners or controllers with respect to delinquent civil penalties for violations cited prior to October 3, 1988. In paragraph (b)(1) of the final rule, OSM has inserted language providing for a presumption of NOV abatement for

NOV's whose abatement periods have not yet expired where the permit applicants have certified that such NOV's are in the process of being corrected to the satisfaction of the agency with jurisdiction over the violation. In the final rule, OSM has also deleted the language contained in the proposed rule which would have provided the safe harbor for certain owners or controllers. OSM has otherwise adopted the provisions of the proposed rule as the final rule.

Section 773.20—Improvidently Issued Permits: General Procedures. In the proposed rule, OSM proposed to amend paragraph (b)(1)(ii) of 30 CFR 773.20 to delete the reference to the presumption of NOV abatement contained in 30 CFR 773.15(b)(1). See Proposed Rule, Use of the Applicant/Violator Computer System in Surface Coal Mining and Reclamation Permit Approval, 56 FR 45780, 45784–45785 (September 6, 1991). The basis for such deletion was to assure consistency with the provisions of 30 CFR 773.15(b)(1) which were to be similarly amended.

In the final rule, OSM has reinserted language which addresses the situation which occurs when a permit is issued in reliance upon the presumption that an NOV is being abated in the absence of a cessation order and a cessation order is, in fact, issued with respect to the violation. In such an event, a regulatory authority is required to find that the permit has been improvidently issued. The September, 1991, proposed rule deleted this language to assure consistency with OSM's proposal to delete the presumption of NOV abatement from the permit review process of 30 CFR 773.15(b). As described in this preamble in the discussion relating to 30 CFR 773.15(b), OSM has decided to include a presumption of NOV abatement for that regulation. To assure consistency between the treatment of improvidently issued permits and permit applications, OSM has reinserted language which addresses the presumption of NOV abatement into 30 CFR 773.20(b)(1)(i)(B). The agency's reasons for retaining a presumption of NOV abatement are described fully in the preamble discussion with respect to 30 CFR 773.15(b)(1).

In the proposed rule, OSM also proposed to renumber certain provisions of the then current 30 CFR 773.20 such that paragraph (b)(2) would become (b)(1)(ii), paragraph (b)(2)(i) would become (b)(1)(ii)(A), paragraph (b)(2)(ii) would become (b)(1)(ii)(B), and paragraph (b)(3) would become (b)(1)(iii). In the final rule, such renumbering is also adopted.

OSM also proposed to amend the then current 30 CFR 773.20 by inserting a new paragraph (b)(2), which would have made the provisions of proposed § 773.26, standards for challenging ownership or control links and the status of violations, applicable when a regulatory authority makes determinations with respect to improvidently issued permits. Proposed § 773.26 would have been applicable when a regulatory authority determines whether a violation, penalty, or fee remains unabated or delinquent, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, and whether any ownership or control link between the permittee and the person responsible for the violation, penalty, or fee existed, still exists, or has been severed.

The proposed insertion of the language referring to § 773.26 would have had the effect of assuring that the standards, responsibilities, and procedures created by proposed § 773.26 were consistently applied to permit issuance and to determinations regarding improvident permit issuance. OSM took such an approach in the belief that this would enhance the fairness of the permitting process and the prospect for the uniform enforcement of nationwide minimum standards.

In the final rule, this approach is adopted. The reference to § 773.26 is changed, however, to § 773.25 to reflect the renumbering of that section. Also, as has been indicated previously, OSM has inserted language in paragraph (b)(2) of final § 773.20 to clarify that a challenge as to the existence of a violation at the time it was cited may be made within the context of the improvident permit issuance process.

OSM further proposed to renumber provisions of the regulation at 30 CFR 773.20(c), which relate to remedial measures for improvidently issued permits, so that then current paragraph (c) would become (c)(1), then current paragraph (c)(1) would become (c)(1)(i), then current paragraph (c)(2) would become (c)(1)(ii), then current paragraph (c)(3) would become (c)(1)(iii), and then current paragraph (c)(4) would become (c)(1)(iv). In the final rule, such renumbering is adopted.

Further, proposed renumbered paragraph (c)(1)(iv), which would authorize the regulatory authority to use rescission as one of the remedial measures for improvident permit issuance, would have deleted a specific reference contained in the former 30 CFR 773.20(c)(4) to the rescission procedures of 30 CFR 773.21.

The reason for such proposed deletion was that OSM sought to establish a prior notice and common appeal procedure for both permit suspensions and permit rescissions with respect to improvidently issued permits. The then current regulation governing permit suspensions at 30 CFR 773.20(c)(3) did not impose any specific requirements for prior notice, opportunity to be heard, or right of appeal for the permittee whose permit is to be suspended. See 54 FR 18450 (1989). In contrast to this, then current regulations governing permit rescissions at 30 CFR 773.21 contained specific requirements for prior notice to a permittee and an explicit right of appeal. Accordingly, through its proposed rule, OSM sought to provide for greater consistency in its procedures governing suspension and rescission of permits. In the final rule, the proposed change has been adopted.

OSM further proposed to amend 30 CFR 773.20 to add a new paragraph (c)(2) which would have required that a regulatory authority which decides to suspend a permit must provide at least 30 days' prior written notice to the permittee. The proposed rule would have provided that, in the event that the regulatory authority decides to rescind a permit, it would provide notice in accordance with the provisions of 30 CFR 773.21. The proposed amendment further provided that a permittee would be given the opportunity to request administrative review of the notice under proposed OHA rules 43 CFR 4.1370 *et seq.*, where OSM is the regulatory authority, or under the State program equivalent, where the State is the regulatory authority. In the absence of such temporary relief, the regulatory authority's decision would have remained in effect during the pendency of appeal.

OSM's proposed rule amendments made no change in the requirement contained at 30 CFR 773.20(b) that a regulatory authority analyze a potentially improvidently issued permit "[U]nder the violations review criteria of the regulatory program at the time that the permit was issued."

A commenter representing one of the State regulatory authorities criticized the provisions of the proposed rule which would have required that the regulatory authority provide thirty days' written notice to the permittee, if the regulatory authority decides to suspend the permit. This commenter asserted that there may be circumstances which require the immediate suspension and, possibly, outright rescission of a permit. This commenter asserted that delay, in the interests of due process rights, may not serve the public interest.

OSM appreciates the commenter's concerns. It is entirely conceivable that a permittee could have been issued a permit even though the permittee was linked, through ownership or control, to a string of unabated violations at the time of permit issuance. The permittee could have willfully and fraudulently concealed such links through some clever scheme or artifice at the time of permit application. While AVS has reduced the potential for such a scenario to occur, it remains possible. Such a permit ought to be subject to immediate suspension.

Nevertheless, OSM must weigh the public interest in preventing violators from keeping permits against the public interest in assuring that permittees' due process rights are protected. The remedies of permit suspension and rescission are serious. Unlike an applicant who merely has an expectancy in his application to receive a permit to mine, a permittee has, in fact and as a matter of law, assumed the rights and responsibilities incident to the permit to engage in surface coal mining operations. Indeed, OSM's regulations provide that a valid permit carries with it the right of successive renewal. See 30 CFR 774.15(a). Thus, a permittee has an interest which is deserving of a higher level of protection than the interest of an applicant.

Further, the provisions of 30 CFR 773.21 previously provided for notice to the permittee only prior to a proposed permit suspension and rescission. Thus, a permittee got prior notice of a suspension only if the suspension was the precursor to a subsequent rescission. If the regulatory authority did not intend the suspension of a permit to be followed by the permit's rescission, there was no requirement for prior notice. Also, the provisions of 30 CFR 773.21 provided appeal rights for a notice of suspension and rescission. There were no similar appeal rights in 30 CFR 773.20 with respect to suspension. In substance, permit suspension had the potential of being a harsher punishment than permit rescission by reason of these procedural differences. These were anomalies that OSM wanted to correct.

Accordingly, the final version of 30 CFR 773.20(c)(2) provides for notice prior to permit suspension; for administrative review of the notice of suspension under 43 CFR 4.1370 et seq. or under the State program equivalent; for a common appeal procedure for both permit suspensions and permit rescissions with respect to improvidently issued permits and for the regulatory authority's decision to remain in effect during the pendency of an appeal, unless temporary relief has been granted in accordance with 43 CFR 4.1376 or the State program equivalent. States can be more stringent with respect to providing less prior notice, but they are responsible for the legal consequences of such actions.

Industry commenters objected to OSM's assertion of any role in revoking or setting aside improvidently issued permits based upon the totality of their objections to the AVS, the ownership and control rules, and the proposed rules. These reasons included the proposed rules' alleged deficiencies with respect to due process, State primacy, dispersion of authority for permit decisionmaking, and all other objections asserted by industry commenters.

OSM disagrees with the commenters' views, including their view that OSM has no legitimate role in the improvidently issued permit process. OSM has an essential role to play, both as a regulatory authority and as an agency of the Federal government overseeing the States' programs. OSM incorporates by reference its previous responses to industry commenters in this preamble which address the commenters' concerns. Further, in the preamble to the rules governing improvidently issued permits, OSM has explained the legal basis for the improvidently issued permit rules and the rationale for OSM's role with respect to the implementation of such rules in relation to the States. See Preamble to 30 CFR 773.20, 773.21, and 843.21; Final Rule, 54 FR 18438 *et seq.*, especially see pages 18458–18461 (April 28, 1989). OSM also incorporates these explanations by reference.

Environmentalist commenters criticized the portions of 30 CFR 773.20 which provide that the test for evaluating whether a permit was improvidently issued is "the violations review criteria of the regulatory program at the time the permit was issued." See 30 CFR 773.20(b). These commenters asserted that OSM should clearly spell out the violations review criteria, rather than rely upon the individual regulatory programs' criteria at the time of permit issuance as the applicable standards. These commenters criticized the provisions of OSM's regulations as being contrary to the Act and cited in support portions of their brief filed in the case of *National Wildlife Federation* v. *Lujan*, No. 88–3117 (D.D.C.).

OSM disagrees with the commenters' position. As indicated above, OSM's proposed rule did not propose substantive changes to this provision of the regulation. In the preamble to the improvidently issued permit rules cited above, OSM explained its rationale for using the violations review criteria of the regulatory program at the time the permit was issued as the standard for improvident issuance. See Preamble to 30 CFR 773.20, 773.21, and 843.21; Final Rule, 54 FR 18438, 18440–18441 (April 28, 1989).

Further, in the case of *National Wildlife Federation* v. *Lujan*, No. 88–3117 (D.D.C.), and *Save Our Cumberland Mountains, Inc.* v. *Lujan*, No. 81–2134 (D.D.C.), environmental advocates advanced similar arguments with respect to the agency's improvidently issued permit rules and the provisions of the rules applying the violations review criteria of the regulatory program at the time of permit issuance. In the briefs submitted by the Department of the Interior in those cases, the Department analyzed relevant statutory language and legislative history and carefully explained why the environmental advocates' criticisms were not well taken. Copies of these briefs are being placed in the Administrative Record of this rulemaking. OSM incorporates the arguments advanced by the Department in those briefs herein by reference.

Environmental commenters also criticized other portions of 30 CFR 773.20 for which OSM did not propose any substantive amendments as part of the September, 1991, proposed rules. The commenters asserted that OSM should clarify that the remedial measures available to a regulatory authority to cure an improvidently issued permit require that the regulatory authority impose both an abatement plan and a permit condition incorporating such plan before an improvidently issued permit is considered resolved. They asserted that the provisions of 30 CFR 773.20(c) inappropriately allow the regulatory authority to choose whether to require a permit condition or an abatement plan.

OSM disagrees with the commenters that a rule amendment is needed. The provisions of the regulation require that the regulatory authority "use one or more" of the listed remedial measures including requiring the implementation of an abatement agreement; conditioning the permit upon abatement of outstanding violations within a reasonable period of time; suspension of the permit; or rescission of the permit. This provision affords the regulatory authority the opportunity to exercise discretion, in light of the circumstances, to make a reasoned choice as to the appropriate remedy. In the preamble to the improvidently issued permit rule, OSM stated, in relevant part, as follows:

This section * * * includes four alternative remedial measures because of the diversity of circumstances under which a regulatory authority might find that a permit was improvidently issued, and the resulting need to apply a remedy that not only is administratively appropriate, but also is fair and equitable to the permittee * * *.

OSMRE believes that the term ["improvidently issued"] reflects the severity of the problem involved when a regulatory authority should not have issued a permit, while at the same time not foreclosing reasonable flexibility in the adoption of appropriate remedial measures * * *.

[T]he rule affords the regulatory authority reasonable discretion to consider the circumstances involving a particular improvidently issued permit and to fashion an appropriate remedy * * *.

Although the rule does not require a regulatory authority to use any particular one of the four remedial measures, OSMRE intends that the measure or measures used will be commensurate with the circumstances under which a permit was improvidently issued.

(Emphasis added.) *See* 54 FR 18438, 18447–18448 (April 28, 1989). Certainly, it could be reasonable, depending upon particular circumstances, for a regulatory authority to require both a plan of abatement and a permit condition implementing such plan. The agency has previously rejected the view, however, that there is only one correct option or options from the alternative remedies provided in the improvidently issued permit rule which is or are appropriate for all circumstances. *Id.* The provisions of the regulation afford the regulatory authority the opportunity to tailor a remedy "package" appropriate for the particular circumstances under which a permit was improvidently issued. The goals of any such remedy are "to correct the defect in the permit and achieve a state of compliance." *Id.*, at 18447. If either a permit condition or an abatement agreement could reasonably be expected to accomplish these goals under the circumstances, then either would be sufficient to resolve the improvidently issued permit. In the event that it becomes apparent that selected remedial measures are not effective, each of the remedies affords leverage to the regulatory authority to compel compliance. Such choices are appropriately made by the regulatory authority, subject to OSM's oversight under 30 CFR 843.21. At this time, OSM sees no reason to amend the regulation to routinely require the use of both remedies in all circumstances where abatement of a violation is to be undertaken as a necessary part of the resolution of an improvidently issued permit.

Section 773.21—Improvidently issued permits: Rescission procedures. In the proposed rule, OSM proposed to amend the then current regulation at 30 CFR 773.21(a) to make the provisions of proposed § 773.26, standards for challenging ownership or control links and the status of violations, applicable when a regulatory authority invokes the automatic suspension and rescission procedures of 30 CFR 773.21. The rationale for such amendment is the same as that discussed above with respect to similar language contained in § 773.20. In substance, that was to assure that the standards, responsibilities, and procedures created by proposed § 773.26 were consistently applied to permit issuance and to determinations regarding improvident permit issuance. OSM proposed such an approach in the belief that this would enhance the fairness of the permitting process and the prospect for the uniform enforcement of nationwide minimum standards.

Further, OSM proposed to delete paragraph (c) of then current 30 CFR 773.21 which provided for appeals of rescission notices. Under the proposal, rescission appeal procedures were to be incorporated in 30 CFR 773.20.

One commenter representing a State regulatory authority asserted that the States typically have provisions for the administrative review of a regulatory authority's decision to suspend or rescind a permit. Accordingly, this commenter questioned why OSM's proposed rules needed to include provisions for the appeals of permit rescissions due to improvidently issued permits.

The rationale for providing appeal procedures for permit rescissions incident to improvidently issued permits is essentially the same as the rationale for providing appeal procedures for permit suspensions. In substance, a permittee has, in fact and as a matter of law, assumed the rights and responsibilities incident to the permit to engage in surface coal mining operations. Indeed, OSM's regulation provides that a valid permit carries with it the right of successive renewal. See 30 CFR 774.15(a). Thus, a permittee has an interest which is deserving of protection. Thus, a permittee whose permit has been rescinded is entitled to a review of the decision to rescind.

Prior to the proposed amendment of September, 1991, then current 30 CFR 773.21 provided notice and appeal rights with respect to permit rescission incident to improvidently issued permits. By proposing to amend this rule to achieve a common set of procedural protections for permit suspensions and permit rescissions incident to improvidently issued permits, it was not OSM's intention to reduce the appellate rights previously provided by 30 CFR 773.21 or comparable State provisions. Instead, OSM wanted to assure that procedures of review were available for both permit suspensions and permit rescissions. The absence of such procedures for suspensions was a matter which OSM sought to address.

To the extent that State programs already have adequate appeals and notice procedures with respect to permit rescissions incident to improvidently issued permits, OSM believes that the proposed rules should impose little, if any, additional burden upon such States. Under the Act, OSM's responsibility is to establish minimum national standards which approved State programs are required to meet. Accordingly, individual State programs may exceed OSM's standards. A State which has such provisions may respond to any 732 letters OSM sends as a result of this rule by affirming that the State already interprets its program consistent with this Federal provision.

For the above reasons, the commenter's position is rejected.

OSM has decided to adopt the proposed changes as part of the final rules. In adopting the proposal, OSM has modified the provisions at paragraph (a) of 30 CFR 773.21 to make the provisions of § 773.25, standards for challenging ownership or control links and the status of violation, applicable when a regulatory authority invokes the automatic suspension and rescission procedures of 30 CFR 773.21. The proposed rule contained a reference to § 773.26. This change reflects that proposed § 773.26 has been renumbered as final § 773.25. OSM has made an additional non-substantive change to the introductory paragraph of § 773.21 to reflect that § 773.20(c)(4) has been renumbered to be § 773.20(c)(1)(iv). Further, OSM deletes former paragraph (c) of 30 CFR 773.21 which provides for appeals of rescission notices. As discussed above, rescission appeal procedures are incorporated in 30 CFR 773.20.

Section 773.22—Verification of ownership or control application information. OSM proposed § 773.22 to mandate an inquiry whose focus was to assure that the regulatory authority develops complete and accurate information as to the identification of the applicant and all owners or controllers of the applicant prior to making a determination on a permit

application. Accordingly, the proposed section focused on verification of ownership or control application information. Such accurate and complete information would enable the regulatory authority to make an informed decision as to whether the applicant was linked to a surface coal mining and reclamation operation in violation of the Act or of any other environmental laws within the terms of 30 CFR 773.15(b)(1).

Paragraph (a) of proposed § 773.22 would have imposed a duty upon a regulatory authority to review the information provided in the permit application, pursuant to 30 CFR 778.13(c) and 778.13(d), to determine whether the information provided, including the identification of the operator and all owners and controllers of the operator, was complete and accurate. In making such determination, the regulatory authority would have been required to compare information provided in the application with information contained in manual and automated data sources. Manual sources for review would have included the regulatory authority's own enforcement and inspection records and State corporation commission or tax records, to the extent they contain information concerning ownership or control links. Automated data sources would have included the regulatory authority's own computer systems, if any, and the AVS.

Paragraph (b) of proposed § 773.22 would have provided that, if it appeared from information provided in the application pursuant to paragraphs (c) and (d) of § 778.13 that none of the persons identified in the application had had any previous mining experience, the regulatory authority would have been required to inquire of the applicant whether anyone other than those persons identified in the application would own or control the mining operation as either an operator or as another type of owner or controller.

The proposed rule assumed that, given the complexity of modern coal mining operations, it was likely that most applicants would have at least someone in an ownership or control capacity who had had previous mining experience. If it appeared from the face of an application that that was not the case, the regulatory authority would have been required to contact the applicant to verify that the applicant had not omitted from the application an operator or other owner or controller who had such experience. The intent of this proposal was to ensure that the regulatory authority obtains information on other, experienced persons who may actually be running the operation and should therefore have been disclosed as part of the ownership and control data in a permit application, but were not.

Paragraph (c) of proposed § 773.22 provided that if, after conducting the information review described above, the regulatory authority identified any potential omission, inaccuracy, or inconsistency in the ownership or control information provided in the application, it would be required to contact the applicant prior to making a final determination with respect to the application. The applicant would then be required to resolve the potential omission, inaccuracy, or inconsistency through submission of an amendment to the application or a satisfactory explanation which includes credible information sufficient to demonstrate that no actual omission, inaccuracy, or inconsistency existed. The regulatory authority was also required to take action in accordance with the provisions of proposed § 843.23, sanctions for knowing omissions or inaccuracies in ownership or control and violation information, or the State program equivalent, where appropriate.

Paragraph (d) of proposed § 773.22 would have required that, upon completion of the information review mandated by § 773.22, the regulatory authority promptly enter all ownership or control information into AVS.

Industry commenters objected to the provision of the proposed rule requiring that the regulatory authority compare information provided in the permit application with sources such as State corporation commission or tax records. They asserted that such records are typically updated only on an annual basis and may be obviously inaccurate. They further asserted that requiring the applicant to explain discrepancies between information contained in the application and the State corporation commission or tax records will lead to inappropriate delays in the permit process.

OSM disagrees with the commenters' criticisms of the proposed requirement. The proposed requirement was designed to assure that the regulatory authority reviewing an application has complete ownership and control information. Such information is necessary to enable the regulatory authority to determine whether the application should be issued in accordance with the provisions of section 510(c) of the Act and 30 CFR 773.15(b)(1).

Unfortunately, a regulatory authority cannot simply rely upon all applicants to supply complete ownership or control information. Some applicants may err in good faith, others may conceal information knowingly. Accordingly, the regulatory authority must look to other sources of information. The information contained in the records of State corporation commissions or taxing authorities is a good potential source of ownership or control information. Depending upon particular State requirements, such information may have been submitted under oath. Further, such information is submitted subject to the review of State corporation commissions and State taxing authorities. Thus, a State regulatory authority reviewing such information has the benefit of any efforts made by these other agencies to assure that information submitted to them is accurate and complete.

Moreover, such information is important because it provides a basis for inquiry and for comparison with information submitted in the permit application. If there are discrepancies between the ownership or control information in such records and that submitted in the permit application, the applicant should be able to readily explain such discrepancies. Thus, if any information previously submitted to State taxing authorities or corporation commission has become subsequently outdated, this can be explained with minimal inconvenience to an applicant and minimal delay in the permit application process. On the other hand, if important ownership or control information has been omitted from a permit application, the State taxing and corporation commission records may be the key to identifying such omissions. In any event, the benefits of such information to the regulatory authority outweigh the risks identified by the industry commenters.

A commenter representing State regulatory authorities also asserted that these records rarely provide information not contained in previous permit applications or in AVS. This commenter also indicated that these records are difficult to obtain because tax records are not typically available for review by State agencies other than the taxing authorities.

OSM disagrees with the view that these types of records merely contain information which is duplicative of information already available to the State regulatory authorities through permit applications or AVS. While OSM makes every effort to assure that AVS contains complete and accurate information with respect to ownership or control links, OSM has never asserted that AVS is perfect. Even if AVS were a perfectly complete source of such information, new corporations are being formed and new applications to conduct

surface coal mining operations are submitted. AVS must be regularly updated. It is likely that there is relevant ownership or control information contained in corporation commission and tax records of the various States which is not yet reflected on AVS. Thus, there is a need for State regulatory authorities to review such information and compare such information with permit applications to identify accurate and complete ownership or control information. Such information can then be added to the AVS database.

With respect to commenter's concern about the availability of State tax and corporation commission records, OSM recognizes that particular State laws may limit a State regulatory authority's access to such records. The requirement of the proposed regulation was for the regulatory authority to review "reasonably available sources." Thus, if a State law explicitly forbids the regulatory authority's access to State tax information, the information would not be "reasonably available" for review. In the absence of such explicit prohibition, however, State regulatory authorities should review such information. OSM encourages State regulatory authorities to work with their sister tax and corporation commission agencies to develop information access arrangements to the extent permissible under applicable laws. Nevertheless, OSM rejects the view that the difficulty of obtaining the information justifies withdrawing or amending the proposing regulation.

The commenter representing State regulatory authorities further questioned the requirement contained in paragraph (c)(2) of proposed § 773.22 that "credible information," rather that "credible evidence," support an applicant's satisfactory explanation of omissions, inaccuracies, or inconsistencies with respect to ownership or control information in an application. OSM used the term "credible information," rather than "credible evidence" because this is a broader concept than credible evidence. This term would include credible evidence which would be admissible at trial. Nevertheless, an applicant might be able to provide a satisfactory explanation based upon information which would not necessarily be admissible at trial, but which is a reliable and believable basis to conclude that no actual omission, inaccuracy, or inconsistency exists. Accordingly, the language of the proposed regulation was intended to provide flexibility to the regulatory authority to consider such information, including credible evidence.

OSM has determined to adopt the proposed rule at § 773.22 as a final rule with minor modifications which are now described.

As indicated above, paragraph (b) of the proposed rule would have required that, if it appeared from information provided in the application pursuant to paragraphs (c) and (d) of § 778.13, that none of the persons identified in the application had any previous mining experience, the regulatory authority had to inquire of the applicant whether anyone other than those persons identified in the application would own or control the mining operation as either an operator or as another type of owner or controller. The final rule imposes the duty upon the regulatory authority to both inquire of the applicant and to investigate.

In the proposed rule, there may have been an implication that the regulatory authority could simply conclude its inquiry in reliance upon the applicant's explanation. Such an implication was not intended. Accordingly, OSM has added explicit language to paragraph (b) of final § 773.22 to insure that, if none of the persons identified in the permit application has had any previous mining experience, the regulatory authority will not simply rely upon the applicant's explanations. Instead, the regulatory authority will go forward to investigate whether any persons other than those identified in the application will conduct the mining.

In the final version of § 773.22, OSM has retained language from paragraph (c) of the proposed § 773.22 requiring the regulatory authority to take action in accordance with the provisions of § 843.23 or the State program equivalent. However, OSM has deferred action on the adoption of proposed § 843.23 for a later rulemaking. See 58 FR 34652 *et seq.* (June 28, 1993). The reference to that rule has been left in final § 773.22 in the event that a final version of § 843.23 is adopted. The inclusion of such reference, however, does not prejudge whether OSM will ultimately adopt such a rule.

As indicated above, paragraph (d) of the proposed rule would have required that, upon completion of the information review mandated by § 773.22, the regulatory authority promptly enter all ownership or control information into AVS. OSM has adopted the final version of this paragraph to require that, upon completion of its review, the regulatory authority enter ownership or control information "into" AVS. If such information is already on the system, the regulatory authority is required to "update" such information. Such changes have been made to provide better clarity to the rule language.

Section 773.23—Review of Ownership or Control and Violation Information. OSM proposed § 773.23 as a new section which would delineate the regulatory authority's review obligations with respect to a permit application after the regulatory authority had completed the process of verifying ownership or control application information as described in § 773.22.

The provisions of paragraph (a) of proposed § 773.23 would have required the regulatory authority to review all reasonably available information concerning violation notices and ownership or control links involving the applicant to determine whether the application could be approved under the provisions of 30 CFR 773.15(b). With respect to ownership or control links involving the applicant, such information would have included all information obtained under 30 CFR 773.22 and 778.13. With respect to violation notices, such information would have included all information obtained under § 778.14, information obtained from OSM, including information shown in the AVS, and information obtained from the regulatory authority's own records concerning violation notices.

In substance, the proposed regulation was designed to assure that the regulatory authority considers complete ownership, control, and violation information in making the decision required by 30 CFR 773.15(b)(1) with respect to a permit application.

The provisions of paragraph (b) of proposed § 773.23 were proposed to provide the course of action which a regulatory authority would be required to take if the review conducted pursuant to paragraph (a) of the section disclosed any ownership or control link between the applicant and any person cited in a violation notice.

Thus, paragraph (b)(1) of proposed § 773.23 would have required that the regulatory authority notify the applicant of such link and refer the applicant to the agency with jurisdiction over the violation notice.

Paragraph (b)(2) of proposed § 773.23 would have required that the regulatory authority not approve the permit application unless and until it determined that all ownership or control links between the applicant and any person cited in a violation notice were erroneous or had been rebutted, or the regulatory authority determined that the violation to which the applicant had been linked had been corrected, was in the process of being corrected, or was the subject of a good faith appeal,

within the meaning of 30 CFR 773.15(b)(1) or the State program equivalent. The determinations to be made by the regulatory authority under paragraph (b)(2) of the proposed regulation were to have been made in accordance with the provisions of proposed § 773.24, procedures for challenging ownership or control links shown in AVS, and proposed § 773.26, standards for challenging ownership or control links and the status of violations, or their State program equivalents.

Paragraph (c) of proposed § 773.23 would have required that, following the regulatory authority's decision on the application or following the applicant's withdrawal of the application, the regulatory authority be required to promptly enter all relevant information related to the decision or withdrawal into AVS. The regulatory authority's decision could have included unconditional issuance, conditional issuance, or denial of the permit. The requirement that all relevant information be promptly entered into AVS was intended to insure that AVS was continually updated to reflect the most current information available with respect to permit applicants. A critical source of such information would be the regulatory authority.

Commenters representing members of the coal industry criticized the provisions of the proposed regulation as being unnecessarily duplicative of the provisions of proposed § 773.22 and of 30 CFR 773.15(b). In support of this position, they pointed to the provisions of the proposed regulation which require the review of violation information and ownership or control links to determine whether an application could be approved. They questioned why the requirements of proposed §§ 773.22 and 773.23 would be imposed as two separate stages, rather than as a single stage of the permit application process under 30 CFR 773.15(b)(1).

OSM disagrees with the view that the provisions of proposed §§ 773.22 and 773.23 are duplicative or redundant to each other or with respect to the provisions of 30 CFR 773.15(b)(1). Further, OSM does not believe that these provisions should be consolidated with the provisions of 30 CFR 773.15(b)(1).

While each of the regulatory sections at issue are part of the permit application and review process, the two proposed §§ 773.22 and 773.23 represent separate tasks for the regulatory authority. In implementing the provisions of proposed § 773.22, the regulatory authority would be focusing upon information contained in the permit application and attempting to verify such information by comparing it with other readily available sources of information. The purpose of such activity is to identify complete and accurate information with respect to the application, including identification of the person or persons who will own or control the surface coal mining operation. In implementing the provisions of proposed § 773.23, the regulatory authority takes the information gleaned from its research on the application and then evaluates whether there are any ownership or control links between the applicant and any person cited in a violation notice. In this stage, the focus of inquiry is to determine whether the permit can be approved in accordance with the provisions of 30 CFR 773.15(b).

While both of these stages involve the use of AVS, this does not mean that such stages are redundant or duplicative. The AVS should be consulted throughout the permit application process to assure that the regulatory authority has the most current ownership or control and violation information available from OSM and other State regulatory authorities. The AVS is an evolving information system which is routinely supplemented with new information. The use of AVS in the earlier stage, proposed § 773.22, provides an information resource for comparison with application ownership or control information and a basis for inquiry with the applicant. During the later stage, proposed § 773.23, the regulatory authority takes previously developed ownership or control information and compares such information with outstanding violation information in deciding whether or not to issue the permit. The use of AVS in this stage enables the regulatory authority to have the benefit of any information which may have been subsequently added to AVS by OSM or other State regulatory authorities.

Further, neither of the provisions of proposed sections are redundant with 30 CFR 773.15(b)(1). The provisions of 30 CFR 773.15(b)(1) do not delineate the means by which a regulatory authority may comply with the mandates of section 510(c) of the Act or 30 CFR 773.15(b)(1). Proposed §§ 773.22 and 773.23 fill this need. These proposed sections provide the specific steps to be taken by a regulatory authority to achieve compliance with the provisions of 30 CFR 773.15(b)(1).

One industry commenter suggested that all of these provisions should be consolidated into a single violations review provision. While this is a reasonable alternative, OSM is convinced that the approach contained in the proposed rules is a better alternative. The placement of the required tasks in separate sections of the regulations, with appropriate cross references, better highlights the particular duties necessary at each stage of the permit application review process in a way which is more likely to support compliance. Also, as the above discussion demonstrates, the tasks are sufficiently separable that they lend themselves to separate regulatory sections. Such separation, however, does not mean that there must be unnecessary delays. A regulatory authority can move forward methodically through each required task in a timely manner.

A commenter representing State regulatory authorities criticized the provisions of paragraph (b)(2)(ii) of proposed § 773.23 because such provision would prohibit the issuance of a permit if there are outstanding violations. He asserted that these provisions would significantly increase the burden on applicants, because the provisions did not incorporate the presumption that an NOV is considered abated unless an FTACO has been issued.

In this preamble, OSM has already addressed the matter of the presumption of NOV abatement within the discussion of the amendments to 30 CFR 773.15(b)(1) which have been adopted today. As indicated, OSM has determined to retain a presumption of NOV abatement where the abatement period for the NOV has not expired and the applicant has provided certification that the violation is in the process of being corrected to the satisfaction of the agency with jurisdiction over the violation. Since the provisions of proposed § 773.23 incorporate the provisions of 30 CFR 773.15(b)(1), such presumption would be similarly applied as part of proposed § 773.23. Thus, the substance of commenter's concern has been addressed.

Commenters representing environmental advocacy groups urged that paragraph (a) of proposed § 773.23 be clarified with respect to the regulatory authority's duty to review the accuracy of ownership or control information. They pointed out that there are many additional sources of ownership or control information beyond those listed in the regulation which a regulatory authority could review. They asserted that the regulatory authority should be required to review the sources listed in the

regulation, the AVS and the regulatory authority's own records, *at a minimum*.

OSM agrees that there are many potential sources of ownership or control information and that the sources for review listed in the proposed regulation are those which the regulatory authority should be required to review, at a minimum. OSM disagrees, however, that the proposed regulation needs to be further clarified or modified. There is already language in the proposed regulation which meets the substance of commenters' concerns. In paragraph (a) of proposed § 773.23, the regulatory authority is required to "review *all reasonably available information* concerning violation notices and ownership or control links involving the applicant * * *." (Emphasis added.) In addition, the language makes clear that "[s]uch information shall include" the listed items which follow in paragraphs (a)(1–2) of the proposed regulation. The clear meaning of this proposed language is that the listed examples are those sources which the regulatory authority must review. In addition, the regulatory authority can choose to review other sources.

Commenters representing environmental advocacy groups also urged OSM to incorporate standards to demonstrate whether an outstanding violation has been corrected or is in the process of being corrected to the satisfaction of the agency with jurisdiction over such violation. OSM believes that the regulatory authority which issued the violation can effectively define the status of such violation with additional standards. This regulatory authority is well positioned to determine whether the violation which it has issued has been abated or is in the process of being abated to its satisfaction. A regulatory authority before which a permit application is pending should consult the regulatory authority which issued the violation to ascertain the status of any violation to which an applicant has been linked through ownership or control.

OSM has determined to adopt the proposed rule as a final rule with a small modification which is now described. In adopting the proposal, OSM has modified the provisions of paragraph (b)(2) of section 773.23 to make the provisions of §§ 773.25, standards for challenging ownership or control links and the status of violations, along with those contained in § 773.24, applicable when a regulatory authority makes a determination whether to approve a permit. The proposed rule contained a reference to proposed section 773.26. This change reflects that proposed section 773.26 has been renumbered as final § 773.25. The rule is otherwise adopted as proposed.

Section 773.24—Procedures for Challenging Ownership or Control Links Shown in AVS. OSM proposed § 773.24 to establish the procedures to be followed in the event that the AVS showed an ownership or control link between a person and any person cited in a violation notice. The proposed section would have provided procedures for direct appeals of such links to OSM by persons who had been so linked. The proposed section would also have provided for challenges concerning the status of violations to which persons shown on AVS had been linked. The proposed section would have further provided the opportunity for those persons making a challenge to have obtained temporary relief from any adverse use of the challenged link or violation information during the pendency of such challenge.

Paragraph (a)(1) of proposed § 773.24 would have provided that an applicant or anyone else shown in AVS in an ownership or control link to any person cited in a Federal or State violation could have challenged such a link in accordance with the provisions of paragraphs (b) through (d) of proposed § 773.24 and in accordance with the provisions of proposed § 773.26, standards for challenging ownership or control links and the status of violations. Paragraph (a)(1) of proposed § 773.24 would have provided, however, that such challenge would not be available if the challenger was bound by a prior administrative or judicial decision with respect to the link.

In substance, paragraph (a)(1) of proposed § 773.24 would have provided that challenges of ownership or control links shown on AVS be made before OSM. The theory of the proposed regulation was that, once information with respect to particular ownership or control links has become part of the AVS and accessible to regulatory authorities across the country, the responsibility for the maintenance of such information would be a Federal responsibility. Accordingly, the process for challenging such information would be a Federal process.

Paragraph (a)(2) of proposed § 773.24 would have provided that an applicant or anyone else shown in AVS in an ownership or control link to a person cited in a Federal violation notice would have challenged the status of such violation in accordance with the provisions of paragraphs (b) through (d) of proposed § 773.24 and in accordance with the provisions of proposed § 773.26, standards for challenging ownership or control links and the status of violations. The procedures applicable would have been similar to those described in paragraph (a)(1) of proposed § 773.24.

Paragraph (a)(2) of proposed § 773.24 would have provided, in language similar to that contained in paragraph (a)(1) of the proposed regulation, that the opportunity to challenge the status of a violation would not be available to any person who was bound by a prior administrative or judicial determination concerning the status of the violation.

The "status of the violation" would have meant whether the violation remained outstanding, had been corrected, was in the process of being corrected, or was the subject of a good faith, direct administrative or judicial appeal to contest the validity of the violation. See 30 CFR 773.15(b)(1)(i)-(ii). This usage was to have been carried forward into the provisions of proposed § 773.26, standards for challenging ownership or control links and the status of violations. Further, the provisions of proposed § 773.26 would have limited challenges make to the status of violations under proposed § 773.24 to prevent challenges of the existence of the violation at the time that it was cited. Again, the process for challenging the status of a Federal violation was to have been a Federal process. Challenges would have been made before OSM.

Paragraph (a)(3) of proposed § 773.24 would have provided that any applicant or person shown in AVS to have been linked by ownership or control to a person cited in a State violation notice could challenge the status of such violation before the State that issued the violation notice. Such challenge would have to have been made in accordance with that State's program equivalents to paragraphs (b) through (d) of proposed § 773.24 and proposed § 773.26. Again, the provisions of proposed section 773.26 would have been incorporated under proposed § 773.24 to prevent challenges as to the existence of the violation at the time that it was cited.

Paragraph (a)(3) of proposed § 773.24 would have provided, in language similar to that contained in paragraph (a)(2) of the proposed regulation, that the opportunity to challenge the status of a violation before a State program would not be available to any person who was bound by a prior administrative or judicial determination concerning the status of the violation.

Paragraph (b) of proposed § 773.24 would have required that a person seeking to challenge ownership or

control links shown in AVS or the status of Federal violations submit to OSM a written explanation of the basis for his or her challenge and provide relevant evidentiary materials and supporting documents. The proposed regulation would have required that such information be submitted to the Chief of OSM's AVS Office in Washington, DC.

Paragraph (c) of proposed § 773.24 would have required that OSM make a written determination with respect to the ownership or control link and/or with respect to the status of the violation. The proposal required that, if an ownership or control link had been challenged, OSM would then determine whether the link had been shown to be erroneous or had been rebutted.

Paragraph (d)(1) of proposed § 773.24 would have provided that, if OSM had determined that the ownership or control link had been shown to be erroneous or had been rebutted and/or that the violation covered by the violation notice had been corrected, appropriately appealed, or otherwise resolved within the terms of 30 CFR 773.15(b)(1) (i)–(ii), OSM would be required to have provided notice of its determination to the permit applicant or other person challenging the link or the status of the violation. Under the proposed regulation, if an application was pending, OSM would also have to notify the regulatory authority before which the application was pending. Further, OSM would have been required to correct information contained in AVS to reflect the determination which had been made.

Paragraph (d)(2) of proposed § 773.24 would have provided that, if OSM had determined that the challenged ownership or control link had not been shown to be erroneous and had not been rebutted, and that the violation remained outstanding, OSM would have been required to provide notice of its determination to the permit applicant or other person challenging the link or the status of the violation. Under the proposed regulation, if an application was pending, OSM would have also been required to notify the regulatory authority before whom the application was pending. Further, OSM would have been required to update information contained in AVS, if necessary, to reflect OSM's determinations.

Paragraph (d)(2)(i) of proposed § 773.24 would have provided that OSM be required to serve a copy of its decision with respect to a challenge upon the applicant or other challenger by U.S. certified mail or by any other means consistent with the rules governing service of a summons and complaint under Rule 4 of the Federal Rules of Civil Procedure.

Paragraph (d)(2)(ii) of proposed § 773.24 would have provided that the applicant or other challenger could have appealed OSM's decision to the Department of the Interior's Office of Hearings and Appeals (OHA) within 30 days of such decision in accordance with proposed OHA regulations at 43 CFR 4.1380 *et seq.* Paragraph (d)(2)(ii) would have further provided that OSM's decision remained in effect unless temporary relief was granted in accordance with OHA regulations at 43 CFR 4.1386.

Paragraph (d)(2)(ii) of proposed § 773.24 would have further provided for temporary relief from OSM's decision, if OHA granted such relief in accordance with proposed OHA regulations at 43 CFR 4.1386. Under the proposed regulation, OSM's decision would have remained in effect during the pendency of appeal, unless temporary relief was granted.

Commenters representing the coal industry took exception to the provisions of paragraph (a)(2) of the proposed section which would preclude an applicant or other person from challenging the status of a violation if he or she was "bound by a prior administrative or judicial determination concerning" the status of the violation. The commenters asserted that determining whether a person was "bound" by a prior determination was vague and susceptible to conflicting interpretations. They further asserted that if, by this proposed language, OSM intended to apply the doctrines of res judicata or collateral estoppel, there was no need to include such language in the proposed regulation, since these doctrines would be available as legal defenses to OSM in any event. The commenters indicated that their objection to this language also applied to the other portions of the proposed regulations where similar language imposing such a limit on challenges was incorporated.

OSM disagrees with the commenters' characterization of the rule language. The proposed rule language is clear in standing for the principle that a person is entitled to his or her challenge opportunity before an administrative or judicial tribunal. Nevertheless, a person is not entitled to the multiple relitigation of issues which he or she has already litigated to conclusion. Accordingly, the proposed rule is explicit in requiring that a person who is bound by a prior administrative or judicial determination with respect to the status of a violation may not relitigate such issue. In determining whether a person is bound by a prior determination, traditional principles of res judicata and collateral estoppel will apply. Contrary to commenters' view, however, it is insufficient to assume that such principles will apply as a matter of law and that there is no need to provide an explicit limitation in the regulation. Such a limitation is necessary to eliminate any ambiguity in the regulation with respect to this issue and to assure that judicial and administrative tribunals are not clogged with duplicative, repetitive claims by persons who have already litigated such claims. The limiting language provides a clear statement of OSM's intent and will be adopted as part of the final rule.

Commenters representing environmental advocacy groups indicated approval of the provisions of the proposed regulation which would have limited challenges of the existence of the violation at the time it was cited. Such commenters did indicate concern, however, that the proposed regulation did not provide an explicit time limit for OSM to make its decision with respect to a challenge. They urged that the regulation incorporate an explicit time limit of 30 days for OSM to make a decision to avoid undue delay with respect to the permit application process.

OSM disagrees with the view that the regulation needs to contain an explicit time limit for the agency to make a decision with respect to challenges of ownership or control links or the status of violations. While OSM makes every effort to decide these issues in an expeditious manner, the review and determination of an ownership or control link can be a complex endeavor, requiring the review of significant amounts of complex documentary material. Such a process typically involves a dialogue involving the exchange of numerous documents and testimony between the agency and the challenger. Such issues may require extensive research and investigation by trained specialists. The imposition of artificial time limits on the process could create a risk that decisions will be inaccurate and that investigations will be incomplete.

Further, there is no risk to the environment during the period of challenge. During the period of challenge, the permit is not issued. Once a presumption of ownership or control has been established pursuant to 30 CFR 773.5 and such presumption is shown on AVS, the burden is upon an applicant to rebut the presumption. The regulatory authority should not issue the permit until the presumption has been rebutted. While an expeditious

process is encouraged, the regulatory authority should not be rushed in making such a decision. It should conduct a thorough investigation and review all of the relevant evidence presented. Some challenges can be resolved within 30 days. Other challenges may require six months. Imposing an absolute time limit disregards the differences that particular cases have with respect to factual and legal complexity. Accordingly, OSM must reject the commenters' suggestion that a time limit should be incorporated into the proposed regulation.

A commenter representing State regulatory authorities criticized the provisions of proposed § 773.24 which would require that challenges of ownership or control links shown on AVS be heard before OSM. In substance, the commenter was concerned that, for such challenges to be meaningfully addressed, OSM would need copies of supporting documentation from the States and challengers would be referred to the States to review various documents with respect to ownership or control relationships and with respect to violations. The commenter asserted that the States would have an "unnecessary burden" to provide duplicate copies of documents to OSM and other participants.

While OSM appreciates commenter's concern, OSM disagrees that the process provided in the proposed rule will impose an unnecessary burden upon the States. Under the proposed regulation, OSM is assuming the responsibility to entertain challenges to ownership or control information shown on AVS. In the absence of OSM's assumption of such responsibility, the States would have to hear such challenges. Further, regardless of which party assumes responsibility for addressing such challenges, that party would have to obtain complete documentation from all other parties which might have relevant records. Thus, each State would have to provide copies of essential documentation to the participants and to whichever regulatory authority was reviewing the case, be it OSM or a specific State, to enable the challenges to be fairly considered and resolved. It is in the interests of all concerned with the process—including OSM, the States, the challengers, and the public—that determinations of such challenges are based upon a complete administrative record. OSM is confident that the cooperative relationship between OSM and the States which has characterized the development and implementation of AVS would be carried forward with respect to challenges of ownership or control information on AVS made before OSM.

Commenters representing State regulatory authorities also questioned whether proposed § 773.24 was inconsistent with other provisions of the proposed rules which would allocate responsibility to State regulatory authorities to make ownership or control decisions. In support of these positions, the commenters cited the provisions of proposed § 773.26(b) which they considered to be inconsistent with proposed § 773.24. As is noted elsewhere in this preamble, proposed § 773.26 is being modified, renumbered, and adopted today as final § 773.25. The commenters were concerned that there would be confusion in the permit application process if OSM would be the deciding agency with respect to ownership or control information on AVS.

OSM disagrees with the commenters' analysis. The provisions of proposed § 773.24 were designed to avoid confusion. In substance, the proposed rule would provide challengers with a single forum, OSM, before which they could contest ownership or control information shown on AVS. The alternative to the proposed rule's approach would be for challengers to challenge ownership or control links shown on AVS before the various States. There is a greater likelihood of inconsistent results with multiple jurisdictions making such decisions as opposed to a single agency making such decisions. Further, the content of AVS would be subject to such inconsistency, since the resolution of challenges would have to be reflected in the AVS database. Given that AVS is a national database which is used across State lines, there is a need for consistency in the decisionmaking which forms the content of AVS. Moreover, the approach provided in proposed § 773.24 is consistent with that provided in proposed § 773.26(b).

Paragraph (b)(1)(i) of proposed § 773.26 would provide that the regulatory authority before which an application is pending has authority for making decisions with respect to the ownership or control of the applicant. Paragraph (b)(1)(ii) of proposed § 773.26 would provide that the regulatory authority that issued a permit would have authority for making decisions with respect to the ownership or control of the permittee. As will be discussed below in detail, OSM's final regulation adopted as final § 773.25 modifies this language to refer to ownership or control of applications, permits, and violations, rather than ownership or control of applicants, permittees, and violators.

Under paragraph (b) of proposed § 773.26, the authority of the regulatory authority is initial authority, subject to OSM's oversight. Under that paragraph of proposed § 773.26, a regulatory authority would analyze the facts and make an initial decision with respect to the ownership or control links of an applicant or a permittee. Such decision would be subject to OSM's oversight. Then, the regulatory authority would enter such information into AVS, to the extent necessary to update the system. The entry of such information into AVS would also be subject to OSM's oversight. Since OSM has ultimate authority, through the exercise of oversight, as to the content of the ownership or control information on AVS, it is consistent for OSM to be the single forum for the challenge of ownership or control information shown on AVS as provided by proposed § 773.24. If OSM later amends the AVS to reflect a different conclusion with respect to a particular ownership or control link than that reached by a State regulatory authority, that reflects OSM's exercise of its oversight authority and its responsibility for the ownership or control information contained in AVS. If a regulatory authority would then consider a subsequent application, it would be required to review AVS and to factor the information shown in AVS, as amended by OSM, into the regulatory authority's decision with respect to the later permit application. Thus, proposed §§ 773.24 and 773.26 are consistent with each other and will not lead to confusion in the permit application process.

A commenter representing State regulatory authorities also proposed a revision of proposed § 773.24 such that OSM's decisions made under the proposed regulation would be considered preliminary decisions which would become final within 30 days thereafter if the person challenging the link could show no valid reason why the decision should not become final. The commenter asserted that such a provision would enable the challenger to provide supplemental information which could lead to a corrected final decision and, thus, obviate the need for an appeal to OHA.

OSM appreciates the commenter's suggestion. OSM believes, however, that persons should have the opportunity to seek review of the agency's decision by OHA as soon as possible upon the agency's determination that they are linked, through ownership or control, to violations. In the absence of a final agency decision, such review by OHA

would not be routinely available. Accordingly, the proposed regulation provides for a final agency decision which may then be appealed to OHA by a challenger. If a challenger has new information which would lead OHA to conclude that the challenger is likely to win a reversal of OSM's decision, then such information would support temporary relief with respect to the decision. On the other hand, where OSM has reviewed information submitted and concluded that an ownership or control link has been severed, OSM may choose to reserve the right to reopen such decision in the event that new information or evidence comes to light subsequently. Such reservation of the right to reopen by the agency would be necessary to assure that the agency can correct its mistakes and assure the accuracy of the AVS. Thus, OSM can supplement the record with information discovered subsequent to any decision. Accordingly, OSM has determined not to adopt the commenter's proposal.

In accordance with the above discussion, OSM has decided to adopt a final version of § 773.24 which is substantively similar to the proposed version. OSM has, however, made some minor modifications to the proposed rule which are now described.

In paragraph (a)(1) of the proposed rule, the rule provided for the challenge of links by persons linked to any person cited in a Federal or State violation notice. At the time that this proposal was published in September, 1991, OSM expected that most challenges would be by persons seeking to challenge links to violators to avoid permit blocks. In actuality, members of the regulated community have also routinely come before OSM seeking to challenge ownership or control links to persons who are not violators. The language of the proposal did not reflect this reality and was, therefore, too narrow. Further, the language was potentially inconsistent with language contained in the 1988 preamble to OSM's ownership and control rules. In that preamble, OSM stated, in relevant part, as follows:

> *Procedures to Amend Applicant Violator System Information.* In addition to the procedures described above, both individuals and organizations may seek to amend the information in the Applicant Violator System, independent of the existence of a permit application if they believe that the records are not accurate, relevant, timely or complete.

See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38879 (October 3, 1988). Accordingly, the final rule broadens the proposed language to provide that "[a]ny applicant or other person shown in AVS in an ownership or control link to any person may challenge such link" even if the link is to persons who are not violators. OSM intends to protect due process rights and provide an efficient avenue to challenge information shown on AVS. The substance of paragraph (a)(1) of the rule proposed in September, 1991 is otherwise retained.

Proposed § 773.24 has been further modified to delete references in paragraphs (a)(2) and (a)(3) to proposed § 773.26 and substitute references to final § 773.25 in the place of the deleted section references. This reflects OSM's renumbering of the sections of the proposed rule. No substantive change in the rule has been made by such modification.

Paragraph (b) of proposed § 773.24 would have required that a person seeking to challenge ownership or control links or the status of Federal violations submit to OSM a written explanation of the basis for his or her challenge and provide relevant evidentiary materials and supporting documents. Proposed paragraph (b) did not explicitly state that the process of challenge described in this paragraph applied to links *shown in AVS*. That was OSM's intent, however, as stated in the preamble to the proposed rule. Accordingly, OSM has corrected the oversight in the rule language by explicitly incorporating this language into this final rule.

Paragraph (c) of proposed § 773.24 has been adopted as proposed. This provision requires OSM to make a written determination with respect to the ownership or control link and/or with respect to the status of the violation. The provision of the rule requires that, if an ownership or control link is challenged, OSM then determines whether the link has been shown to be erroneous or has been rebutted. While no change has been made to the proposed rule, OSM believes that the following explanation will be helpful in clarifying the operation of the rule.

Under the rule, a determination that a link is "erroneous" means that the facts in the case show that no ownership or control relationship set forth in 30 CFR 773.5 ever existed. Thus, if an individual is shown on AVS as being linked to a corporation by virtue of his or her position as an officer of such corporation, see 30 CFR 773.5(b)(1), evidence demonstrating that such individual is not and has never been an officer of the corporation would support a determination that an ownership or control link based upon such a relationship is erroneous.

A determination that a link has been "rebutted" means that, while the facts in the case show that a presumed ownership or control relationship as set forth in 30 CFR 773.5(b) exists or existed, sufficient evidence has been presented to demonstrate that the "person subject to the presumption [did] * * * not in fact have the authority directly or indirectly to determine the manner in which the relevant surface coal mining operation [was] conducted * * *." See 30 CFR 773.5(b).

Accordingly, if the individual in the preceding example was, in fact, an officer of the corporation, but did not have authority or demonstrated control over the conduct of the surface coal mining operation, the presumption of ownership or control would be rebutted.

The provisions of paragraph (d) of the proposed rule have been adopted as proposed. Paragraph (d)(2)(i) of § 773.24 provides that OSM is required to serve a copy of its decision with respect to a challenge upon the applicant or other challenger by U.S. certified mail or by any other means consistent with the rules governing service of a summons and complaint under Rule 4 of the Federal Rules of Civil Procedure.

The date of service of the decision will set a date certain from which the time for appeals will begin to run. The regulation provides that service is complete upon tender of the notice or of the mail and is not deemed incomplete by virtue of a challenger's refusal to accept the notice or mail. The theory of this provision is to assure that a challenger is not able to delay the running of the time for appeal by avoiding or refusing service of OSM's decision and then claiming that he or she was never served.

Paragraph (d)(2)(ii) of § 773.24 has been adopted as proposed. As provided in the proposed rule, the final version of this paragraph provides that the applicant or other challenger can appeal OSM's decision to OHA within 30 days of such decision in accordance with OHA regulations at 43 CFR 4.1380 *et seq.*

As provided in the proposed rule, paragraph (d)(2)(ii) of the final regulation provides all challengers to an OSM decision in these matters with the opportunity to appeal the decision to OHA.

The preamble to the ownership or control rules published in 1988 provided that appeals by individuals from OSM decisions with respect to information contained in AVS were

made to the Department's Assistant Secretary—Policy, Management, and Budget under procedures developed under the Privacy Act of 1974. Appeals by entities other than individuals were made to OHA. See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38879 ("Procedures to Amend Applicant Violator System Information") (October 3, 1988).

In 1993, pursuant to a delegation from the Department's Assistant Secretary—Policy, Management and Budget, the authority to decide appeals with respect to information contained in AVS was delegated to OHA. Consistent with such delegation, OSM believes that a single process of appeal for both individuals and entities will promote consistency for both the public and the regulated community and that such appeal process should be explicitly contained in the final rule. As provided in the proposed rule, paragraph (d)(2)(ii) of the final rule provides that OSM's decision would remain in effect unless temporary relief were granted in accordance with OHA regulations at 43 CFR 4.1386.

Paragraph (d)(2)(ii) of § 773.24 provides for temporary relief from OSM's decision, if OHA grants such relief in accordance with OHA regulations at 43 CFR part 4. Under the final regulation, the period during which a person may file a notice of appeal or the actual filing of an appeal will not automatically suspend the use of the information in AVS during the pendency of such appeal. The challenger will have to explicitly seek such relief in appeal proceedings before OHA and be granted such relief. See also 43 CFR 4.21(a).

In considering a request for temporary relief, OHA will apply the criteria of Section 525(c) of the Act, 30 U.S.C. 1275(c), to determine whether such relief is warranted. See OHA regulations at 43 CFR 4.1386. To grant temporary relief under such criteria, OHA will have to find that the challenger has a substantial likelihood of prevailing in his appeal of the OSM decision and that temporary relief, if granted, will not adversely affect the health or safety of the public or cause significant, imminent environmental harm to land, air, or water resources.

In determining whether the granting of temporary relief would cause significant, imminent environmental harm, OHA will not attempt to decide whether a denial of temporary relief will compel the applicant or other challenger to abate a violation posing such harm. It is not the intent of these rules to force a person to abate a violation even if he or she is able to show a substantial likelihood that he or she had no ownership or control over the operation that is in violation.

Instead, OHA will focus its attention upon the compliance history of those persons who do appear to have had ownership or control over operations in violation, to determine whether the granting of temporary relief would pose a risk of significant, imminent environmental harm at sites for which new permits could be issued during the pendency of the appeal process.

In accordance with the above discussion, the provisions of the proposed rule are adopted with the modifications noted.

Withdrawal of former proposed § 773.25 which would have provided procedures for challenging ownership or control links prior to entry in AVS. In the September, 1991 proposal, OSM proposed a rule to provide procedures for challenging ownership or control links prior to entry in AVS. That proposal which was numbered as proposed § 773.25 represented OSM's attempt to go beyond the Constitutional requirements of due process. The proposal would have prospectively required OSM or a State regulatory authority to provide notice to those persons who were actively involved in surface coal mining operations and who were linked to a violation through ownership or control before such link information would be used to subject them to permit denial through AVS. Such persons would then have had an opportunity to challenge such information. Upon further consideration, OSM has decided to withdraw the proposed regulation.

OSM believes that adequate due process rights to notice and an opportunity to be heard are afforded by current practices which permit a challenge to ownership or control and violation information after it is incorporated into AVS. Such challenges can be made currently both within the context of a permit application and independent of such an application. OSM believes that these opportunities suffice to pass constitutional muster. See Preamble to *Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule*, 53 FR 38868 at page 38885 ("Due Process Provided") and at page 38879 ("Procedures to Amend Applicant Violator System Information") (October 3, 1988).

Further, the Department's OHA is contemporaneously adopting a rule providing for temporary relief from an ownership or control link, under specified conditions. Such a rule significantly enhances the already available due process protections available to the members of the regulated community. The risk that someone will be inappropriately subjected to a permit block due to an erroneous link is substantially mitigated by the temporary relief procedures available before OHA.

Moreover, the proposed rule would have subjected OSM and State regulatory authorities to a substantial paperwork morass as a condition precedent to implementing the provisions of § 510(c) of the Act. OSM, which has been utilizing procedures similar to those proposed in the September, 1991, rule, discovered that the process was taking substantial amounts of time and resources to implement. The dialogue and paper exchange between the agency and persons debating the proposed ownership or control link was a prolonged exercise lasting, in some cases, for many months. Also, OSM was finding that most of these debates made no difference in the ultimate outcome, except where entities refuted the facts which would invoke a link. Typically, the ownership or control link was found to be well taken. The prolonged debate was preventing accurate information from being incorporated into AVS. During the period of the dialogue, the individual or entity subject to the ownership or control link was not relieved of the cloud of the potential link and the agency was not able to directly implement the link. Neither OSM nor the person challenging the link benefited by this course of events.

Further, industry, environmental advocates, and representatives of State regulatory authorities were dissatisfied with the proposed rule. Industry commenters condemned the proposed rule as providing insufficient due process for challengers of ownership or control links. Environmental advocates criticized the proposal as deficient in not providing a set time frame for OSM to bring ownership or control decisions to closure and to incorporate such decisions into AVS. A commenter representing State regulatory authorities asserted that the proposed rules should either provide for no challenge of an ownership or control link prior to permit denial or for conditional issuance of a permit pending full challenge of an ownership or control link. As is stated above in the portion of this preamble captioned "Due Process," OSM is unwilling, for a number of significant reasons, to accept that permits may be conditioned upon the appeal of ownership or control links. Nevertheless, the criticisms of the

commenter representing the State regulatory authorities, the industry commenters, and the environmental advocacy groups also caused OSM to reconsider the proposed rules.

Given that the incorporation of accurate and complete information into AVS in a timely manner is critical to the development and implementation of AVS, OSM believes that the needs of these constituent groups are addressed more effectively by the provisions of the OHA rule. OSM remains committed to developing complete and accurate information for entry into AVS, and as part of this process will of course consider information submitted by any party which would establish or refute facts relevant to an ownership or control link. To the extent that a person is injured by an erroneous ownership or control link, the OHA temporary relief procedure quickly and effectively neutralizes such injury in a timely manner. The availability of such a process enables OSM to go forward in an expeditious manner to utilize its resources to develop information, rather than engage in prolonged paper exchanges; to avoid delay in incorporating information into AVS, thus responding to the concerns of environmental advocates; and to address effectively the concerns of the industry which can invoke an administrative process outside of OSM for quick relief if the claims of injury are meritorious. Additionally, by enabling challengers to go to OHA more quickly, the focus of the challenge procedures shifts to OHA, a forum created to address such challenges of agency decisions. Finally, OSM can meet the terms of its continuing mandate from Congress to develop and implement the AVS. *See* Report of the Senate Appropriations Committee, Senate Report No. 103–114, at page 47 (July 28, 1993).

In appropriate cases, OSM may engage in a dialogue and exchange of documents with persons subject to a proposed ownership or control link prior to incorporating an ownership or control link into AVS. OSM will do this, however, only when OSM believes it needs additional information concerning the proposed ownership or control link. In that case, such a dialogue would enhance OSM's investigative process and assist in the development of relevant information.

In accordance with the above, OSM has withdrawn this portion of the September, 1991, proposal and is renumbering the remaining provisions of the final rules presented today to reflect the deletion of former proposed § 773.25.

Section 773.25—Standards for Challenging Ownership or Control Links and the Status of Violations. Proposed section 773.26 would have established standards for challenges to ownership or control links and for challenges to the status of violations. The proposed section would have allocated responsibilities between OSM and State regulatory authorities for resolving issues related to ownership and control and would have provided the substantive criteria for resolving such issues. In recognition of OSM's withdrawal of former proposed § 773.25, proposed § 773.26 has been renumbered as final rule § 773.25. For the reasons discussed below, the final rule also has been modified to delete the substantive criteria to resolve ownership or control issues previously contained in the proposed rule.

Paragraph (a) of proposed § 773.26 provided that its provisions would have been applicable to any challenge concerning an ownership or control link or the status of a violation when such challenge was made under the provisions of 30 CFR 773.20 and 30 CFR 773.21 (improvidently issued permits); proposed § 773.23 (the regulatory authority's review of ownership or control and violation information), proposed § 773.24 (procedures for challenging ownership or control links shown in AVS), and proposed § 773.25 (procedures for challenging ownership or control links prior to entry in AVS); or 30 CFR part 775 (administrative and judicial review of permitting decisions).

Paragraph (b) of proposed § 773.26 would have provided the basic allocation of authority among regulatory authorities to make decisions with respect to ownership or control and with respect to the status of violations.

Paragraph (b)(1)(i) of proposed § 773.26 would have provided that the regulatory authority before which an application was pending would have had authority for making decisions with respect to the ownership or control of the applicant. Such regulatory authority would have had responsibility for reviewing information submitted by the applicant and other available information to ensure the complete identification of the applicant's ownership or control links.

Paragraph (b)(1)(ii) of proposed § 773.26 would have provided that the regulatory authority that issued a permit would have had authority for making decisions with respect to the ownership or control of the permittee. Such decisions would be necessary in determining whether the permit was improvidently issued, pursuant to 30 CFR 773.20. The regulatory authority which issued a permit would have done so based upon a complete review of ownership or control information.

Paragraph (b)(1)(iii) of proposed § 773.26 would have provided that the State regulatory authority that issued a State violation notice would have had authority for making decisions with respect to the ownership or control of any person cited in the notice.

Paragraph (b)(1)(iv) of proposed § 773.26 would have provided that the regulatory authority that issued a violation notice, whether State or Federal, would have had authority for making decisions concerning the status of the violation covered by the notice. The "status" of the violation meant whether the violation remained outstanding, had been corrected, was in the process of being corrected, or was the subject of a good faith appeal, within the meaning of 30 CFR 773.15(b)(1).

Paragraph (b)(2) of proposed § 773.26 would have provided that OSM would have authority for making decisions with respect to the ownership or control of any person cited in a Federal violation notice.

Under the allocation principles set forth in paragraphs (b)(1) and (b)(2) of the proposed rule, a regulatory authority that was deciding whether a permit application should be granted or whether a permit had been improvidently issued would have determined for itself the ownership or control of the applicant or permittee, but it would have deferred to the regulatory authority that issued a violation notice for a determination of the ownership or control of the violator. The application would be blocked or the permit would be found improvidently issued if any owner or controller of the applicant or permittee were also an owner or controller of a violator, as determined by the respective regulatory authorities.

Paragraph (b)(3) of proposed § 773.26 would have provided that the authority of State regulatory authorities to make decisions with respect to ownership or control links or the status of violations would have been subject to OSM's oversight authority under 30 CFR parts 733, 842, and 843. Under paragraph (b)(3) of proposed § 773.26, when OSM disagreed with a decision of a State regulatory authority, it would have taken action, as appropriate, under proposed § 843.24, oversight of State permitting decisions with respect to ownership or control of the status of violations.

Paragraph (c) of proposed § 773.26 would have established evidentiary standards applicable to the formal and

informal review of ownership or control links and the status of violations.

Paragraph (c)(1) of proposed § 773.26 would have provided that in any formal or informal review of an ownership or control link or of the status of a violation, the agency responsible for making a decision would be required to make first a prima facie determination or showing that the link exists or that the violation remains outstanding.

Under paragraph (c) of proposed § 773.26, a challenger of a link to a violation would have had to prove at least one of three proposed conclusions by a preponderance of the evidence to succeed in his or her challenge.

First, under paragraph (c)(1)(i) of proposed § 773.26, a challenger could have proven that the facts relied upon by the responsible agency to establish ownership or control within the terms of 30 CFR 773.5(a) or to establish a presumption of ownership or control under 30 CFR 773.5(b) do not or did not exist.

Paragraph (c)(1)(ii) of proposed § 773.26 provided that a person subject to a presumption of ownership or control under 30 CFR 773.5(b) could have rebutted such presumption by demonstrating that he or she does not or did not in fact have the authority directly or indirectly to determine the manner in which surface coal mining operations are or were conducted. Such demonstration would have been made in accordance with the provisions of paragraph (d) of proposed § 773.26.

Paragraph (c)(1)(iii) of proposed § 773.26 provided that a challenger could have proven that the violation covered by a violation notice did not exist, had been corrected, was in the process of being corrected, or was the subject of a good faith appeal within the meaning of 30 CFR 773.15(b)(1).

Paragraph (c)(2) of proposed section 773.26 described the type of evidence that a person challenging an ownership or control link or the status of a violation would have had to present to meet the burden of proof by a preponderance of the evidence. The proposed regulation provided that the evidence presented would have had to have been probative, reliable, and substantial. See 5 U.S.C. 556(d).

Paragraph (c)(2)(i)(A) of proposed § 773.26 provided that a challenger could have submitted affidavits setting forth specific facts concerning the scope of responsibility of the various owners or controllers of an applicant, a permittee, or any person cited in a violation notice; the duties actually performed by such owners or controllers; the beginning and ending dates of such owners' or controllers' affiliation with the applicant, permittee, or person cited in a violation notice; and the nature and details of any transaction creating or severing an ownership or control link; or specific facts concerning the status of the violation.

Paragraphs (c)(2)(i)(B) and (c)(2)(i)(C) of proposed § 773.26 looked to official certification as the basis for the reliability of a submitted document. Paragraph (c)(2)(i)(B) would have allowed for the submission of certified copies of corporate minutes, stock ledgers, contracts, purchase and sale agreements, leases, correspondence, or other relevant company records. Paragraph (c)(2)(i)(C) would have allowed for the submission of certified copies of documents filed with or issued by any State, municipal, or Federal governmental agency.

Paragraph (c)(2)(i)(D) of proposed § 773.26 provided for a challenger's submission of an opinion of counsel in support of his or her position. Under the proposed rule, such opinion would have been appropriate for submission when it was supported by evidentiary materials and when it was rendered by an attorney who certified that he or she had personally and diligently investigated the facts of the matter and that he or she was qualified to render the opinion.

Paragraph (c)(2)(ii) of proposed § 773.26 provided that, when the decision of the responsible agency was reviewed by an administrative or judicial tribunal, the challenger could have presented any evidence to such tribunal which was admissible under the rules of the tribunal. Under the proposed regulation, however, the evidence submitted would still have to have been probative, credible, and substantial.

Paragraph (d) of proposed § 773.26 represented OSM's attempt to offer substantive standards which would have established what must be proved by those seeking to rebut the presumptions of ownership or control contained in current § 773.5(b) of this title. Proof of the facts set forth in the proposed regulation would have established that the presumed owner or controller did not, in fact, have the authority directly or indirectly to determine the manner in which the relevant surface coal mining operation was conducted, under the provisions of 30 CFR 773.5(b).

In general, the proposed standards contained in paragraph (d) of proposed § 773.26 would have allowed a presumed owner or controller to demonstrate that he or she lacked control over a surface coal mining operation by presenting evidence that he or she actually lacked authority directly or indirectly to determine the manner in which the relevant surface coal mining operation would be conducted. In the alternative, with respect to a presumed owner or controller of a violator, the proposed standards would have allowed a person to present evidence that he or she took all reasonable steps within his or her authority to cause the violation to be abated and that such abatement was prevented by those in actual control of the mining operation.

Paragraph (e) of proposed § 773.26 would have provided for the review and revision of information in AVS to reflect determinations made by regulatory authorities in response to challenges of ownership or control links or the status of violations. The proposed provision would have provided that, following any determination by a State regulatory authority or other State agency, or following any decision by an administrative or judicial tribunal reviewing such determination, the State regulatory authority would have been required to review the information in AVS to determine if such information was consistent with the determination or decision. If it were not consistent, the State regulatory authority would have been required to promptly inform OSM and to request that the AVS information be revised to reflect the determination or decision.

Industry commenters criticized the provisions of paragraphs (a) and (b) of proposed § 773.26 as violating due process by not providing an owner or controller with the opportunity to challenge the existence of the violation at the time it was cited. They further criticized the provisions of the proposed rule as violating State primacy. In substance, they asserted that the proposed rule "balkanized" the permit application process by allowing the regulatory authority that issued a violation to identify the ownership or control links to the violation. They asserted that this provision impermissibly allowed such regulatory authority to play a role in the permit application process. They further argued that the regulatory authority before which an application was pending should be the sole decisionmaker.

OSM disagrees with these views. OSM has already addressed these issues in detail in previous sections of this preamble captioned "Due Process" and "Primacy." Further, OSM has clarified that a permittee may, within the context of the improvident permit issuance process, challenge the existence of the violation at the time it was cited. See discussion above in this preamble.

"Section 773.20—Improvidently Issued Permits: General Procedures."

A commenter representing State regulatory authorities took exception to the provisions of paragraph (b)(3) of proposed § 773.26 which would have provided that State determinations of ownership or control challenges be subject to OSM's oversight authority. The commenter asserted that those provisions were duplicative of other provisions of current regulations which provide for OSM's oversight of the States such as 30 CFR parts 733, 842, and 843. He further asserted that the Act established OSM's oversight power over the States and that such power required no reiteration by the proposed regulation.

In addition, commenters representing State regulatory authorities argued that, under a system of State primacy, OSM has no authority to act, on a case by case basis, with respect to a particular permit decision by a State regulatory program, other than revoking the State's approved regulatory program. Thus, they questioned OSM's authority to review a State's decision with respect to ownership or control. They also argued that, if OSM review of State ownership or control decisions was done, this would lead to duplication and disruption in the permit application process.

While these commenters asserted that the provisions of the proposed regulation should be deleted, they proposed that, if OSM insisted on going forward with the proposed provision or a similar rule providing for OSM oversight of State decisions, the final rule should make explicit that the initial decision of a State regulatory authority with respect to an ownership or control issue would be considered presumptively correct. They also proposed that a standard such as "gross inadequacy" should be the standard for OSM to apply to the review of the State decision.

OSM disagrees with the commenters' analysis. First, OSM rejects the commenters' view that the proposed regulation is unnecessary since the Act and regulations already provide for OSM's oversight of the States. The provisions of SMCRA such as sections 201, 503, 504, 505, and 521, and the provisions of the Federal regulations at 30 CFR parts 733, 842, and 843 do establish a system of State primacy subject to Federal oversight. Nevertheless, such provisions do not explicitly address every question which could arise in the implementation of the relationship between OSM and the States with respect to § 510(c) of the Act which, as has been previously discussed in this preamble, invokes significant issues of State primacy and Federal oversight. Further, the implementation of the AVS also invokes issues of State primacy and Federal oversight. Multiple State regulatory authorities and OSM will be making ownership or control decisions at various stages which are relevant to issues arising under section 510(c) of the Act. While the proposed regulation is consistent with the Act and with OSM's existing regulations, the proposed regulation's allocation of responsibilities among the regulatory authorities who will be making ownership or control decisions relevant to section 510(c) of the Act has not been previously part of the Federal regulations. The allocation of responsibilities provides necessary clarification to the regulated community, to regulatory authorities, and to the public. Accordingly, OSM must reject the view that the proposed regulation is duplicative of current regulations.

OSM further rejects the view that, under a system of State primacy, OSM has no authority to act, on a case by case basis, with respect to a particular permit decision by a State regulatory program, other than revoking the State's approved regulatory program. A number of provisions of the Federal regulations, including 30 CFR 842.11 and 843.21, are very explicit in providing that OSM can exercise necessary oversight authority with respect to a particular permit without revoking a State's entire regulatory program. These other provisions are consistent with the system of State primacy established by SMCRA. The proposed regulation is similarly consistent.

Moreover, OSM has a particularly strong interest in working to assure that ownership or control decisions are made correctly because the fruits of such decisionmaking will be incorporated into AVS. As has been previously discussed, AVS is used across State lines by the various State regulatory authorities and by OSM itself. Accordingly, a decision made with respect to an ownership or control link by one State regulatory authority has the potential to effect the outcomes of permit decisions by many regulatory authorities. Without consistency, there would be chaos. Federal oversight in these matters supports consistency among the various States in the application of the ownership or control rules and the outcomes of the decisions on ownership or control issues. Since these State decisions are ultimately incorporated into AVS, OSM's oversight supports the quality of the AVS.

Also, there is no reason to conclude that the exercise of Federal oversight, pursuant to the provisions of the proposed regulation, will lead to disruption in the permit application process. Paragraph (b)(1) of proposed § 773.26 and the provisions of the final regulation discussed below are designed to avoid such disruption by allocating responsibilities among the various regulatory authorities who each have a legitimate interest in the outcome of an ownership or control issue. The oversight provisions of paragraph (b)(3) of proposed § 773.26 are designed to support such allocation of responsibilities in a way that is consistent with SMCRA and OSM's implementing regulations.

OSM further believes that the commenter's proposal that a final rule should make explicit that the initial decision of a State regulatory authority with respect to an ownership or control issue will be considered presumptively correct is adequately addressed. In substance, the provisions of paragraph (b)(3) of final § 773.25 discussed below already provide that State regulatory authorities who are issuing violations, considering permit applications, and issuing permits with the first opportunity to decide the owners or controllers of, respectively, violations, applications, and permits. While the first opportunity to make a particular decision is not equivalent to a legal presumption in favor of the decision, such an opportunity does give a State regulatory authority the chance to define the status quo which would be subject to oversight review. OSM declines, however, to convert such initial decisionmaking opportunity into a presumption. The need for consistency with respect to ownership or control decisions and with respect to AVS require that OSM conduct oversight reviews of such State decisions as are necessary without the application of a presumption favoring the affirmance of such decisions.

OSM also declines to incorporate a standard such as "gross inadequacy" or some other criterion as the basis for Federal oversight of State ownership or control decisions under paragraph (b)(3) of proposed § 773.26. The application of such a standard would limit OSM's ability to review State decisions for purposes of protecting the consistency and accuracy of information in the AVS. As will be discussed with respect to the final rule § 773.25 below, OSM has made modifications to proposed § 773.26 to reflect OSM's responsibility for the ownership or control information shown on AVS and to enable OSM to act to maintain the integrity of the AVS

database. With respect to oversight incident to particular applications, permits, and violations, paragraph (b)(3) of proposed § 773.26 already contains references to 30 CFR parts 733, 842, and 843. Final rule § 773.25 contains identical references. Each of these parts of Title 30 of the Code of Federal Regulations contains provisions which have explicit criteria and triggering standards for OSM's review and action with respect to State decisions. Such criteria and standards are incorporated by reference in paragraph (b)(3) of proposed § 773.26 and would be applied, as appropriate, by OSM. Accordingly, there is no need for additional review criteria in OSM's oversight under the proposed regulation. As discussed below, final rule § 773.25 adopts the same approach.

A commenter representing environmental advocacy groups questioned whether the provisions of paragraph (b) of proposed § 773.26 sufficiently explained the allocation of responsibilities between OSM and State regulatory authorities. The commenter questioned the provision of the proposal contained at paragraph (b)(3) which provided that State regulatory authorities' authority to make ownership or control decisions would be subject to OSM's review as an element of State program oversight. The commenter asserted that this provision required further clarification as to the respective roles of OSM and the State regulatory authorities in the making of ownership or control decisions.

OSM agrees with the commenter's observation that further clarification is in order with respect to the allocation of responsibilities and authority contained in paragraph (b)(3) of proposed § 773.26. Accordingly, OSM has made a change to the final rule to clarify that, with respect to information shown on AVS, State responsibilities to make decisions with respect to ownership or control are subject to OSM's plenary authority. Thus, under the final rule, once ownership or control information is entered into AVS, OSM will assume control of such data. If OSM reviews such information and concludes that it is incorrect, OSM will act to correct such ownership or control information and will incorporate such corrected information into AVS. The rationale for OSM's plenary authority is that AVS is used across State lines by all of the State regulatory authorities and the Federal government must act to protect the accuracy and integrity of AVS. With respect to the State regulatory authority's decision underlying such ownership or control information, OSM will further act pursuant to the provisions of final § 843.24, which is described in detail below.

Nevertheless, OSM must reject the view that, because ownership or control issues are invoked, OSM must be initially involved in every permit application decision made by a State regulatory authority. The primary responsibility and authority for making a decision whether to issue or deny a permit is with the regulatory authority before which an application is pending. The primary responsibility and authority under a State regulatory program for issuing a violation is with that State's regulatory authority. The primary responsibility for the ongoing supervision of a permit is with the State regulatory authority which issued the permit. Accordingly, while OSM has changed some of the terminology in the final rule for reasons which are discussed below, OSM has not changed the basic conceptual framework contained in paragraph (b)(3) of proposed section 773.26. That framework is that the regulatory authority which is considering an application, which has issued a permit, or which has issued a violation has initial authority for making decisions with respect to the ownership or control relationships respectively invoked by the application, the permit, and the violation. OSM has program oversight authority of such decisions under 30 CFR parts 733, 842, and 843.

This commenter further indicated that the provisions of paragraph (b)(3) of the proposed section allocated the authority to review State decisions with respect to permit applications to OSM, but that OSM could exercise such authority only after a permit had been issued, in accordance with proposed § 843.24, and that this would cause friction between OSM and the States. The commenter proposed that, if OSM believed that an ownership or control link had not been made or had been severed improperly by a State regulatory authority considering a permit application, the permit should not be issued until OSM and the State regulatory authority resolved their dispute.

OSM appreciates the commenter's concern. In any system involving Federal oversight of the States, there is the potential for disagreements between the States and the Federal government. SMCRA is no exception. For instance, the invocation of the improvidently issued permit process by OSM, pursuant to 30 CFR 843.21, subjects the State's permit application review process to close scrutiny with respect to the permit in question. This is one of the remedies provided in proposed § 843.24 which paragraph (b)(3) of proposed § 773.26 would make applicable. There is potential for stress in this process. To help avoid to improvident issuance of permits, however, OSM, through its AVS Office, has attempted to be accessible to the States and to work with the States have the benefit of OSM's most current opinions with respect to particular ownership or control situations. Whether a State regulatory authority chooses to avail itself of this service is a matter within the discretion of the State regulatory authority which has the primary authority to decide whether to issue a permit. Principles of State primacy make it inappropriate, however, to mandate such consultations with respect to every permit application. Accordingly, OSM declines to modify the rule to mandate that OSM intervene in the State permit application process to require that the State not issue a permit if OSM disagrees with the State's resolution of an ownership or control issue.

Industry commenters criticized the provisions of paragraph (c)(1) of proposed § 773.26. They questioned the requirement contained in the proposed regulation that a regulatory authority make a prima facie determination whether an ownership or control link exists to a violation and that such violation remains "outstanding." They asserted that the provisions of section 510(c) of the Act require the denial of permits for "unabated" violations only, not "outstanding" violations.

OSM disagrees with the commenters' analysis. The provisions of section 510(c) of the Act require that a regulatory authority not issue a permit if information available to it indicates that "any surface coal mining operation owned or controlled by the applicant *is currently in violation* of the Act" or other laws specified. (Emphasis added.) Paragraph (c)(1) of proposed § 773.26 requires a prima facie determination whether the violation covered by a violation notice "remains outstanding." A violation which "remains outstanding" is one which is "current." The plain meaning of these phrases is the same. Further, by the use of the words "remains outstanding" in the proposed regulation, OSM did not intend to change the standard established by section 510(c) of the Act. Instead, OSM merely sought, as the Federal agency charged with implementing SMCRA, to provide a workable phrase defining a current violation.

Industry commenters further objected to paragraph (c)(1) of proposed § 773.26 insofar as such proposal required an applicant to demonstrate, by a preponderance of the evidence, that the

applicant did not own or control the violator within the meaning of the regulations. The commenters asserted that the imposition of such a burden of proof upon the applicant was inconsistent with section 510(c) of the Act and that the use of such an evidentiary burden was only appropriate for formal proceedings before tribunals, rather than informal proceedings before State regulatory authorities.

OSM disagrees with commenters' objections. The imposition of such a burden of proof is entirely consistent with the provisions of section 510(c) of the Act which require that, when available information indicates that a surface coal mining operation "owned or controlled by the applicant" is in current violation of the Act or other laws listed, the permit not be issued "until the applicant submits proof that such violation has been corrected or is in the process of being corrected."

Moreover, the statute is silent as to how an applicant may demonstrate that he or she does not own or control a surface coal mining operation. Under the Act, it is the duty of OSM, the administrative agency charged with implementing the Act, to "publish and promulgate such rules and regulations as may be necessary to carry out the purposes and provisions of * * * [the] Act." See section 201(c)(2) of the Act.

Thus, OSM proposed, and today is finalizing, a regulation which carries out the purposes of section 510(c) of the Act and places the burden of evidence production and persuasion upon the person challenging an ownership or control link to a current violation. This is consistent with the provisions of that section of the Act which clearly place the burden of going forward with proof that a violation has been corrected or is in the process of correction upon the applicant who owns or controls a surface coal mining operation which is in violation of the Act.

Moreover, in the absence of some means of showing that he or she does not own or control a particular surface coal mining operation which is in violation of the Act, an applicant who owned or controlled such an operation would only be able to receive a permit if he or she could produce proof that the current violation was corrected or was in the process of correction. As indicated above, consistent with its statutory role to propose regulations, OSM has provided the "means" for an applicant to show that he or she does not control a surface coal mining operation by establishing the burden of proof and evidentiary standards contained in paragraph (c) of proposed § 773.26.

Finally, OSM must reject the notion that the burden of proof contained in the proposed regulation is inappropriate for use by State regulatory authorities. Burdens of proof are used in formal litigation before tribunals because they are helpful to the resolution of such litigation. Such burdens establish the parameters of what parties to litigation must do to prevail in their claims. Similarly, challengers of ownership or control links need to know what parameters they need to meet in proceedings before regulatory authorities to challenge such links. Also, in making decisions with respect to ownership or control or with respect to the status of violations, regulatory authorities need guidance in assisting their decisionmaking process. In the absence of guidance establishing burdens of proof and evidentiary standards, the resulting decisions made may be inconsistent and based upon uncertain standards. For instance, one regulatory authority may believe the any quantity of evidence, including a mere scintilla, is sufficient to successfully challenge an ownership or control link to a violation. Another regulatory authority may believe that a successful challenge requires a challenger to demonstrate that an ownership or control link is rebutted beyond any reasonable doubt.

Thus, OSM's proposed rule has provided a single standard of persuasion and production, a preponderance of the evidence, to be required for the successful challenge of an ownership or control link. OSM believes that such a standard represents a prudent middle ground between the possible extremes of burdens of proof requiring a mere scintilla of evidence and those requiring proof beyond a reasonable doubt. OSM is confident that State regulatory authorities will be able to implement such a standard and that it will prove helpful. Accordingly, OSM rejects the commenters' assertion that the use of the evidentiary burden of production contained in the proposed rule is inappropriate for State regulatory authorities.

Industry commenters further criticized paragraph (c)(1) of proposed § 773.26 for requiring, as one of the bases to rebut a presumption of ownership or control, proof that the facts relied upon to establish such presumption do not or did not exist. The commenters asserted that such a test may foreclose a demonstration that the regulatory authority which established such presumption reached the wrong legal conclusion, notwithstanding the truth of the facts. Further, the commenters asserted, in substance, that the provisions of the proposed section imply that the challenger would have to disprove all of the facts which were considered by the agency which established the presumption of ownership or control, not just the relevant facts which support the presumption.

OSM does not agree with commenters' assertions. Paragraph (c)(1) of proposed § 773.26 was intended to provide the parameters as to what factual demonstration must be made by a challenger of an ownership or control link. Accordingly, paragraph (c)(1)(i) of proposed § 773.26 provision provides for the challenge of a link by proof that the facts necessary to invoke the presumption of ownership or control did not or do not exist. Nothing in such proof of facts precludes legal arguments which could be made, including those questioning the application of the presumption under the operative facts. Further, facts relevant to that legal issue could be presented under the provisions of paragraph (c)(1)(ii) of proposed § 773.26 which provides that a person could demonstrate that he or she does not or did not have authority directly or indirectly to determine the manner in which surface coal mining operations are or were conducted.

Moreover, under the provisions of the proposed regulation, challengers would only have to present proof with respect to factual issues which are relevant to the invocation of the presumption of ownership or control. If the presumption turns upon certain key factual issues, these are the issues upon which the challenge will focus. Challengers will not be required to disprove irrelevant facts which may have been included in the administrative record of the agency which initially established the presumption of ownership or control.

The industry commenters further objected to paragraph (c)(1)(ii) of proposed § 773.26 which provides that a person seeking to challenge a presumption could demonstrate that he or she did not have authority directly or indirectly to determine the manner in which surface coal mining operations were conducted. The commenters questioned whether the requirement that a person prove that he or she did not have such indirect authority was an attempt by OSM to impermissibly extend the reach of the ownership or control regulations to cover persons remote from surface coal mining operations.

OSM denies that the proposed provision represents an attempt to

impermissibly extend the reach of the ownership or control regulations. In fact, the proposed standard was taken from currently operative ownership and control regulations. The provisions of paragraph (b) of 30 CFR 773.5, which have been effective since November 2, 1988, state that a person subject to one or more of the presumptions contained in paragraph (b) of that regulation is presumed to be an owner or controller unless there is a demonstration that "the person subject to the presumption does not in fact have the *authority directly or indirectly* to determine the manner in which the relevant surface coal mining operation is conducted." (Emphasis added.) This is the same standard which is also contained in paragraph (a)(3) of 30 CFR 773.5. The purpose of this standard is to enable:

> the regulatory authority * * * [to] examine any relationships and the facts surrounding them, such as informal agreements, personal relationships, and the mining history of the parties in question to determine if the relationship results in control over a surface coal mining operation. The regulatory authority may also consider any of the circumstances surrounding a surface coal mining operation to determine control. Such circumstances might include, for example, the fact that a person has financed the operation, or owns the equipment or the rights to the coal, or directs on-site operations.

See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38870 (October 3, 1988). Further, whether a person is "remote" in a corporate chain of command is not the issue under the standard. The issue is whether the totality of the circumstances indicate that the person had the authority to exercise control over the relevant surface coal mining operation. Such "authority" includes control or the power to control. *Id.*, at pages 38870–38871. The resolution of such issues is necessary for the regulatory authority's analysis of an ownership or control challenge. Accordingly, requiring a person challenging a presumption of ownership or control to make such demonstration is appropriate.

Industry commenters proposed that paragraph (c) of proposed § 773.26 be modified to provide that a person challenging the presumption be able to prove that the agency relied upon incorrect facts to support its determination of ownership or control; that the person subject to the presumption did not have knowledge of the violation, did not authorize the activity that led to the violation, or did not have direct authority to determine the manner in which surface coal mining operations were conducted; or that the ownership or control link has been severed.

OSM appreciates the commenters' proposal. Nevertheless, OSM will not adopt the commenters' proposed modifications for the following reasons.

The provisions of paragraph (c)(1)(i) of proposed § 773.26 already contain language providing for a challenger's proof that the facts relied upon by regulatory authority to make a determination of ownership or control did not or do not exist. Such language is inclusive of the commenters' proposal that a challenger be allowed to submit proof that the agency relied upon incorrect facts to support its determination of ownership or control.

Further, the language contained in OSM's proposed regulation would also encompass the commenters' proposal that a challenger be able to provide proof that an ownership or control link has been severed. Under paragraph (c)(1)(i) of the proposed regulation, such proof would be included as evidence that the facts relied upon by the regulatory authority to establish ownership or control or a presumption of ownership or control did not or do not exist. Whether such proof is sufficient to support a successful challenge to an ownership or control link will depend upon the facts of each case. OSM must reject the implication of commenters' proposal that the severance of a current ownership or control link to a violator would relieve a person from permit block in all cases. For instance, if a person was an owner or controller of a violator during the period in which the violation was committed, severance of his or her current ownership or control relationship with the company would not relieve him or her of responsibility created through the prior ownership or control link.

OSM must further reject commenters' proposal to the extent that it would establish a standard which would enable a challenger of an ownership or control link to a violation to challenge the link by proof that he lacked knowledge of the violation; that he did not authorize the activity which led to the violation; or that he did not have direct authority to determine the manner in which surface coal mining operations were conducted. Commenters' proposal must be rejected because it ignores the control which stems from indirect authority.

OSM agrees that all of commenters' proposed standards invoke factual matters which may be relevant when a regulatory authority considers an ownership or control link to a violation. As such, proof of each of these matters could be presented within the context of the presentation of facts made under paragraph (c) of proposed § 773.26. For instance, proof presented that a person had no knowledge of a violation; that he or she did not actually authorize a violation; or that he or she did not have direct authority for the surface coal mining operation may well reflect on the contours of the person's responsibilities with a presumptively owned or controlled entity. Nevertheless, such facts may also constitute a false shield which has been created to conceal the substantive, indirect control that the person has over a surface coal mining operation. Commenters' proposal is flawed, therefore, because it would enable a challenger to successfully challenge an ownership or control link by simply proving lack of actual knowledge, actual authority, or direct control, without requiring proof that a presumed owner or controller also lacked indirect authority over the surface coal mining operation.

Industry commenters further proposed a modification to paragraph (c)(1)(iii) of proposed § 773.26. In OSM's proposal, that paragraph prohibited a challenge as to the existence of the violation within the context of a challenge to an ownership or control link or a challenge to the status of the violation. Commenters proposed changes to allow a challenge as to the existence of the violation at the time it was cited. For the reasons discussed with respect to this issue in the section of this preamble captioned "Due Process" and in the previous discussion of changes made to final § 773.20, OSM has generally rejected commenters' proposal but has accepted such proposal with respect to the improvident permit issuance process. Also, at the time of permit denial, a permit applicant can appeal any reason for such denial including the existence of a violation assuming that the applicant is not bound by a prior administrative or judicial determination or has not had a prior opportunity to challenge the existence of the violation. Accordingly, OSM has amended paragraph (c)(1)(iii) of final rule § 773.25 to clarify that a challenge may be made by a permittee acting within the context of the improvident permit issuance process under §§ 773.20–773.21. This is in recognition of the more significant interest that a permittee has in a permit compared to the limited interest that an applicant has in a permit application. A

permittee's ability to assert such a challenge will be limited, however, if he or she had a prior opportunity to challenge the violation notice and failed to do so in a timely manner or if he or she is bound by a prior administrative or judicial determination concerning the existence of the violation.

A commenter representing State regulatory authorities indicated concern that paragraph (c) of proposed § 773.26 contained legal terms such as "prima facie determination," proof "by a preponderance of the evidence," and "probative, reliable, and substantial evidence" without providing definitions of such terms. The commenter indicated that all of these terms have "particular legal meanings." He urged that the proposed regulation be amended to incorporate definitions of such terms, "consistent with their common legal meanings."

OSM appreciates the commenter's proposal. OSM disagrees, however, with commenter's view that the cited terms need formal definition in the proposed regulation. As commenter has correctly noted, each of the cited terms has a traditional, common legal meaning. In a proceeding to challenge an ownership or control link or the status of a violation, such terms would have their traditional legal meanings. It is anticipated that such meanings will further evolve on a case by case basis over time. Finally, with respect to the terms "probative, reliable, and substantial" as such terms describe evidence, paragraph (c)(2) of proposed § 773.26 provides some examples of this type of evidence.

A commenter representing a State regulatory authority criticized the provisions of paragraph (c)(2)(ii) of the proposed regulation because such provisions would potentially allow a challenger of an ownership or control link to present evidence to a tribunal reviewing a decision of a regulatory authority which had not previously been presented to the regulatory authority. The commenter proposed a modification to the regulation such that any evidence presented on appeal by a challenger be limited to that which was presented to the regulatory authority at the time when the decision being reviewed was made. The commenter proposed that evidence which was not reasonably available to the challenger at the time of the regulatory authority's decision could, however, be presented for the consideration of the reviewing tribunal.

OSM appreciates the commenter's proposal. One legitimate approach to the process of such challenges might be to limit the presentation of evidence on review to that which had been previously presented to the regulatory authority which made the decision which has been subjected to review. OSM believes, however, that the better approach is to allow the presentation of any evidence admissible under the rules of the reviewing tribunal, including evidence which was not previously presented to the regulatory authority. This will assure that the review of the decision with respect to the ownership or control link or the status of a violation is based upon the most complete evidence available to all parties participating in the review process. Such a review will help assure that all parties have the opportunity to present their complete proof with respect to their respective positions in what is, substantively, a de novo proceeding. Such complete evidence presentation and review may aid the legitimacy and acceptance of any final decision made incident to such review.

Further, OSM disagrees with the view that such a process might encourage a challenger to withhold relevant evidence for surprise presentation at a subsequent review proceeding. A challenger will have sufficient incentive to overcome a presumed ownership or control link at the earliest possible time because he or she will want to avoid permit blocks or further litigation. Accordingly, he or she can be expected to present the best evidence available to make the case in favor of overcoming the presumed ownership or control link. Thus, OSM must reject the commenter's suggested modification to the proposed regulation.

A number of commenters criticized paragraph (c)(2) of the proposed regulation for allowing the use of affidavits in support of a challenge to an ownership or control link or to the status of a violation. The commenters asserted that such materials contain self-serving statements and are unreliable. The commenters further asserted that affidavits should not be the basis to overcome a presumption, in the absence of additional evidence supporting such affidavits. The commenters proposed various modifications to the proposed rule which would require the submission of additional information when affidavits are presented in support of a challenge to an ownership or control link. In this respect, one commenter proposed a "best evidence" rule which would not allow the presentation of affidavits when there was "better" documentary evidence available, such as official copies of corporate records previously filed with State corporation commissions.

OSM appreciates the commenters' concern with respect to affidavits. Nevertheless, affidavits do have certain indicators of reliability. They are made under oath before a government official licensed to witness such oaths, a notary public. Further, affidavits are recognized as evidence sufficient to support a motion for summary judgment in civil litigation. *See* Rule 56 of the Federal Rules of Civil Procedure. Accordingly, OSM continues to consider affidavits as appropriate evidence for a regulatory authority's review in the evaluation of a challenge to an ownership or control link.

Nevertheless, OSM agrees that, in most cases, an affidavit unsupported by other evidence may be insufficient to overcome a presumption of ownership or control. There could be rare circumstances, however, where an affidavit by itself could be the basis for rebuttal, given the totality of the circumstances involved. Such matters are appropriately addressed on a case by case basis, rather than through a rule. Under the proposed rule, challengers are encouraged to submit additional evidence along with affidavits.

Accordingly, OSM will not modify the proposed regulation to delete the use of affidavits or to require that affidavits only be allowed as proof if accompanied by other supporting evidence in every case. Also, while OSM agrees that State corporation commissions may be a good source of relevant ownership or control information, OSM declines to adopt a "best evidence" test which would prevent the submission of affidavits when documents have been filed with State corporation commissions.

One commenter representing environmental advocacy groups criticized paragraph (c)(2)(i)(D) of proposed § 773.26 insofar as the provisions allowed for the submission of an opinion of counsel in support of a challenge with respect to an ownership or control link or with respect to the status of a violation. In substance, the commenter asserted that such opinions present no factual evidence for the regulatory authority. Such opinions of counsel represent legal opinions with respect to ownership or control and invade the province of the decisionmaker, the regulatory authority.

OSM agrees that an opinion of counsel should not, in itself, be considered "evidence." Indeed, opinions of counsel constitute legal analysis based upon factual information. Both proposed and final regulations require that such opinions "be supported by evidentiary materials."

Nevertheless, OSM must disagree that such opinions should be excluded. By providing an opportunity for the submission of such opinions, OSM is seeking to encourage counsel to conduct a diligent investigation of the facts and to assist regulatory authorities by presenting the fruits of such investigation—the factual materials—along with counsel's legal opinions as to the import of such evidence. The decision as to the weight to be given to the evidentiary materials and the persuasiveness of the counsel's opinions remain with the regulatory authority considering the challenge to the ownership or control link. Lawyers routinely argue their clients' positions to triers of fact and law. Such argument does not invade the province of the decisionmaker which retains the authority to make the decision.

OSM has decided to allow for a challenger's submission of an opinion of counsel in support of his or her position as part of final § 773.25. Such opinion would be appropriate for submission when it is supported by evidentiary materials; when it is rendered by an attorney who certifies that he or she is qualified to render an opinion of law; and when counsel states that he or she has personally and diligently investigated the facts of the matter or where counsel states that such opinion is based upon information which has been supplied to counsel and which is assumed to be true.

Whereas the proposed rule only provided for such opinion when counsel made a personal investigation of the facts, the final rule incorporates language to provide for opinions where such investigation has not been made. The basis for this change is to reflect that, under certain circumstances, attorneys might not choose to conduct a complete personal investigation of the factual representations made within the opinion. See Formal Opinion 346 (Revised), Tax Law Opinions in Tax Shelter Investment Offerings, Standing Committee on Ethics and Professional Responsibility, American Bar Association (January 29, 1982).

Such opinion is similar in type to that provided by counsel to an adversary party as to title, tax issues, or environmental compliance in real estate transactions. The indicator of reliability in this document is that the attorney is offering his or her opinion subject to professional standards provided by national and local bar associations and possible sanctions for the violations of such standards which may be imposed by applicable rules of conduct governing attorneys. In addition, under the final regulation, the attorney's opinion by itself is not enough to challenge an ownership or control link. Evidentiary materials need to be submitted along with such opinion.

In addition to the substantive change noted above, OSM has made non-substantive changes to the provision which clarify the requirements of the final rule provision. Accordingly, OSM has adopted the proposed rule with the changes noted as paragraph (c)(2)(i)(D) of final § 773.25.

As described above, paragraph (d) of proposed § 773.26, required proof for the rebuttal of ownership or control presumptions, represented OSM's attempt to offer substantive standards which would have established what must be proved by those seeking to rebut the presumptions of ownership or control contained in current § 773.5(b) of this title. Proof of the type of facts set forth in the proposed regulations would have established that the presumed owner or controller did not, in fact, have the authority directly or indirectly to determine the manner in which the relevant surface coal mining operation was conducted, under the provisions of 30 CFR 773.5(b).

OSM has determined not to go forward with paragraph (d) of proposed § 773.26 and has, therefore, withdrawn that portion of the proposed rule. In substance, OSM believes that ownership and control determinations are inherently a case specific process. Each ownership or control matter turns on the totality of circumstances in a given case and whether the evidence presented demonstrates that the presumed owner or controller does not or did not, in fact, have the authority directly or indirectly to determine the manner in which the relevant surface coal mining operation was conducted. See 30 CFR 773.5(b)(1). The pragmatic focus of such an inquiry will continue to be whether a presumed controller actually exercised control over an entity or had the substantive power to exercise control over an entity, even if he or she chose not to actually exercise such power. As OSM has stated previously in the preamble to 30 CFR § 773.5(b), "To the extent that a coal company *controls or can exercise control over a contract operator, it should be held responsible* for any outstanding violations of the Act which it should have prevented or corrected." (Emphasis added.) See Preamble to Requirements for Surface Coal Mining and Reclamation Permit Approval; Ownership and Control; Final Rule, 53 FR 38868 at page 38877 (October 3, 1988). In effect, a person challenging a presumption of control must demonstrate, by a preponderance of the evidence, that neither of these two circumstances is applicable.

While it might be initially attractive for the agency to create a standard containing three or four elements, the proof of which automatically rebuts a presumption, OSM is unwilling to impose such potentially rigid substantive tests upon the process of analyzing ownership or control cases. OSM believes that such rigid standards do not serve the interests of the States, industry, or OSM, because they might be taken to preclude consideration of other rebuttal evidence not listed or, conversely, might force a State regulatory authority to accept a rebuttal which conforms substantially to OSM's model but which, in the opinion of the regulatory authority, does not in fact rebut the presumption. OSM's experience has taught that each ownership or control rebuttal requires an analysis of the presumed relationship within the complete factual context.

Accordingly, in analyzing the ownership or control profile of an entity, OSM will look to the totality of circumstances—with the view to understanding how a particular entity operates and operated—to determine the true owners or controllers of a surface coal mining operation.

Commenters representing environmental advocacy groups asserted that the rules should provide that any documents submitted by persons challenging presumptions of ownership or control be considered part of the public record and part of the permit file. On the other hand, industry commenters argued that the rules are deficient because they do not contain a provision by which documentation submitted could be held confidential. They further asserted that there was no means for a challenger to obtain a protective order with respect to confidential materials submitted in support of a challenge.

OSM agrees that documents submitted in support of a challenge to an ownership or control link or in support of a challenge to the status or the existence of a violation should normally be considered part of the public record. The public has a legitimate interest in knowing and understanding the basis for a regulatory authority's decisions in these matters. In a democracy, it is unreasonable for a governmental agency to make such decisions based upon secret information. Further, the credibility of the regulatory authority and the integrity of its decisionmaking process require that its decisions be supported by an adequate record.

At the same time, OSM also recognizes that there may be valid competitive reasons why industry operators believe that certain information needs to be kept confidential. For instance, a person may not wish to reveal the price which he or she has paid for the coal extracted by a mine contractor for fear that other contractors or competitors will learn of this information and change their prices or bids to the disadvantage of the person revealing the information. A person concerned about such disclosure may be reluctant to submit a copy of the relevant contract because it contains the agreed price. OSM disagrees; however, that these industry concerns require special provisions in the rules to seal documents or to otherwise protect confidentiality.

In balancing the concerns of the public and the coal industry with respect to public access to the submitted documents, OSM will be guided by the principles of the Freedom of Information Act, 5 U.S.C. 552 (FOIA), and the Departmental regulations implementing FOIA. See 43 CFR 2.11–2.22. Upon request by a member of the public, OSM will ordinarily make available to the requestor documents provided by challengers of ownership or control links, the status of violations, and the existence of violations. To the extent that a person submitting information to OSM asserts that the materials should be kept confidential, OSM will evaluate that request in accordance with the applicable provisions of FOIA.

In accordance with the above analysis, OSM has determined that the interests of the commenters can be addressed under current law and that the rule does not need to be modified.

In accordance with the above discussion, OSM has determined to adopt a final version of the proposed rule. The final rule has been renumbered as § 773.25 to reflect the withdrawal of proposed § 773.25, procedures for challenging ownership or control links prior to entry in AVS. As indicated above, OSM has modified the provisions of the proposal to allow for the submission of an opinion of counsel based upon evidence developed through counsel's personal investigation or based upon facts which have been supplied to counsel in support of a challenge of an ownership or control presumption. As further discussed above, OSM has inserted language in paragraph (c)(1)(iii) to clarify that a permittee may challenge the existence of the violation at the time it was cited within the context of improvident permit issuance as provided by §§ 773.20 and 773.21. OSM has also withdrawn paragraph (d) of the proposed rule, required proof for the rebuttal of ownership or control presumptions, described above. The final rule contains no other substantive changes from proposed rule § 773.26. The final rule contains certain other non-substantive modifications as described below.

Paragraph (a) of final § 773.25 provides that provisions of § 773.25 are applicable to any challenge concerning an ownership or control link or the status of a violation when such challenge is made under the provisions of 30 CFR 773.20 and 30 CFR 773.21 (improvidently issued permits); §§ 773.23 (the regulatory authority's review of ownership or control and violation information), and 773.24 (procedures for challenging ownership or control links shown in AVS); or under 30 CFR part 775 (administrative and judicial review of permitting decisions).

Paragraph (a) of the final rule differs from the proposed rule in that references to proposed § 773.25, procedures for challenging ownership or control links prior to entry in AVS, have been deleted. A further change in this paragraph from the proposed rule provides that the provisions of final § 773.25 apply to challenges of an ownership or control "link to any person" rather than only to a "link to any person in a violation notice." The purpose of this change is to clarify that the provisions of the section apply to challenges of ownership or control links including those which do not generate a current link to an outstanding violation. OSM's experience has demonstrated that members of the regulated community have, in many cases, sought proactively to challenge ownership or control links to other persons, without regard to whether there were outstanding violations. Such challenges have been asserted, among other reasons, to avoid the risk of being linked to future violations through such ownership or control relationships. OSM recognizes that this is a legitimate concern. Accordingly, the change in the final rule allows the challenge of ownership or control links without regard to whether there are outstanding violations.

Paragraph (a)(2) of final § 773.25 contains a further change from the proposed rule in that the regulation provides that the provisions of the rule apply to challenges of "the status of *any* violation covered by *a* notice." (Emphasis added.) The comparable section of the proposed regulation provided that the regulation applied to the status of "the violation covered by such notice." The purpose of the change is to recognize that there may be multiple violations, rather than a single violation, to which a person is linked through ownership or control. A person may wish to challenge the status of each of these violations, rather than only the violation contained in a single notice. If so, the provisions of final § 773.25 apply to such challenges. Consistent with this change, "such notice" is changed to "a notice."

Paragraph (b) of final § 773.25 provides the basic allocation of responsibility among regulatory authorities to make decisions with respect to ownership or control and with respect to the status of violations. State regulatory authorities are expected to have procedures in place to address challenges made in accordance with these rules, including in situations where there are ongoing State proceedings in other jurisdictions on permit applications.

Paragraph (b)(1)(i) if final § 773.25 provides that the regulatory authority before which an application is pending has "responsibility" for making decisions with respect to the "ownership or control relationships of the application." This represents a change of terminology from the comparable provision of the proposed rule which provided that the regulatory authority would have "authority for making decisions with respect to the ownership or control of the applicant."

First, the use of the word "responsibility," rather than "authority," more accurately describes the regulatory authority's mandate under this regulation. "Responsibility" encompasses both authority, the power to act, and the obligation to act.

Further, paragraph (b)(1)(i) of final § 773.25 speaks of "ownership or control relationships of the application," rather than of the "ownership or control of the applicant," as provided in the proposed rule. This change clarifies that the regulatory authority before which an application is pending will evaluate and make decisions with respect to the ownership and control issues with respect to an entire application, rather than just the particular applicant, consistent with this regulatory authority's primary responsibility for the application. This regulatory authority has responsibility for revising ownership or control information submitted as part of the permit application and other available information to ensure the complete identification of ownership or control relationships relevant to the decision to be made with respect to the application.

The word "relationships" has been added to the regulation because it better explains the focus of this process.

Paragraph (b)(1)(ii) of final § 773.25 provides that the regulatory authority that issued a permit has responsibility for making decisions with respect to the ownership or control relationships of the permit. The regulatory authority which issued a permit would have done so based upon a complete review of ownership or control information as required by the regulations. In the event that the improvidently issued permit regulations of 30 CFR 773.20 and 773.21 are invoked, this regulatory authority will have to decide whether such permit has been improvidently issued and whether, if the basis for such improvident issuance was an ownership or control link to a violator, whether such improvident issuance has been remedied. Accordingly, that regulatory authority must make decisions with respect to ownership or control relationships incident to the permit.

In paragraph (b)(1)(ii) of final § 773.25, "responsibility" has replaced the word "authority" contained in the proposed rule. The reasoning provided with respect to the changes made to paragraph (b)(1)(i) of the final rule is applicable here. Again, the regulatory authority will be making decisions "with respect to the ownership or control relationships of the permit, "rather than with respect to the ownership or control of the permittee," as provided in the proposed rule. This reflects that regulatory authority's primary responsibility for the permit which it has issued.

Paragraph (b)(1)(iii) of final § 773.25 provides that the State regulatory authority that issued a State violation notice has responsibility for making decisions with respect to the ownership or control relationships of the violation. The State regulatory authority issuing the violation is in the best position to be aware, in the first instance, of operative facts which identify those owners or controllers who have the "authority directly or indirectly to determine the manner in which the relevant surface coal mining operation is conducted" and who can thus cause the abatement of the violation. See 30 CFR 773.5(b).

As in paragraph (b)(1)(i) of final § 773.25, "responsibility" has replaced the word "authority" contained in the proposed rule. The reasoning provided with respect to these changes in paragraph (b)(1)(i) of the final rule is applicable here. Again, the regulatory authority will be making decisions "with respect to the ownership or control relationships of the violation," rather than "with respect to the ownership or control of any person cited in such notice [of violation]," as provided in the proposed rule.

Paragraph (b)(1)(iv) of the final § 773.25 provides that the regulatory authority that issued a violation notice, whether State or Federal, would have responsibility for making decisions concerning the status of the violation covered by the notice. As in paragraph (b)(1)(i) of the final rule, "responsibility" has replaced the word "authority" previously contained in the proposed rule. The reasoning provided with respect to the similar change in paragraph (b)(1)(i) of this final rule is applicable here.

As in the proposed rule, the "status" of the violation means whether the violation remains outstanding, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, within the meaning of 30 CFR 773.15(b)(1). This approach is consistent with the provisions of section 510(c) of SMCRA which require that a regulatory authority considering a permit application look to the "agency that has jurisdiction over such violation" to determine whether a violation "has been or is in the process of being corrected."

Paragraph (b)(2) of final § 773.25 provides that OSM has responsibility for making decisions with respect to the ownership or control relationships of a Federal violation notice.

As in paragraph (b)(1)(i) of final § 773.25, "responsibility" has replaced the word "authority" contained in the proposed rule. The reasoning provided with respect to this change in paragraph (b)(1)(i) is applicable here.

Paragraph (b)(2) of final § 773.25 is essentially a Federal counterpart to paragraph (b)(1)(iii) and the same basic rationale applies here, as well. This provision differs from (b)(1)(iii), however, in that OSM's authority to decide the ownership and control relationships of a Federal violation notice is not initial responsibility as the State's responsibility is in (b)(1)(iii). Instead, OSM's responsibility is final.This difference recognizes that State regulatory authorities are subject to oversight by OSM. OSM is not subject to similar oversight by the States.

Under the allocation principles set forth in paragraphs (b)(1) and (b)(2) of final § 773.25, a regulatory authority deciding whether a permit application should be granted or whether a permit has been improvidently issued determines for itself the ownership or control relationships of the application or permit, but it defers to the regulatory authority that issued a violation notice for a determination of the ownership or control relationships of the violation. The application is then denied or the permit subject to treatment under the regulations governing improvident issuance if any owner or controller of the applicant or permittee is also an owner or controller of a violator, as determined by the respective regulatory authorities.

Paragraph (b)(3)(i) of final § 773.25 provides that with respect to information shown on AVS, the responsibility of State regulatory authorities to make decisions concerning ownership or control links will be subject to the plenary authority of OSM. This represents a change from the comparable provision of the proposed rule which provided that the authority of regulatory authorities to make ownership or control decisions with respect to applicants, permittees, and persons cited in violation notices and decisions with respect to the status of violations would be subject to OSM's review as an element of State program oversight under parts 733, 842, and 843.

The rationale for this change is simply that OSM is ultimately responsible for the maintenance and content of the AVS with respect to ownership or control information. OSM believes that the quality of ownership or control information is the core of AVS. OSM must closely monitor such information to maintain the accuracy of such information and the integrity of AVS. The need to protect the integrity of the AVS dictates that OSM have the ability to review the underlying basis supporting any ownership or control link shown on the system and to change information with respect to any ownership or control link or all such links, if necessary. Accordingly, the final rule provides that OSM's authority will be plenary with respect to ownership or control information shown on AVS.

Thus, once ownership or control information is entered into AVS, OSM will assume control of such data. If OSM reviews such information and concludes that it is incorrect, OSM will act to correct such ownership or control information and incorporate such corrected information into AVS. OSM intends to coordinate any such changes with the regulatory authority responsible for initial entry of the data in question.

Under paragraph (b)(3)(ii) of final § 773.25, with respect to information shown on AVS relating to the status of a violation and with respect to ownership or control information which has not been entered into AVS by a State, the authority of a State regulatory authority will be subject to OSM's

program oversight authority under 30 CFR parts 733, 842, and 843. OSM relies primarily upon the States to determine whether State violations have been abated or not. SMCRA section 510(c) explicitly states that an applicant must demonstrate that any current violation "has been corrected or is in the process of being corrected to the satisfaction of the regulatory authority, department, or agency which has jurisdiction over such violation * * *" See also 30 CFR 773.15(b)(1).

Further, where State ownership or control information has not yet become part of AVS, the information has not yet entered the Federal information stream and has not yet become OSM's immediate responsibility. Such information is, in effect, still the primary responsibility of the State regulatory authority and potentially subject to correction through procedures of the State regulatory program. If correct information fails to enter the AVS, that may represent a weakness of the regulatory authority's decisionmaking process. Accordingly, that process may require review. With respect to the State's decisionmaking process, principles of primacy require that OSM review State actions in these matters in accordance with OSM's program oversight under parts 733, 842, and 843. In the exercise of program oversight however, it is also probable that OSM would review particular decisions with a view to determining whether the State regulatory authority complied with the provisions of its approved program. Accordingly, in the event that a State determines not to enter an ownership or control link into AVS, OSM will review such decision when it has reason to believe, through information provided in a citizen's complaint or otherwise, that the State's ownership or control decision is arbitrary, capricious, or an abuse of discretion under the State program.

In final § 773.25, OSM has deleted language contained in the proposed rule which would have provided that when OSM disagreed with the decisions of State regulatory authorities, OSM would take action, as appropriate, under § 843.24, oversight of State permitting decisions with respect to ownership or control or the status of violations. This language has been deleted for two reasons. First, the proposed language was redundant. Paragraph (b)(3)(ii) of final § 773.25 already provides that State regulatory authorities' decisions are subject to OSM's oversight under parts 733, 842, and 843 of 30 CFR. As a section of part 843, the provisions of final § 843.24 would thus be applicable under appropriate circumstances. Further, the agency was concerned that additional language specifically requiring OSM to take action under final § 843.24 could somehow be construed as a limiting factor on OSM's authority to take action under parts 733 or 842 or under other sections of part 843 as provided by previous paragraph (b)(3)(ii) or 773.25.

Paragraph (c) of final § 773.25 establishes evidentiary standards applicable to the formal and informal review of ownership or control links and the status of violations. The provisions of the final section are substantively similar to the provisions of the comparable provisions of the proposed rule. Certain minor changes described below have been made to the proposal.

Paragraph (c)(1) of final § 773.25 provides that in any formal or informal review of an ownership or control link or of the status of a violation covered by a violation notice, the agency responsible for making a decision is required to first make a prima facie determination or showing that the link exists, existed during the relevant period, and/or that the violation remains outstanding. The language "existed during the relevant period" has been added to the final rule to clarify that, even when a person is not a current owner or controller of a surface coal mining operation, a previous ownership or control link to that operation may be the basis for permit denial where the surface coal mining operation has an outstanding violation and that violation had its inception during the previous period of ownership or control. The requirement of a prima facie determination or prima facie showing is satisfied by evidence presented establishing a presumption of ownership or control. A prima facie determination is made when the agency is reviewing the evidence itself, in an informal process; a prima facie showing is made when the agency's determination is the subject of a formal administrative or judicial review process. When the agency makes such a determination or showing, the person seeking to challenge the link or the status of the violation than has the burden of proving the necessary elements of his or her challenge to the link or to the status of the violation by a preponderance of the evidence.

Also, in the comparable provision of the proposed rule, the rule language referred to the evidentiary standards applicable to the review of ownership or control links "to a person cited in a violation notice." The final rule has been changed to reflect that these standards will be applicable to the review of an ownership or control link, without regard to whether such relationship involves a link to an outstanding violation. The rationale for such a change has been explained previously in this preamble in the discussion of a similar change made in paragraph (a)(1) of this final rule section. As in the proposed rule, where there is a link to a violation, these evidentiary standards will apply to the review of the status of a violation.

Paragraph (c)(1) of final § 773.25, requires a challenger of an ownership or control link to prove at least one of three proposed conclusions by a preponderance of the evidence to succeed in his or her challenge.

Under paragraph (c)(1)(i) of final § 773.25, a challenger can demonstrate that the facts relied upon by the responsible agency to prove ownership or control under the definitions of "owned or controlled" or "owns or controls" contained in 30 CFR 773.5 do not or did not exist. The final regulation differs from the comparable provision of the proposed regulation in that while the final regulation refers to 30 CFR 773.5, it does not specifically cite particular paragraphs of 30 CFR 773.5 defining presumed and deemed relationships of ownership or control. On June 28, 1993, OSM proposed rules which, if adopted, would modify the organization of regulatory language in 30 CFR 773.5. See Proposed Rule, 58 Fed. Reg. 34652 (June 28, 1993). By changing the language in paragraph (c)(1)(i) of final § 773.25 to delete references to the current paragraph organization of 30 CFR 773.5, OSM retains the flexibility to adopt or reject its rule proposal of June 28, 1993, without having to further modify final § 773.25.

Paragraph (c)(1)(ii) of final § 773.25 provides that a person challenging a presumption of ownership or control can prove that the person subject to the presumption does not and did not have authority directly or indirectly to determine the manner in which surface coal mining operations were conducted. The final rule deletes a reference contained in the proposed rule to the paragraph (d) of the proposed rule which provided the required proof for the rebuttal of ownership or control presumptions. As indicated above, that portion of the proposed rule has been withdrawn.

Paragraph (c)(1)(iii) of final § 773.25 provides that a challenger can prove that the violation covered by a violation notice did not exist, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal within the meaning of 30 CFR

773.15(b)(1). The final rule provides that a person challenging the status of a violation under § 773.24 will not be able to challenge the existence of the violation at the time it was cited unless such challenge is made by a permittee within the context of §§ 773.20–773.21 of this part. As indicated previously, the proposed rule did not explicitly allow challenge of the existence of the violation by a permittee within the context of improvident permit issuance. The proposed rule also did not include the words "at the time it was cited" with respect to the concept "existence of the violation." The final rule has provided such clarification. Also, references to proposed § 773.25, procedures for challenging ownership or control links prior to entry in AVS, have been deleted. In addition, while no further substantive change has been made to the text of paragraph (c)(1)(iii) of final § 773.25, some editing has been done to clarify the parallel construction of the regulatory text.

Under the provisions of final § 773.25, the existence of the violation at the time it was cited could also be challenged in a proceeding under 30 CFR part 775 (involving administrative or judicial appeals of permitting decisions), unless the challenger has failed to take timely advantage of a prior opportunity to litigate the violation or is bound by a previous administrative or judicial determination concerning the existence of the violation.

In addition, certain minimal changes have been made to the proposed rule with respect to the submission of documents in the proof of challenges. Paragraphs (c)(2)(i)(B) and (c)(2)(i)(C) of proposed § 773.26 provided that certified copies of corporate documents and certified copies of documents filed with or issued by State, Municipal, or Federal government agencies could be submitted. Paragraphs (c)(2)(i)(B) and (c)(2)(i)(C) of final § 773.25 clarify that copies of such documents can be submitted only "if certified."

Paragraph (c)(2)(i)(D) of final § 773.25 provides for a challenger's submission of an opinion of counsel in support of his or her position. Such opinion would be appropriate for submission when it is supported by evidentiary materials; when it is rendered by an attorney who certifies that he or she is qualified to render an opinion of law; and when counsel states that he or she has personally and diligently investigated the facts of the matter or where counsel states that such opinion is based upon information which has been supplied to counsel and which is assumed to be true.

In accordance with the discussion above, the proposed rule has been renumbered as final rule § 773.25 and adopted as modified.

Deferral of action on proposed § 773.27—Periodic Check of Ownership or Control Information. In the September, 1991 proposed rule package, OSM proposed this section which would have required that the regulatory authority engage in periodic review of a permitted site to assure that basic ownership and control information contained in the current official record of the permit was and remains complete and accurate. Subsequent to the publication of that proposal, OSM published a modified version of such proposal as part of a comprehensive rule proposal designed to address permit information requirements; ownership or control; and the transfer, assignment and sale of permit rights. See 58 FR 34652, 34666 (June 28, 1993). OSM intends to address the proposed rule within the context of the subsequent rulemaking. Accordingly, OSM defers any decision with respect to this proposed rule.

3. Part 778—Permit Applications—Minimum Requirements for Legal, Financial, Compliance, and Related Information

Deferral of action on proposed § 778.13—Identification of Interests. In the September, 1991 proposal, OSM proposed to revise the provisions of paragraphs (c) and (d) of then current 30 CFR 778.13 to clarify that permit applicants would be required to disclose relevant information with respect to both "deemed" and "presumed" owners or controllers within the meaning of the definitions of "owned or controlled" and "owns or controls" under 30 CFR 773.5 (a) and (b), respectively.

Subsequent to the publication of that proposal, OSM published a new proposed amendment to 30 CFR 778.13 as part of the comprehensive rule proposal cited above which was designed to address permit information requirements; ownership or control; and the transfer, assignment and sale of permit rights. See 58 FR 34652, 34668 (June 28, 1993). Accordingly, OSM hereby defers any decision with respect to the amendments proposed to 30 CFR 778.13 in today's rulemaking. Instead, OSM will address proposed amendments to 30 CFR 778.13 within the context of that subsequent proposal.

Section 778.14—Violation information. The proposed amendment would have provided that the introductory language in paragraph (c) of 30 CFR 778.14 be amended to require a permit applicant to disclose all violation notices received by the applicant within the preceding three years. In addition, such introductory language would have been amended to require the disclosure of all outstanding violation notices for any surface coal mining operation that is deemed or presumed to be owned or controlled by either the applicant or by any person who is deemed or presumed to own or control the applicant under definitions of "owned or controlled" or "owns or controls" under 30 CFR 773.5.

The regulation to be amended required the applicant to disclose violations of various laws listed in 30 CFR 778.14(c). Use of the proposed amended definition of "violation notice" from 30 CFR 773.5 would have obviated the need for such a list.

The regulation to be amended further required that the applicant provide only a list of unabated cessation orders and unabated air and water quality violation notices received prior to the date of the application by any surface coal mining and reclamation operation owned or controlled by either the applicant or by any person who owns or controls the applicant. With respect to this second list, that regulation did not require that an applicant list notices of violation received or unpaid penalties or fees incurred by any surface coal mining operation owned or controlled by the applicant or by any person who owns or controls the applicant.

Moreover, in litigation relating to §§ 778.14, 773.15(b)(1), and related matters before the U.S. District Court of the District of Columbia, the Secretary advised the court that he had decided to reconsider § 778.14(c). The Secretary stated that he intended to propose a regulation "which considers the extent to which violation information should be reported concerning owners and controllers of applicants as well as entities owned or controlled by the applicant." See *National Wildlife Fed'n v. Lujan*, No. 88–3117–AER (D.D.C.), Memorandum of Points and Authorities in Support of the Federal Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment, footnote 33, at page 90.

Consistent with the representation made to the court, the proposed amendment to paragraph (c) of § 778.14 would have required an applicant to disclose all outstanding violation notices received by any surface coal mining operation that was deemed or presumed to be owned or controlled by either the applicant or any person who was deemed or presumed to own or control the applicant.

Commenters representing members of the coal industry expressed concern over the proposed amendment to 30 CFR 778.14(c) for essentially three reasons. They asserted that the proposed amendment impermissibly expanded the types of violations which must be reported by an applicant by incorporating the newly amended definition of "violation notice" as the basis for reporting; that the proposal inappropriately expanded the definition of "owners or controllers" which must be reported; and that the proposal inappropriately expanded the type of information required for operations linked through ownership or control.

OSM disagrees with the commenters' assertions. First, the proposed regulation does incorporate the new definition of the term "violation notice" which had been proposed, and has now been adopted, in § 773.5. The new definition of violation notice, however, is not overly broad. In this preamble, OSM has already responded to similar comments made with respect to this definition in the section of this preamble captioned "Section 773.5—Definitions."

By incorporating the amended definition of "violation notice," the proposed amendment to paragraph (c) of § 778.14 would have incorporated the list and types of violations which are relevant to a regulatory authority's decision whether to issue a permit under section 510(c) of the Act and under the provisions of 30 CFR 773.15(b)(1). In contrast to this, the unamended version of the regulation did not require that an applicant list unpaid penalties or fees incurred by any surface coal mining operation owned or controlled by the applicant or by any person who owns or controls the applicant. Accordingly, the proposed amendment would expand what has to be reported to enable the regulatory authority to have necessary information to make its decision. It is entirely appropriate to require that a permit applicant report such information to the regulatory authority so that the regulatory authority can make an informed decision.

As indicated above, commenters further asserted that the proposal inappropriately expanded the definition of "owners or controllers" by requiring the reporting of all outstanding violations received prior to the date of permit applications by surface coal mining operations deemed or presumed to be owned or controlled by the applicant or by any person who owns or controls the applicant. The commenters asserted that this placed the applicant in an untenable position. OSM disagrees with this assertion.

Even if 30 CFR 778.14(c) would not be amended by the proposal, the regulation already required the reporting of violations of surface coal mining operations which the applicant is deemed or presumed to own or control under the provisions of 30 CFR 773.5. Such reporting is required even if the applicant believes that he or she can rebut the presumption of ownership or control. The permit application is not forced to admit ownership or control. On the contrary, such reporting can be done by an applicant who, at the same time, reserves his or her rights to deny ownership or control. Even under current law, the applicant must disclose violations incident to the presumed ownership or control relationship so that the regulatory authority can evaluate this information. Thus, the amendment would just clarify what the regulation already does. Therefore, the amendment has not inappropriately expanded the definition of what constitutes surface coal mining operations owned or controlled by the applicant.

Commenters further asserted that the proposal inappropriately expanded the type of information required for operations linked through ownership or control. In substance, the commenters argued that the proposed regulation is overbroad and vague in requiring the reporting of "all outstanding violation notices" received prior to the date of application which are linked, through ownership or control, to the applicant. Again, OSM disagrees with the commenters.

As discussed previously in this preamble with respect to § 773.25 of the final rule, an "outstanding violation" is one which is currently in violation of the Act or of other laws specified in § 510(c) of the Act. Under the proposed amendment to 30 CFR 778.14(d), an "outstanding violation notice" is a written notification from a governmental entity advising of a violation which remains uncorrected. Such violations are the basis for permit denial unless an applicant can demonstrate that the violation is in the process of being corrected or is the subject of a good faith appeal, within the meaning of 30 CFR 773.15(b)(1). It is reasonable to require, prior to the date of application, that a permit applicant disclose such violations to the regulatory authority with respect to surface coal mining operations to which it is linked through ownership or control.

One commenter suggested that the proposed amendment should be modified to require only the reporting of violations which would subject an applicant to permit block. OSM considers this proposal to be too restrictive. For instance, under commenter's proposal, an applicant correcting a violation to the satisfaction of the agency which has jurisdiction over such violation would not report such violation at the time of application. Nevertheless, any permit to be issued should be conditioned upon the performance of the corrective work being accomplished. Absent the reporting of such violation by the applicant, a regulatory authority might overlook the violation and issue the permit unconditioned upon such performance. The same rationale would apply with respect to the reporting of violations which are the subject of good faith appeal, within the meaning of 30 CFR 773.15(b)(1). Accordingly, OSM must reject the proposed change.

In addition, commenters asserted that requiring such disclosure by large companies with multiple affiliates and multiple surface coal mining operations is overly burdensome. OSM believes that companies which own or control surface coal mining operations should be aware of the compliance status of such operations. If companies choose to engage in surface coal mining operations, they should also have the capability of monitoring such operations. It is reasonable to require the disclosure of outstanding violations. Thus, OSM disagrees with the commenters' assertion.

Nevertheless, OSM intends to further address the issues of compliance under 30 CFR 778.13 and 778.14. In a recently proposed rule package of June 28, 1993, OSM proposed the streamlining of companies' reporting under 30 CFR 778.13 and 778.14 through the use of information already incorporated into AVS. See 58 FR 34652 *et seq.* (June 28, 1993). Further, OSM's AVS Office stands ready to work with companies in the development of methods to report such companies' ownership or control relationships and to track the compliance of surface coal mining operations.

As indicated previously in the preamble discussion of final section 773.15, OSM has decided to retain a limited presumption that notices of violation are in the process of being abated for purposes of a regulatory authority's review of a permit application. OSM made this decision as result of comments received in response to its proposed rules. Accordingly, OSM has amended paragraph (b)(1) of final § 773.15 to provide that a regulatory authority may presume, in the absence

of a cessation order, that a notice of violation is in the process of abatement if certain conditions are present. These conditions include that the abatement period for the notice of violation has not yet expired and that the applicant has provided certification that such violation is in the process of being corrected to the agency with jurisdiction over the violation as part of the violation information provided pursuant to § 778.14. In accordance with that change made to final § 773.15, OSM has added language to paragraph (c) of final § 778.14 requiring that an applicant provide such certification along with his or her disclosure of violations.

In accordance with the above discussion, OSM has determined to adopt, with the modification noted, the proposed amendment to 30 CFR 778.14(c) as a final rule.

4. Part 840—State Regulatory Authority: Inspection and Enforcement

Section 840.13—Enforcement Authority. The proposed rule provided that paragraph (b) of 30 CFR 840.13 be amended to include a reference to proposed § 843.23 as an enforcement provision whose stringency must be matched by State programs. As has been stated previously in this preamble, OSM has deferred action on the adoption of proposed § 843.23 for a later rulemaking. See Proposed Rule, 58 FR 34652 *et seq.* (June 28, 1993). While OSM has adopted the reference to 843.23 for inclusion in paragraph (b) of 30 CFR 840.13, the adoption of such reference does not prejudge whether OSM will ultimately adopt proposed § 843.23 as a final rule.

5. Part 843—Federal Enforcement

Part 843—Table of Contents. In the September, 1991, proposal, OSM proposed to amend the Table of Contents of 30 CFR part 843 to add, in numerical order, the proposed regulations for the Federal enforcement of the proposed AVS-related regulations. The proposed additions would have included § 843.23, sanctions for knowing omissions or inaccuracies in ownership or control and violation information, and § 843.24, oversight of State permitting decisions with respect to ownership or control of the status of violations.

Subsequent to the publication of the proposed additions to the Table of Contents, OSM proposed a modified version of 843.23 as part of a separate rulemaking. See Proposed Rule, 58 FR 34652 *et seq.* (June 28, 1993). OSM has deferred action on the adoption of proposed § 843.23 for that later rulemaking. Since action on proposed § 843.23 has been deferred, OSM will not adopt a reference to § 843.23 for inclusion in the Table of Contents at this time. If a final version of 843.23 is adopted, a reference to the section will be added to the Table of Contents.

OSM has adopted the proposed reference to 843.24, oversight of State permitting decisions with respect to ownership or control or the status of violations, for inclusion in the Table of Contents.

Section 843.10—Information collection. The September, 1991, proposal would have removed existing section 843.10 since part 843 did not contain any information collection requirements which required the approval by the Office of Management and Budget under 44 U.S.C. 3507. The references to § 843.14(c) and 843.16 in existing 843.10 did not represent information collection requirements. The requirements in § 843.14(c) for OSM to furnish copies of notices and orders to the State regulatory authority and to any person having an interest did not require OMB approval because the obligation to provide the information was imposed upon OSM and not upon the State or upon a member of the public. Section 843.16 merely informed the public of the right to file an application for review and request a hearing under 43 CFR part 4.

In accordance with the proposal, OSM has deleted section 843.10.

Deferral of decision with respect to proposed § 843.23—Sanctions for knowing omissions or inaccuracies in ownership or control and violation information. Proposed § 843.23 was designed to respond to those circumstances in which there had been a knowing failure to provide the regulatory authority with complete and accurate ownership and control or violation information in an application or other document submitted pursuant to parts 773 and 778 of Title 30.

Proposed § 843.23 was designed "to carry out the purposes" of sections 507(b)(4), 510(b), 510(c), and 518(g) of SMCRA. The proposed section was designed to deter and punish the intentional failure to provide the complete and accurate ownership and control information required by sections 507(b)(4) and 510 (b)–(c) of the Act. It would have further implemented the criminal provisions of section 518(g) where appropriate.

Subsequently, OSM again proposed this rule with certain modifications. See 58 FR 34652 *et seq.* (June 28, 1993).

At this time, OSM has determined to defer further action on the proposed rule. OSM will address the proposed rule within the context of the subsequent rulemaking initiated on June 28, 1993.

As has been discussed previously in this preamble, OSM has allowed references to § 843.23 to remain in various sections of some of the other final rules adopted today in the event that a final § 843.23 is adopted. That such references have been allowed to remain, however, does not constitute a prejudgment by OSM to ultimately adopt proposed § 843.23 or some version of that rule. Any decision of this type will be made within the context of the subsequent rulemaking.

Section 843.24—Oversight of State permitting decisions with respect to ownership or control or the status of violations. Proposed § 843.24 would have provided standards for OSM's oversight of State permitting decisions with respect to ownership or control or the status of violations.

Paragraph (a) of proposed § 843.24 would have established the bases which would have required OSM to have taken action under the provisions of paragraphs (b) and (c) of proposed § 843.24.

Paragraph (a)(1) of proposed § 843.24 would have provided that OSM would have been required to take action whenever it determined, through its oversight of the implementation of State programs, that a State had issued a permit without complying with the State program equivalents of proposed §§ 773.22 (verification of ownership or control application information), 773.23 (review of ownership or control and violation information), 773.24 (procedures for challenging ownership or control links in AVS), 773.26 (standards for challenging ownership or control links and the status of violations), and 843.23 (sanctions for knowing omissions or inaccuracies in ownership or control and violation information).

Paragraph (a)(2) of proposed § 843.24 would have provided that OSM would have been required to take action whenever it had determined, through its oversight of the implementation of State programs, that a State had failed in a systemic manner to comply with the State program equivalent of proposed § 773.27 (periodic check of ownership or control information).

Paragraph (a)(2) of proposed § 843.24 would have defined "failure to comply in a systemic manner" to include a continuing pattern of noncompliance by a State, or one of more instances of noncompliance that result from or evidence a legal or policy decision which the State intended to apply to similar cases.

Under paragraph (a) of proposed § 843.24, a State's isolated failure to comply with proposed § 773.27 (periodic check of ownership and control information) would have been treated differently from isolated failures to comply with the proposed regulations listed in paragraph (a)(1) of proposed § 843.24.

Paragraph (b) of proposed § 843.24 would have required OSM to initiate action under 30 CFR 843.21 if, as a result of the determination made under paragraph (a) of the proposed section, OSM had reason to believe that the State had issued a permit improvidently within the meaning of 30 CFR 773.20.

Paragraph (c) of proposed § 843.24 would have provided for remedial actions by OSM against a State which did not comply with the proposed regulations relating to ownership or control and violation information during the permit application process. Such actions would have been applied where the State had knowingly failed to comply with the State program equivalents of sections 773.22 (verification of ownership or control application information), 773.23 (review of ownership or control and violation information), 773.24 (procedures for challenging ownership or control links in AVS), 773.26 (standards for challenging ownership or control links and the status of violations), or 843.23 (sanctions for knowing omissions or inaccuracies in ownership or control and violation information), or where the State had failed in a systemic manner to comply with § 773.27 (periodic check of ownership and control information).

Under the proposed regulation, the remedial actions against a non-complying State could have included grant reduction or termination under 30 CFR 735.21 or 30 CFR 886.18 and the substitution of Federal enforcement or other action pursuant to 30 CFR 733.12(b). Such remedial actions would not have been used where the State's actions were mandated by court order or where the State had not knowingly failed to comply.

A commenter representing environmental advocacy groups expressed concern that proposed § 843.24 did not expressly provide that citizens could petition OSM to take enforcement action where they had reason to believe that violations of the sections subject to § 843.24 exist. OSM recognizes commenter's concern about citizen participation and has addressed that issue in some detail above in this preamble in the section captioned "Citizen Participation." The analysis in that section of the preamble is generally applicable to proposed § 843.24. For reasons similar to those expressed in that section of the preamble, OSM must reject commenter's proposal to explicitly modify the proposed rule at this time.

Until these matters are addressed directly by further proposal of the agency, citizens could, however, assert their rights in a number of ways in accordance with the provisions of proposed § 843.24. With respect to specific permits under paragraph (b) of proposed § 843.24, concerned citizens could assert their complaints within the context of 30 CFR 842.11, 842.12, 842.15, and 843.21. With respect to more global remedies such as the reduction of State grants or the termination or the substitution of Federal enforcement provided by paragraph (c) of proposed § 843.24, OSM could accept and review information submitted by citizens with a view to determining whether such remedies were appropriate under the circumstances.

The commenter also took issue with the provision of paragraph (b) of proposed § 843.24 in that such provision would have provided that OSM take action under the provisions of 30 CFR 843.21 if OSM had reason to believe that a State had issued a permit improvidently within the meaning of 30 CFR 773.20. The commenter questioned the legality of 30 CFR 773.20 and 843.21 and asserted that these improvidently issued permit rules violated SMCRA. OSM disagrees with commenter's criticisms. OSM considers these rules to be legal. OSM incorporates by reference the arguments that the Department has made defending such rules in briefs filed in the case of *National Wildlife Federation* v. *Lujan*, No. 88–3117 (D.D.C.), and *Save Our Cumberland Mountains, Inc.*, v. *Lujan*, No. 81–2134 (D.D.C.). As indicated previously, copies of these briefs are being placed in the Administrative Record of this rulemaking.

A commenter representing State regulatory authorities questioned the provision of paragraph (c) of proposed § 843.24 which stated that a State regulatory authority would be excused from a failure to comply with the State program equivalents of the AVS-related regulations if such non-compliance was the result of a "mandatory injunction." The commenter asked for clarification of this term.

Under the proposed regulation, a mandatory injunction would be an order to a regulatory authority by a court with jurisdiction over which the regulatory authority has no control. Such an order would have the effect of ordering or otherwise preventing the regulatory authority from complying with the provisions of the regulations cited in paragraph (c) of proposed § 843.24.

A commenter representing a State regulatory authority indicated approval of the requirement contained in paragraph (c) of proposed § 843.24 that a State's failure to comply with proposed §§ 773.22, 773.23, 773.24, 773.26, and 843.23 be a "knowing" failure, before sanctions could be imposed.

OSM agrees with commenter and has retained the "knowing" standard in paragraph (c) of the final rule adopted as described below. The determination of what constitutes a State's "knowing" behavior would be made based upon a full consideration of the facts. In substance, the issue would be whether the State knew or had reason to know that its actions constituted a failure to comply with the regulations.

OSM has determined to adopt the proposed rule, with certain modifications, as final rule § 843.24. The final rule and the rationale behind such modifications are now described.

First, in paragraph (a) of the proposed rule, a reference to proposed § 773.26 has been deleted from among the list of regulations with which a State must comply to avoid action by OSM. As discussed previously, proposed § 773.26 has been renumbered and adopted as final § 773.25. Accordingly, a reference to § 773.25 has been substituted in paragraph (a) of final § 843.24. A similar substitution has also been made in paragraph (c) of the final rule.

Second, OSM has deleted subparagraph (a)(2) of proposed § 843.24. The proposed section would have required action by OSM when OSM determined that a State had systemically failed to comply with proposed § 773.27, periodic check of ownership or control information. As has been discussed previously, OSM is deferring action on proposed § 773.27 as part of a subsequent rulemaking. See 58 FR 34652 *et seq.*

In dealing with a similar deferral with respect to proposed § 843.23 described above in this preamble, OSM was able to allow references to proposed § 843.23 to remain in other final rules in the event of the ultimate adoption of 843.23. If § 843.23 is ultimately not adopted, the references in the final rules to it will be mere surplusage.

Unlike those other references to proposed § 843.23, the references to proposed § 773.27 contained in final § 843.24 are presented within a context of defining and applying a special standard, systemic noncompliance, applicable only to a State's failure to comply with § 773.27. The rationale for

adopting the particular standard of systemic noncompliance is inextricably linked to the issue of whether the adoption of proposed § 773.27 is appropriate. Accordingly, both issues will be appropriately addressed together in the separate rulemaking. Thus, OSM has deleted all of subparagraph (a)(2) of proposed § 843.24.

Further, the provisions of paragraph (c) of proposed § 843.24 would have required OSM to initiate action under §§ 735.21 or 886.18 and/or § 733.12 if OSM determined that a State had failed to comply in a systemic manner with the State program equivalent to § 773.27. In the final § 843.24, OSM has deleted such language for the reasons justifying a similar deletion of subparagraph (a)(2) of the proposed rule.

OSM emphasizes that the deletion of this language does not indicate that OSM has made a prejudgment with respect to the ultimate adoption of proposed § 773.27 or with respect to the issue of systemic noncompliance with respect to such proposed section. These matters will be addressed in the subsequent rulemaking.

In accordance with the above discussion, § 843.24 is adopted as modified.

III. Procedural Matters

Effect of the Rule in Federal Program States and on Indian Lands

This rule will apply, through cross-referencing, in those States with Federal programs: California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for these States appear at 30 CFR parts 905, 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. The rule will also apply through cross-referencing to Indian lands as provided in 30 CFR part 750. No comments were received concerning unique conditions in any of these Federal program states or on Indian lands which would require changes to the national rules or as specific amendments to any or all of the Federal programs or the Indian lands program.

Effect of the Rule on State Programs

The provisions of section 503(a)(1) of the Act require that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of the Act. Further, section 503(a)(7) of the Act requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to the Act.

These terms are defined at § 730.5 of title 30 of the Code of Federal Regulations to require that State programs contain procedures which are, with respect to the Act, no less stringent than the Act; and with respect to the Secretary's regulations, no less effective than the Secretary's regulations in meeting the requirements of the Act.

Following promulgation of this final rule, OSM will evaluate State programs to determine whether any changes in these programs will be necessary. If the Director determines that any State program provisions should be amended to be made no less effective than the revised Federal rules, the individual States will be notified in accordance with the provisions of 30 CFR 732.17.

Federal Paperwork Reduction Act

The collection of information contained in this rule has been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance numbers 1029–0034, 1029–0041, and 1029–0051.

Executive Order 12778; Civil Justice Reform Certification

This rule has been reviewed under the applicable standards of Section 2(b)(2) of Executive Order 12778, Civil Justice Reform (56 FR 55195). In general, the requirements of Section 2(b)(2) of Executive Order 12778 are covered by the preamble discussion of this rule. Additional remarks follow concerning individual elements of the Executive Order:

A. What is the Preemptive Effect, if any, to be Given to the Regulation?

The rule would have the same preemptive effect as other standards adopted pursuant to SMCRA. To retain primacy, States have to adopt and apply standards for their regulatory programs that are no less effective than those set forth in OSM's rules. Any State law that is inconsistent with, or that would preclude implementation of this proposed rule would be subject to preemption under SMCRA section 505 and implementing regulations at 30 CFR 730.11. To the extent that the rules would result in preemption of State law, the provisions of SMCRA are intended to preclude inconsistent State laws and regulations. This approach is established in SMCRA, and has been judicially affirmed. See *Hodel* v. *Virginia Surface Mining and Reclamation Ass'n*, 452 U.S. 264 (1981).

B. What is the Effect on Existing Federal Law or Regulation, if any, Including all Provisions Repealed or Modified?

This rule modifies the implementation of SMCRA as described herein, and is not intended to modify the implementation of any other Federal statute. The preceding discussion of this rule specifies the Federal regulatory provisions that are affected by this rule.

C. Does the Rule Provide a Clear and Certain Legal Standard for Affected Conduct Rather than a General Standard, While Promoting Simplification and Burden Reduction?

The standard established by this rule are as clear and certain as practicable, given the complexity of topics covered and the mandates of SMCRA.

D. What is the Retroactive Effect, if any, to be Given to the Regulation?

This rule is not intended to have retroactive effect.

E. Are Administrative Proceedings Required Before Parties may File Suit in Court? Which Proceedings Apply? Is the Exhaustion of Administrative Remedies Required?

No administrative proceedings are required before parties may file suit in court challenging the provisions of this rule under section 526(a) of SMCRA, 30 U.S.C. 1276(a)

Prior to any judicial challenge to the application of the rule, however, administrative procedures must be exhausted. In situations involving OSM application of the rule, applicable administrative procedures may be found at 43 CFR part 4. In situations involving State regulatory authority application of provisions equivalent to those contained in this rule, applicable administrative procedures are set forth in the particular State program.

F. Does the Rule Define Key Terms, Either Explicitly or by Reference to Other Regulations or Statutes That Explicitly Define Those Items?

Terms which are important to the understanding of this rule are set forth in 30 CFR 700.5 and 701.5.

G. Does the Rule Address Other Important Issues Affecting Clarity and General Draftsmanship of Regulations set Forth by the Attorney General, With the Concurrence of the Director of the Office of Management and Budget, That are Determined to be in Accordance With the Purposes of the Executive Order?

The Attorney General and the Director of the Office of Management and Budget

have not issued any guidance on this requirement.

Regulatory Flexibility Act

The Department of the Interior has determined that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. *et seq.* The final rule will not change costs to industry or to the Federal, State, or local governments. Furthermore, the rules produce no adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12866

The final rule has been reviewed under Executive Order 12866.

National Environmental Policy Act (NEPA)

OSM has prepared a final environmental assessment (EA) of this rule and has made a finding that the rules adopted in this rulemaking will not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). A finding of no significant impact (FONSI) has been approved for the final rule in accordance with OSM procedures under NEPA. The EA is on file in the OSM Administrative Record, room 660, 800 North Capitol St., NW., Washington, DC.

Author: The principal author of this final rule is Harvey P. Blank, Attorney-Adviser, Division of Surface Mining, Office of the Solicitor, U.S. Department of the Interior, 1849 C Street, NW, Washington, DC 20240. Inquiries, however, with respect to the rule should be directed to Russell Frum at the address and telephone number specified in **FOR FURTHER INFORMATION CONTACT.**

List of Subjects

30 CFR Part 701

Law enforcement, Surface mining, Underground mining.

30 CFR Part 773

Administrative practice and procedure, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 778

Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 840

Intergovernmental relations, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 843

Administrative practice and procedure, Law enforcement, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: July 18, 1994.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

Accordingly, 30 CFR Parts 701, 773, 778, 840, and 843 are amended as set forth below:

PART 701—PERMANENT REGULATORY PROGRAM

1. The authority citation for part 701 continues to read as follows:

Authority: Pub. L. 95–87 (30 U.S.C. 1201 *et seq.*), and Pub. L. 100–34.

§ 701.5 [Amended]

2. Section 701.5 is amended by deleting the definition of "Violation notice."

PART 773—REQUIREMENTS FOR PERMITS AND PERMIT PROCESSING

3. and 4. The authority citation for part 773 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, 16 U.S.C. 470 *et seq.*, 16 U.S.C. 1531 *et seq.*, 16 U.S.C. 661 *et seq.*, 16 U.S.C. 703 *et seq.*, 16 U.S.C. 668a *et seq.*, 16 U.S.C. 469 *et seq.*, 16 U.S.C. 470aa *et seq.*, and Pub. L. 100–34.

5. Section 773.5 is amended by adding the definitions of "Applicant/Violator System or AVS," "Federal violation notice," "Ownership or control link," "State violation notice," and "Violation notice," in alphabetical order as follows:

§ 773.5 Definitions.

* * * * *

Applicant/Violator System or *AVS* means the computer system maintained by OSM to identify ownership or control links involving permit applicants, permittees, and persons cited in violation notices.

Federal violation notice means a violation notice issued by OSM or by another agency or instrumentality of the United States.

* * * * *

Ownership or control link means any relationship included in the definition of "owned or controlled" or "owns or controls" in this section or in the violations review provisions of § 773.15(b) of this part. It includes any relationship presumed to constitute ownership or control under the definition of "owned or controlled" or "owns or controls" in this section, unless such presumption has been successfully rebutted under the provisions of §§ 773.24 and 773.25 of this part or under the provisions of part 775 of this chapter and § 773.25.

State violation notice means a violation notice issued by a State regulatory authority or by another agency or instrumentality of State government.

Violation notice means any written notification from a governmental entity, whether by letter, memorandum, judicial or administrative pleading, or other written communication, of a violation of the Act; any Federal rule or regulation promulgated pursuant thereto; a State program; or any Federal or State law, rule, or regulation pertaining to air or water environmental protection in connection with a surface coal mining operation. It includes, but is not limited to, a notice of violation; an imminent harm cessation order; a failure-to-abate cessation order; a final order, bill, or demand letter pertaining to a delinquent civil penalty; a bill or demand letter pertaining to delinquent abandoned mine reclamation fees; and a notice of bond forfeiture, where one or more violations upon which the forfeiture was based have not been corrected.

6. Section 773.10 is revised to read as follows:

§ 773.10 Information collection.

(a) The collections of information contained in 30 CFR part 773 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1029–0041. The information will be used by the regulatory authorities in processing applications. Response is required to obtain a benefit in accordance with 30 U.S.C. 1201 *et seq.*

(b) Public reporting burden for this collection of information is estimated to average four and one-half hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate to OSM Information Collection Clearance Officer, Room 640 NC, 1951 Constitution Ave., Washington, DC 20240; and the Office of Management and Budget, Paperwork Reduction Project (1029–0041), Washington, DC 20503.

7. Section 773.15 is amended by revising paragraphs (b)(1) introductory text and (b)(2) as follows:

§ 773.15 Review of permit applications.

* * * * *

(b) *Review of violations.* (1) Based on a review of all reasonably available information concerning violation notices and ownership or control links involving the applicant, including information obtained pursuant to §§ 773.22, 773.23, 778.13, and 778.14 of this chapter, the regulatory authority shall not issue the permit if any surface coal mining and reclamation operation owned or controlled by either the applicant or by any person who owns or controls the applicant is currently in violation of the Act, any Federal rule or regulation promulgated pursuant thereto, a State program, or any Federal or State law, rule, or regulation pertaining to air or water environmental protection. In the absence of a failure-to-abate cessation order, the regulatory authority may presume that a notice of violation issued pursuant to § 843.12 of this chapter or under a Federal or State program is being corrected to the satisfaction of the agency with jurisdiction over the violation where the abatement period for such notice of violation has not yet expired and where, as part of the violation information provided pursuant to § 778.14 of this chapter, the applicant has provided certification that such violation is in the process of being so corrected. Such presumption shall not apply where evidence to the contrary is set forth in the permit application, or where the notice of violation is issued for nonpayment of abandoned mine land reclamation fees or civil penalties. If a current violation exists, the regulatory authority shall require the applicant or person who owns or controls the applicant, before the issuance of the permit, to either—

* * * * *

(2) Any permit that is issued on the basis of a presumption supported by certification under § 778.14 of this chapter that a violation is in the process of being corrected, on the basis of proof submitted under paragraph (b)(1)(i) of this section that a violation is in the process of being corrected, or pending the outcome of an appeal described in paragraph (b)(1)(ii) of this section, shall be conditionally issued.

* * * * *

8. Section 773.20 is amended by revising paragraphs (b) and (c) to read as follows:

§ 773.20 Improvidently issued permits: General procedures.

* * * * *

(b) *Review criteria.* (1) A regulatory authority shall find that a surface coal mining and reclamation permit was improvidently issued if—

(i) Under the violations review criteria of the regulatory program at the time the permit was issued:

(A) The regulatory authority should not have issued the permit because of an unabated violation or a delinquent penalty or fee; or

(B) The permit was issued on the presumption that a notice of violation was in the process of being corrected to the satisfaction of the agency with jurisdiction over the violation, but a cessation order subsequently was issued; and

(ii) The violation, penalty, or fee:

(A) Remains unabated or delinquent; and

(B) Is not the subject of a good faith appeal, or of an abatement plan or payment schedule with which the permittee or other person responsible is complying to the satisfaction of the responsible agency; and

(iii) Where the permittee was linked to the violation, penalty, or fee through ownership or control under the violations review criteria of the regulatory program at the time the permit was issued, an ownership or control link between the permittee and the person responsible for the violation, penalty, or fee still exists, or where the link has been severed, the permittee continues to be responsible for the violation, penalty, or fee.

(2) The provisions of § 773.25 of this part shall be applicable when a regulatory authority determines:

(i) Whether a violation, penalty, or fee existed at the time that it was cited, remains unabated or delinquent, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, and

(ii) Whether any ownership or control link between the permittee and the person responsible for the violation, penalty, or fee existed, still exists, or has been severed.

(c) *Remedial measures.* (1) A regulatory authority which, under paragraph (b) of this section, finds that because of an unabated violation or a delinquent penalty or fee a permit was improvidently issued shall use one or more of the following remedial measures:

(i) Implement, with the cooperation of the permittee or other person responsible, and of the responsible agency, a plan for abatement of the violation or a schedule for payment of the penalty or fee;

(ii) Impose on the permit a condition requiring that in a reasonable time the permittee or other person responsible abate the violation or pay the penalty or fee;

(iii) Suspend the permit until the violation is abated or the penalty or fee is paid; or

(iv) Rescind the permit.

2. If the regulatory authority decides to suspend the permit, it shall afford at least 30 days' written notice to the permittee. If the regulatory authority decides to rescind the permit, it shall issue a notice in accordance with § 773.21 of this part. In either case, the permittee shall be given the opportunity to request administrative review of the notice under 43 CFR 4.1370 through 4.1377, where OSM is the regulatory authority, or under the State program equivalent, where a State is the regulatory authority. The regulatory authority's decision shall remain in effect during the pendency of the appeal, unless temporary relief is granted in accordance with 43 CFR 4.1376 or the State program equivalent.

9. Section 773.21 is amended by replacing the reference to "§ 773.20(c)(4)" in the introductory paragraph with "§ 773.20(c)(1)(iv)" and by revising the introductory language contained in paragraph (a) to read as follows:

§ 773.21 Improvidently issued permits: Rescission procedures.

* * * * *

(a) *Automatic suspension and rescission.* After a specified period of time not to exceed 90 days the permit automatically will become suspended, and not to exceed 90 days thereafter rescinded, unless within those periods the permittee submits proof, and the regulatory authority finds, consistent with the provisions of § 773.25 of this part, that—

* * * * *

10. Section 773.21 is further amended by deleting paragraph (c).

11. Section 773.22 is added as follows:

§ 773.22 Verification of ownership or control application information.

(a) In accordance with § 773.15(c)(1) of this part, prior to the issuance of a permit, the regulatory authority shall review the information in the application provided pursuant to § 778.13 of this chapter to determine that such information, including the identification of the operator and all owners and controllers of the operator, is complete and accurate. In making such determination, the regulatory authority shall compare the information provided in the application with information from other reasonably available sources, including—

(1) Manual data sources within the State in which the regulatory authority exercises jurisdiction, including: (i) The regulatory authority's inspection and enforcement records and (ii) State corporation commission or tax records, to the extent they contain information concerning ownership or control links; and

(2) Automated data sources, including: (i) The regulatory authority's own computer systems and (ii) the Applicant/Violator System.

(b) If it appears from the information provided in the application pursuant to § 778.13(c) through (d) of this chapter that none of the persons identified in the application has had any previous mining experience, the regulatory authority shall inquire of the applicant and investigate whether any person other than those identified in the application will own or control the operation (as either an operator or other owner or controller).

(c) If, as a result of the review conducted under paragraphs (a) and (b) of this section, the regulatory authority identifies any potential omission, inaccuracy, or inconsistency in the ownership or control information provided in the application, it shall, prior to making a final determination with regard to the application, contact the applicant and require that the matter be resolved through submission of (1) An amendment to the application or (2) a satisfactory explanation which includes credible information sufficient to demonstrate that no actual omission, inaccuracy, or inconsistency exists. The regulatory authority shall also take action in accordance with the provisions of § 843.23 of this chapter (or the State program equivalent), where appropriate.

(d) Upon completion of the review conducted under this section, the regulatory authority shall promptly enter into or update all ownership or control information on AVS.

12. Section 773.23 is added as follows:

§ 773.23 Review of ownership or control and violation information.

(a) Following the verification of ownership or control information pursuant to § 773.22(b) of this part, the regulatory authority shall review all reasonably available information concerning violation notices and ownership or control links involving the applicant to determine whether the application can be approved under § 773.15(b) of this part. Such information shall include—

(1) With respect to ownership or control links involving the applicant, all information obtained under §§ 773.22 and 778.13 of this chapter; and

(2) With respect to violation notices, all information obtained under § 778.14 of this chapter, information obtained from OSM, including information shown in the AVS, and information from the regulatory authority's own records concerning violation notices.

(b) If the review conducted under paragraph (a) of this section discloses any ownership or control link between the applicant and any person cited in a violation notice—

(1) The regulatory authority shall so notify the applicant and shall refer the applicant to the agency with jurisdiction over such violation notice; and

(2) The regulatory authority shall not approve the application unless and until it determines, in accordance with the provisions of §§ 773.24 and 773.25 of this part (or the State program equivalent), (i) That all ownership or control links between the applicant and any person cited in a violation notice are erroneous or have been rebutted, or (ii) that the violation has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, within the meaning of § 773.15(b)(1) of this part (or the State program equivalent).

(c) Following the regulatory authority's decision on the application (including unconditional issuance, conditional issuance, or denial of the permit) or following the applicant's withdrawal of the application, the regulatory authority shall promptly enter all relevant information related to such decision or withdrawal into AVS.

13. Section 773.24 is added as follows:

§ 773.24 Procedures for challenging ownership or control links shown in AVS.

(a)(1) Any applicant or other person shown in AVS in an ownership or control link to any person may challenge such link in accordance with the provisions of paragraphs (b) through (d) of this section and § 773.25 of this part, unless such applicant or other person is bound by a prior administrative or judicial determination concerning the link.

(2) Any applicant or other person shown in AVS in an ownership or control link to any person cited in a Federal violation notice may challenge the status of the violation covered by such notice in accordance with the provisions of paragraphs (b) through (d) of this section and § 773.25 of this part, unless such applicant or other person is bound by a prior administrative or judicial determination concerning the status of the violation.

(3) Any applicant or other person shown in AVS in an ownership or control link to any person cited in a State violation notice may challenge the status of the violation covered by such notice in accordance with the State program equivalents to paragraphs (b) through (d) of this section and § 773.25 of this part for the State that issued the violation notice, unless such applicant or other person is bound by a prior administrative or judicial determination concerning the status of the violation.

(b) Any applicant or other person who wishes to challenge an ownership or control link shown in AVS or the status of a Federal violation, and who is eligible to do so under the provisions of paragraphs (a)(1) or (a)(2) of this section, shall submit a written explanation of the basis for the challenge, along with any relevant evidentiary materials and supporting documents, to OSM, addressed to the Chief of the AVS Office, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Washington, D.C. 20240.

(c) OSM shall review any information submitted under paragraph (b) of this section and shall make a written decision whether or not the ownership or control link has been shown to be erroneous or has been rebutted and/or whether the violation covered by the notice remains outstanding, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal within the meaning of § 773.15(b)(1) of this part.

(d)(1) If, as a result of the decision reached under paragraph (c) of this section, OSM determines that the ownership or control link has been shown to be erroneous or has been rebutted and/or that the violation covered by the notice has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, OSM shall so notify the applicant or other person and, if an application is pending, the regulatory authority, and shall correct the information in AVS.

(2) If, as a result of the decision reached under paragraph (c) of this section, OSM determines that the ownership or control link has not been shown to be erroneous and has not been rebutted and that the violation covered by the notice remains outstanding, OSM shall so notify the applicant or other person and, if an application is pending, the regulatory authority, and shall update the information in AVS, if necessary.

(i) OSM shall serve a copy of the decision on the applicant or other person by certified mail, or by any

means consistent with the rules governing service of a summons and complaint under Rule 4 of the Federal Rules of Civil Procedure. Service shall be complete upon tender of the notice or of the mail and shall not be deemed incomplete because of a refusal to accept.

(ii) The applicant or other person may appeal OSM's decision to the Department of the Interior's Office of Hearings and Appeals within 30 days of service of the decision in accordance with 43 CFR 4.1380 through 4.1387. OSM's decision shall remain in effect during the pendency of the appeal, unless temporary relief is granted in accordance with 43 CFR 4.1386.

14. Section 773.25 is added as follows:

§ 773.25 Standards for challenging ownership or control links and the status of violations.

(a) The provisions of this section shall apply whenever a person has and exercises a right, under the provisions of §§ 773.20, 773.21, 773.23, or 773.24 of this part or under the provisions of part 775 of this chapter, to challenge (1) an ownership or control link to any person and/or (2) the status of any violation covered by a notice.

(b) *Agencies responsible.* (1) Except as provided in paragraph (b)(3) of this section—

(i) The regulatory authority before which an application is pending shall have responsibility for making decisions with respect to ownership or control relationships of the application.

(ii) The regulatory authority that issued a permit shall have responsibility for making decisions with respect to the ownership or control relationships of the permit.

(iii) The State regulatory authority for the State that issued a State violation notice shall have responsibility for making decisions with respect to the ownership or control relationships of the violation.

(iv) The regulatory agency that issued a violation notice, whether State or Federal, shall have responsibility for making decisions concerning the status of the violation covered by such notice, i.e., whether the violation remains outstanding, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal, within the meaning of § 773.15(b)(1) of this part.

(2) OSM shall have responsibility for making decisions with respect to the ownership or control relationships of a Federal violation notice.

(3)(i) With respect to information shown on AVS, the responsibilities referred to in paragraph (b)(1) of this section shall be subject to the plenary authority of OSM to review any State regulatory authority decision regarding an ownership or control link.

(ii) With respect to ownership or control information which has not been entered into AVS by a State and with respect to information shown on AVS relating to the status of a violation, State regulatory authorities' determinations are subject to OSM's program authority oversight under parts 733, 842, and 843 of this chapter.

(c) *Evidentiary standards.* (1) In any formal or informal review of an ownership or control link or of the status of a violation covered by a violation notice, the responsible agency shall make a prima facie determination or showing that such link exists, existed during the relevant period, and/or that the violation covered by such notice remains outstanding. Once such a prima facie determination or showing has been made, the person challenging such link or the status of the violation shall have the burden of proving by a preponderance of the evidence, with respect to any relevant time period—

(i) That the facts relied upon by the responsible agency to establish: (A) Ownership or control under the definition of "owned or controlled" or "owns or controls" in § 773.5 of this part or (B) a presumption of ownership or control under the definition of "owned or controlled" or "owns or controlls" in § 773.5 of this part, do not or did not exist;

(ii) That a person subject to a presumption of ownership or control under the definition of "owned or controlled" or "owns or controls" in § 773.5 of this part, does not or did not in fact have the authority directly or indirectly to determine the manner in which surface coal mining operations are or were conducted, or

(iii) That the violation covered by the violation notice did not exist, has been corrected, is in the process of being corrected, or is the subject of a good faith appeal within the meaning of § 773.15(b)(1) of this part; *provided* that the existence of the violation at the time it was cited may not be challenged under the provisions § 773.24 of this part: (A) By a permittee, unless such challenge is made by the permittee within the context of §§ 773.20 through 773.21 of this part; (B) by any person who had a prior opportunity to challenge the violation notice and who failed to do so in a timely manner; or (C) by any person who is bound by a prior administrative or judicial determination concerning the existence of the violation.

(2) In meeting the burden of proof set forth in paragraph (c)(1) of this section, the person challenging the ownership or control link or the status of the violation shall present probative, reliable, and substantial evidence and any supporting explanatory materials, which may include—

(i) Before the responsible agency—

(A) Affidavits setting forth specific facts concerning the scope of responsibility of the various owners or controllers of an applicant, permittee, or any person cited in a violation notice; the duties actually performed by such owners or controllers; the beginning and ending dates of such owners' or controllers' affiliation with the applicant, permittee, or person cited in a violation notice; and the nature and details of any transaction creating or severing an ownership or control link; or specific facts concerning the status of the violation;

(B) If certified, copies of corporate minutes, stock ledgers, contracts, purchase and sale agreements, leases, correspondence, or other relevant company records;

(C) If certified, copies of documents filed with or issued by any State, Municipal, or Federal governmental agency.

(D) An opinion of counsel, when supported by (1) Evidentiary materials; (2) a statement by counsel that he or she is qualified to render the opinion; and (3) a statement that counsel has personally and diligently investigated the facts of the matter or, where counsel has not so investigated the facts, a statement that such opinion is based upon information which has been supplied to counsel and which is assumed to be true.

(ii) Before any administrative or judicial tribunal reviewing the decision of the responsible agency, any evidence admissible under the rules of such tribunal.

(d) Following any determination by a State regulatory authority or other State agency, or any decision by an administrative or judicial tribunal reviewing such determination, the State regulatory authority shall review the information in AVS to determine if it is consistent with the determination or decision. If it is not, the State regulatory authority shall promptly inform OSM and request that the AVS information be revised to reflect the determination or decision.

PART 778—PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR LEGAL, FINANCIAL, COMPLIANCE, AND RELATED INFORMATION

15. The authority citation for part 778 continues to read as follows:

Authority: Public Law 95–87, 30 U.S.C. 1201 *et seq.*, and Public Law 100–34.

16. Section 778.14 is amended by revising the introductory language in paragraph (c) to read as follows:

§ 778.14 Violation information.

* * * * *

(c) A list of all violation notices received by the applicant during the three-year period preceding the application date, and a list of all outstanding violation notices received prior to the date of the application by any surface coal mining operation that is deemed or presumed to be owned or controlled by either the applicant or any person who is deemed or presumed to own or control the applicant under the definition of "owned or controlled" and "owns or controls" in § 773.5 of this chapter. For each notice of violation issued pursuant to § 843.12 of this chapter or under a Federal or State program for which the abatement period has not expired, the applicant shall certify that such notice of violation is in the process of being corrected to the satisfaction of the agency with jurisdiction over the violation. For each violation notice reported, the list shall include the following information, as applicable:

* * * * *

PART 840—STATE REGULATORY AUTHORITY: INSPECTION AND ENFORCEMENT

17. The authority citation for Part 840 continues to read as follows:

Authority: Public Law 95–87, 30 U.S.C. 1201 *et seq.*, and Public Law 100–34, unless otherwise noted.

18. Section 840.13 is amended by revising paragraph (b) to read as follows:

§ 840.13 Enforcement authority.

* * * * *

(b) The enforcement provisions of each State program shall contain sanctions which are no less stringent than those set forth in section 521 of the Act and shall be consistent with §§ 843.11, 843.12, 843.13, and 843.23 and subchapters G and J of this chapter.

PART 843—FEDERAL ENFORCEMENT

19. and 20. The authority citation for part 843 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

§ 843.10 [Removed]

21. Section 843.10 is removed.

22. Section 843.24 is added as follows:

§ 843.24 Oversight of State permitting decisions with respect to ownership or control or the status of violations.

(a) The Office shall take action pursuant to paragraphs (b) and (c) of this section whenever it determines, through its oversight of the implementation of State programs, that a State has issued a permit without complying with the State program equivalents of §§ 773.22, 773.23, 773.24, 773.25, and 843.23 of this chapter.

(b) If, as a result of its determination that a State has failed to comply with the provisions set forth in paragraph (a) of this section, the Office has reason to believe that the State has issued a permit improvidently within the meaning of § 773.20 of this chapter, the Office shall initiate action under the provisions of § 843.21 of this part.

(c) If the Office determines that a State's failure to comply with the State program equivalents of §§ 773.22, 773.23, 773.24, 773.25, and 843.23 of this chapter was knowing, it shall initiate action under §§ 735.21 or 886.18 (as allowed by law) and/or § 733.12(b) of this chapter, unless the State's action was the result of a mandatory injunction of a court of competent jurisdiction.

[FR Doc. 94–26554 Filed 10–27–94; 8:45 am]
BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Hearings and Appeals

43 CFR Part 4

RIN 1094–AA42

Department Hearings and Appeals Procedures; Special Rules Applicable to Surface Coal Mining Hearings and Appeals

AGENCY: Office of Hearings and Appeals, Interior.

ACTION: Final rule.

SUMMARY: The final rulemaking amends regulations of the Office of Hearings and Appeals (OHA) applicable to surface coal mining hearings and appeals by adding procedural rules for administrative review of a decision by the Office of Surface Mining Reclamation and Enforcement (OSM) to suspend or rescind permits that should not have been issued, and a decision by OSM in response to (a) a challenge, by an applicant or other person shown in the Applicant Violator System, to a finding that he or she is in an ownership or control link to any person or (b) a challenge, by an applicant or other person shown in the Applicant Violator System in an ownership or control link to any person cited in a federal violation notice, to the status of the violation in the notice. The final rulemaking provides for a hearing before an administrative law judge and for discretionary review of the administrative law judge's initial decision by the Interior Board of Land Appeals (IBLA). In addition, existing 43 CFR 4.1105(a)(2) is amended to include a reference to the rules added by this rulemaking.

EFFECTIVE DATE: These final regulations are effective on November 28, 1994.

FOR FURTHER INFORMATION CONTACT: Will A. Irwin, Administrative Judge, Interior Board of Land Appeals, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203 (Telephone 703–235–3750).

SUPPLEMENTARY INFORMATION: OHA's proposed rulemaking was published in the **Federal Register** on September 6, 1991 (56 FR 45806–11). Proposed 43 CFR 4.1370–4.1377 set forth new OHA procedures for reviewing OSM decisions to suspend or rescind permits OSM finds were improvidently issued under 30 CFR 773.20. Proposed 43 CFR 4.1380–4.1387 set forth new OHA procedures for reviewing OSM decisions finding that a person is in an ownership or control link to a person currently in violation of the Surface Mining Control and Reclamation Act of 1977 (SMCRA) or other applicable law. In addition, OHA proposed to amend the existing rule that establishes OSM's burden of proof in individual civil penalty proceedings, 43 CFR 3.1307(a).

Proposed 43 CFR 4.1370–4.1377 and 4.1380–4.1387 are based on section 510(c) of SMCRA, 30 U.S.C. 1260(c) (1988). This section requires an applicant for a surface coal mining and reclamation permit to file with the permit application a schedule listing all notices of violations of SMCRA and any law, rule, or regulation of the United States, or of any department or agency in the United States pertaining to air or water environmental protection incurred by the applicant in connection with any surface coal mining operation during the three-year period prior to the date of application. Where the schedule or other information indicates that any surface coal mining operation owned or controlled by the applicant is currently

in violation of the Act or other air or water environmental protection laws, the permit shall not be issued until the applicant submits proof that such violation has been corrected or is in the process of being corrected to the satisfaction of the regulatory authority, department, or agency which has jurisdiction over such violation.

In order to implement section 510(c), OSM has promulgated a rule defining the words "owned or controlled" in that section, as well as "owns or controls." 30 CFR 773.5. It has adopted a rule requiring that an application for a permit include information about each person who owns or controls the applicant, within the meaning of § 773.5, and about any surface coal mining operation owned or controlled by either the applicant or any person who owns or controls the applicant. 30 CFR 778.13(c), (d). It has adopted a regulation concerning review of applications for permits that provides: "[b]ased on available information * * *, the regulatory authority shall not issue the permit if any surface coal mining and reclamation operation owned or controlled by either the applicant or by any person who owns or controls the applicant is currently in violation of the Act or any other law, rule or regulation referred to in this paragraph." 30 CFR 773.15(b)(1). This is the so-called "permit block," referring to the language in section 510(c) that states "the permit shall not be issued until the applicant submits proof" that a violation of a surface coal mining operation owned or controlled by the applicant has been corrected or is in the process of being corrected. OSM has also established the Applicant/Violator System (AVS), a computerized system to store data regarding violations and ownership and control links to those violations. See *Save Our Cumberland Mountains* v. *Lujan*, 963 F.2d 1541, 1545–46 (D.C. Cir. 1992).

OHA's proposed rules were published on the same day as OSM proposed related rules defining the AVS, requiring its use in reviewing permit applications to determine whether there are any ownership or control links between applicants and persons in violation, and proposing procedures and standards for an applicant or other person shown in the AVS to challenge ownership and control links shown in the AVS and the status of the violation. 56 FR 45780–45804 (Sept. 6, 1991). OSM also proposed to amend its existing rules governing suspension and rescission of improvidently issued permits. OSM's proposed rules provided a right to review of its decisions to suspend or rescind a permit under the procedures set forth in OHA's proposed rulemaking of sections 4.1370 through 4.1377. See proposed § 773.20(c)(2), 56 FR 45799 (Sept. 6, 1991). OSM's proposed rules also provided a right to review of its written decisions on challenges to ownership and control links and the status of violations shown in the AVS under the procedures set forth in OHA's proposed rulemaking of sections 4.1380 through 4.1387. See proposed 30 CFR 773.24(d)(2)(ii), 56 FR 45800 (Sept. 6, 1991).

OHA received comments on its proposed rules from Texas Utilities Services, Inc. (TU Services), the Joint National Coal Association/American Mining Congress Committee on Surface Mining Regulations (NCA/AMC), and the National Wildlife Federation (NWF). The NCA/AMC comments dealt with both OHA's and OSM's proposed rules.

Proposed Amendment of 43 CFR 4.1307(a)(3) Withdrawn

As part of its September 6, 1991, proposed rulemaking, OHA proposed an amendment to 43 CFR 4.1307(a)(3) at 56 FR 45808 which set forth an element of OSM's prima facie case in proceedings to review the assessment of individual civil penalties. Proposed 43 CFR 4.1307(a)(3) complemented proposed rules by OSM at 56 FR 48924, 48929–30 (Sept. 26, 1991) addressing individual civil penalties. Both TU Services' and NCA/AMC's comments expressed reservations about the proposed amendment of 43 CFR 4.1307(a)(3). By a notice published in the **Federal Register** on October 16, 1992, OSM withdrew its September 26, 1991, proposed rulemaking. 57 FR 47431 (Oct. 16, 1992). Therefore, OHA hereby withdraws the corresponding proposed amendment to 43 CFR 4.1307(a)(3). Because this proposed rule concerning an element of OSM's prima facie case in individual civil penalty proceedings is withdrawn, no response to the comments concerning it is necessary.

As noted above, the NCA/AMC comments address both the proposed OSM rules and the proposed OHA rules "[b]ecause [their] comments on the proposal by [OHA] are interrelated with [their] concerns about the OSM proposal." NCA/AMC's comments that relate to the procedures for administrative review are addressed here.

Procedural Due Process

NCA/AMC state that although the proposed rules "purport to establish a comprehensive scheme for administrative review of ownership and control determinations emanating from the AVS, they fall far short of providing the meaningful guarantees that the due process clause requires." They fall short, NCA/AMC state, because the procedures do not allow one to challenge the existence of the violation that forms the basis for a permit block under section 510(c). Further, the proposed rules do not provide "any opportunity for challenging either the status of the violation or the validity of the AVS link *prior* to the deprivation of the operator's property interest through permit denial, suspension, or revocation, unless the applicant is able to meet the stringent requirements for seeking temporary relief" contained in proposed 43 CFR 4.1386 (emphasis in original). NCA/AMC state that the "right to notice and a hearing prior to a governmental deprivation of private property is a cornerstone of American jurisprudence, and is a well-established principle in cases involving the constitutionality of SMCRA provisions" that the proposed rules fail to recognize. NCA/AMC state that an appeal or challenge to AVS information "must, of necessity, include the right to a full and fair determination on the merits of the violation in advance of any decision to prohibit mining through the sanctions contained within section 510(c)." Under the balancing test announced in *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), the proposed rules do not afford due process, NCA/AMC argue.

A fundamental requirement of the Fifth Amendment to the Constitution of the United States that "[n]o person shall * * * be deprived of life, liberty, or property, without due process of law" is the opportunity to be heard at a meaningful time and in a meaningful manner. *Armstrong* v. *Manzo*, 380 U.S. 545, 552 (1965). In *Mathews* v. *Eldridge*, *supra*, the U.S. Supreme Court discussed "the extent to which due process requires an evidentiary hearing prior to the deprivation of some type of property interest even if such a hearing is provided thereafter." 424 U.S. at 333. The Court quoted *Morrissey* v. *Brewer*, 408 U.S. 471, 481 (1972), that "due process is flexible and calls for such procedural protections as the particular situation demands," and then stated:

> [O]ur prior decisions indicate that identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the

additional or substitute procedural requirement would entail. See, e.g., *Goldberg* v *Kelly*. [397 U.S.] at 263–271.

Mathews v. *Eldridge, supra* at 334–35. In *Goldberg* v. *Kelly*, 397 U.S. 254 (1970), the Supreme Court decided procedural due process requires that a state grant an evidentiary hearing before suspending or terminating welfare payments to an individual who meets the statutory qualifications for receiving them. "[T]he crucial factor in this context," the Court observed, "is that termination of aid pending resolution of a controversy over eligibility may deprive an *eligible* recipient of the very means by which to live while he waits." *Id.* at 264 (emphasis in original). "[C]ountervailing governmental interests in conserving fiscal and administrative resources * * * are not overriding in the welfare context," the Court stated. *Id.* at 265–66. "[H]owever, * * * the pre-termination hearing need not take the form of a judicial or quasi-judicial trial," the Court commented. *Id.* at 266. A complete record and a comprehensive opinion are not necessary; an opportunity for the welfare recipient to confront and cross-examine witnesses relied on by the government, and to retain an attorney, however, are necessary. *Id.* at 267–270. Also necessary is an impartial decisionmaker, who must "state the reasons for his determination and indicate the evidence be relied on." *Id.* at 271.

OHA believes that, when analyzed under *Mathews* v. *Eldridge*, the procedures proposed for OSM decisions and for OHA administrative review of those decisions provide adequate due process protection of the interests involved.

The proposed rules recognize a distinction between a person who holds a permit that might be suspended or rescinded because OSM determines it was improvidently issued (43 CFR 4.1370–4.1377) and a person who has applied for a permit or might apply for one in the future (43 CFR 4.1380–4.1387). A person who holds a permit is entitled to more protection than the person who has applied for one or plans to do so. In recognition of this distinction, OSM's final rule 30 CFR 773.20(b)(2) will provide, for a person who has a permit, that OSM will determine whether a violation, penalty or fee existed when it was cited and whether an ownership or control link between a permittee and the person responsible for the violation existed, still exists, or has been severed, before issuing a notice to suspend or rescind a permit. An applicant for a permit, however, may challenge the existence of a violation in a review proceeding under 43 CFR 4.1360–4.1369 after the application has been denied, not before. An applicant (or any other person shown in the AVS) may challenge an ownership or control link or the status of a violation before a permit application is denied, or even filed, under proposed 30 CFR 773.24, as discussed further below. (The "status of a violation" concerns whether the violation remains outstanding, has been or is in the process of being corrected, or is the subject of an administrative or judicial appeal. The status of a violation is distinct from "the existence of a violation," i.e., whether the violation existed at the time it was cited.)

The "private interest that will be affected," i.e., a permit, is limited. A permit is issued for a five-year term (with a right of renewal unless its terms or other requirements are not being met), 30 U.S.C. 1256(b), (d) (1988), and is conditioned on compliance with several performance standards, 30 U.S.C. 1265(a) (1988). It may be terminated, revised, reviewed, suspended, or revoked. 30 U.S.C. 1256(c), 1261(c), 1265(c), 1271(a)(4) (1988). Thus, while valuable, a permit to conduct surface coal mining is not a private interest comparable to the welfare benefits in *Goldberg* v. *Kelly, supra*, that entitles the holder to an evidentiary hearing prior to suspension or rescission. In *Mathews* v. *Eldridge, supra* at 343, the Supreme Court held that termination of disability payments may be effected without a pretermination evidentiary hearing. Similarly, suspension or rescission of a surface coal mining permit does not require a prior hearing in addition to the other procedural safeguards provided in the OSM and OHA rules.

Those rules significantly reduce "the risk of an erroneous deprivation" of a permit. If OSM finds a permit was improvidently issued because at the time it was issued one or more of the circumstances set forth in the review criteria in 30 CFR 773.20(b)(1) existed, it does so in accordance with the standards for challenging ownership or control links and the status of violations in proposed 30 CFR 773.26, 56 FR 45801–45803 (Sept. 6, 1991). See proposed 30 CFR 773.20(b)(2), 56 FR 45799 (Sept. 6, 1991). As mentioned above, these standards will apply, under OSM's final rule 30 CFR 773.20(b)(2), to a determination whether a violation, penalty, or fee existed at the time it was cited, remains unabated or delinquent, has been or is in the process of being corrected, or is the subject of an appeal, and whether an ownership or control link between the permittee and the person responsible for the violation, penalty, or fee existed, still exists, or has been severed. OSM has a choice of four remedial measures if it finds a permit was improvidently issued, including suspension or rescission of the permit. 30 CFR 773.20(c); see proposed § 773.20(c)(1), 56 FR 45799 (Sept. 6, 1991). If it decides to suspend, it will give the permittee 30 days written notice and inform the permittee of its right to review under 43 CFR 4.1370 *et seq.* See proposed 30 CFR 773.20(c)(2), 56 FR 45799 (Sept. 6, 1991). If it decides to rescind, it will issue the permittee a notice of proposed suspension and rescission under 30 CFR 773.21 that includes the reasons for finding the permit was improvidently issued and will inform the permittee of its right to review under 43 CFR 4.1370 *et seq.* See proposed 30 CFR 773.20(c)(2), 56 FR 45799 (Sept. 6, 1991).

Under OHA's proposed rules 43 CFR 4.1370–4.1377, the permittee may file a request for review with OHA that includes OSM's notice; documentary proof or offers of proof concerning the § 773.20(b) review criteria (or their analogues in § 773.21(a)(1)–(4)); other relevant information; a request for specific relief; and a request for an evidentiary hearing. § 4.1372. The permittee may amend its request for review once as a matter of right before OSM files a response and may also do so afterwards with leave of the administrative law judge. The administrative law judge is to convene the hearing within 90 days of receiving responses to the request (unless the parties waive this deadline); this gives the parties an opportunity to conduct discovery under 43 CFR 4.1130–4.1141. § 4.1373. The administrative law judge must issue an initial decision within 30 days of the date the hearing record is closed. § 4.1375. OSM has the burden of going forward to present a prima facie case in support of its notice while the person requesting review has the ultimate burden of persuasion that the notice is in error. § 4.1374. Any party may file a petition for discretionary review of the administrative law judge's initial decision with IBLA. The petition shall attach a copy of this decision and specify the alleged errors. Other parties have 30 days to file responses, after which IBLA shall issue a decision within 60 days denying the petition or granting it and deciding the merits. § 4.1377.

OSM's proposed rule provides that its decision to suspend or rescind will remain in effect during the time a request for review is pending in OHA unless temporary relief is granted in accordance with 43 CFR 4.1376. 30 CFR

773.20(c)(2), 56 FR 45799 (Sept. 6, 1991). Proposed 43 CFR 4.1376 provides that with a request for review—or at any time before the administrative law judge issues the initial decision—any party may petition for temporary relief from OSM's notice of suspension or notice of proposed suspension and rescission. Under § 4.1376, the petition must show that the petitioner has a substantial likelihood of prevailing on the merits and that the relief it seeks will not adversely affect public health or safety or cause significant, imminent environmental harm. Other parties have 5 days to file responses. The administrative law judge must hold a hearing within 10 days of the filing of the responses if a hearing has been requested and must issue a decision granting or denying temporary relief within 5 days of the date of the hearing, or the filing of the responses if no hearing is held. If all parties have been notified of the petition and given an opportunity to respond (and a hearing has been held if requested), the administrative law judge may grant temporary relief if the petitioner has demonstrated a substantial likelihood of prevailing on the merits and the relief will not adversely affect public health or safety or cause significant, imminent environmental harm. These standards are based on those contained in 30 U.S.C. 1275(c) (1988). As noted in the preamble to the proposed regulations, 56 FR at 45807 (Sept. 6, 1991), the focus of the adverse effect inquiry would be on the permitted operation rather than operation allegedly in violation. Any party may appeal the administrative law judge's decision granting or denying temporary relief to IBIA, which shall decide the appeal expeditiously, or may seek judicial review.

OHA believes "the probable value, if any, of additional or substitute procedural safeguards"—in particular, an evidentiary hearing before a decision to suspend or rescind is effective—is minimal. As in *Mathews, supra* at 343–345, although the definition of ownership and control in 30 CFR 773.5 includes elements or judgment where witness credibility and veracity will sometimes play a role (e.g., §§ 773.5(a)(3), 773.5(b)(6)), the determination is usually made on the basis of documents, such as instruments of ownership or voting securities, or on the basis of readily and often publicly documentable circumstances such as a person's status as an officer or director of an entity, the permittee or operator of a surface coal mining operation, or a general partner in a parternship (e.g., §§ 773.5(a)(1)–(2), 773.5(b)(1)–(2), (4)–(5)). Further, a permittee receives sufficient notice of OSM's decision to suspend a permit (30 days under proposed § 773.20(c)(2)) or rescind a permit (up to 180 days under § 773.21) to enable it to request review by an administrative law judge before the decision becomes effective. The provisions in §§ 4.1370–4.1377 imposing short time frames for each step of review significantly reduce delay due to "the torpidity of [the] administrative review process," *Mathews, supra* at 342, especially if temporary relief is sought.

The "Government's interest" is to effectively implement section 510(c), specifically, to ensure that no person in violation of SMCRA or the other specified environmental laws obtains or retains a permit to conduct surface mining operations until the violation is corrected or in the process of being corrected. The Department's goal of achieving compliance with these laws would be significantly burdened if it were required to provide an evidentiary hearing before OSM could decide to suspend or rescind a permit because the person should not have received the permit when it was issued. It was OSM's experience in 1992–93 that providing informal review by OSM of the proposed entry into the AVS of information concerning ownership or control links became very time-and-personnel-consuming. For 105 cases in 1993, for example, OSM spent more than 11,000 hours from after investigating an ownership or control link to issuing its final decision, a mean of 105 hours per case. It would be even more costly to require an evidentiary hearing before a permit was suspended or rescinded; meanwhile, mining would continue while alleged outstanding violations existed.

In sum, as the Supreme Court stated in *Mathews, supra* at 343, "there is less reason here than in *Goldberg* to depart from the ordinary principle, established by our decisions, that something less than an evidentiary hearing is sufficient prior to adverse administrative action." OHA believes the procedures for OSM decisionmaking and OHA administrative review on the proposed rules provide all the due process that is due before an improvidently issued permit is suspended or rescinded.

As noted above, OSM's proposed rules also provide that an applicant for a permit or any other person that is shown in the AVS as having an ownership or control link to a person may challenge the link (unless the applicant or other person is bound by an earlier administrative or judicial decision concerning the link). See proposed 30 CFR 773.24(a)(1), 56 FR 45800 (Sept. 6, 1991). An applicant or any other person shown in the AVS may also challenge the status of the violation cited in a federal violation notice naming a person with whom the applicant or other person is linked (unless bound by a decision concerning the status of the violation). See proposed 30 CFR 773.24(a)(2), 56 FR 45800 (Sept. 6, 1991). The applicant or other person may submit a written explanation and supporting evidence to OSM concerning the existence of the link or the status of the violation. See proposed § 773.24(b), 56 FR 45800 (Sept. 6, 1991). Applying the standards for challenging ownership and control links and the status of violations contained in proposed § 773.26, 56 FR 45801–03 (Sept. 6, 1991), OSM will either correct the information in the AVS, if the applicant or other person shows the link is erroneous or the violation is no longer outstanding, or, if this is not shown, OSM will so notify the applicant or other person. See proposed § 773.24(d), 56 FR 45800 (Sept. 6, 1991). In either event, OSM will issue a written decision and serve it by certified mail. See proposed §§ 773.24(d)(2)(i), 56 FR 45800–01 (Sept. 6, 1991). The applicant or other person has a right to request review within 30 days of service of OSM's decision under the procedures proposed by OHA in 43 CFR 4.1380–4.1387. OSM's decision remains in effect pending a decision on review unless temporary relief is granted under proposed § 4.1386. See proposed § 773.24(d)(2)(ii), 56 FR 45801 (Sept. 6, 1991).

OHA's procedures in proposed 43 CFR 4.1380–4.1387 closely parallel those in §§ 4.1370–4.1377. Any person who receives a written OSM decision concerning a challenge to the existence of a link or the status of a violation may request review. § 4.1381. The required contents of the request are set forth in proposed § 4.1382; the request may be amended once as a matter of right before a response is filed by OSM and with the leave of an administrative law judge thereafter. § 4.1382(c). The administrative law judge is to convene a hearing within 90 days of receipt of the responses unless the parties waive that deadline, and give notice at least 10 days in advance of the hearing. § 4.1383. OSM has the burden of going forward to present a prima facie case in support of its decision, while the person requesting review has the ultimate burden of persuasion that the decision is in error. § 4.1384. An initial decision is required within 30 days after the record of the hearing is closed. § 4.1385. At any time

before the initial decision is issued, any party may file a petition for temporary relief from OSM's decision. Temporary relief may be granted if all parties to the proceeding have been notified of the petition, have had an opportunity to respond, and a hearing has been held if requested; and if the petitioner has demonstrated that it has a substantial likelihood of prevailing on the merits and that temporary relief will not adversely affect public health or safety or cause significant, imminent environmental harm. § 4.1386. Expedited review by IBLA or judicial review of a decision granting or denying temporary relief may be requested within 30 days of receipt of the decision. § 4.1386(h). If temporary relief is not requested, any party may file a petiton for discretionary review of the administrative law judge's initial decision within 30 days of receiving it. § 4.1387. The Board is to issue a decision denying the petition or granting it and ruling on the merits within 60 days of the deadline for filing responses to the petition section 4.1387(d).

The nature of a person's interest in an application for a permit cannot be regarded as a "legitimate claim of entitlement" to a permit and therefore requires less due process protection than the interest of a person who holds a permit that is subject to suspension or rescission because it was improvidently issued. See *Board of Regents* v. *Roth*, 408 U.S. 564, 569–71, 577 (1972). For a person who has applied for a permit or may apply for one, due process does not require a hearing on the existence of an ownership or control link or on the existence of a violation when it was cited before OSM issues a decision under proposed 30 CFR 773.24. If the proposed procedures in §§ 4.1370–4.1377 for administrative review of notices of permit suspension or rescission under proposed 30 CFR 773.20(c)(2) provide adequate due process protection, as OHA believes, then the parallel procedures in proposed §§ 4.1380–4.1387 certainly satisfy due process requirements for OSM's decisions regarding ownership and control links or the status of a violation under proposed 30 CFR 773.24. In particular, an applicant's opportunity to obtain temporary relief under 43 CFR 4.1386 from an OSM decision provides sufficient due process at this stage. Further administrative review is available to an applicant for a permit in an appeal of the denial of the application under existing procedures in 43 CFR 4.1360 through 4.1369, when the existence of the violation may be challenged. Providing an evidentiary hearing before OSM decisions under proposed 30 CFR 773.24 would severely impede the Department's effective implementation of section 510(c).

State Primacy

NCA/AMC argue that the proposed OSM and OHA regulations "undermine state primacy [under section 503 of SMCRA, 30 U.S.C. (1988)] entirely, by preempting state permitting authority where the ownership and control presumption is based on information contained within the AVS. * * * Additionally, OSM and OHA propose to require that any appeals from decisions on the ownership and control presumptions be made before the OHA in accordance with the proposed OHA regulations at 43 CFR 4.1380. * * * Moreover, OSM would create a completely federalized process for administrative review of the AVS linkage."

The regulatory authority in a state that has been delegated primacy under section 503 will retain its authority to issue permits. Information in the AVS is "other information available to the regulatory authority," within the meaning of section 510(c), that a state regulatory authority must use in deciding whether or not issuance of a permit should be blocked. The state regulatory authority's decision is its own—subject, of course, to OSM oversight. See 30 U.S.C. 1202(g), 1211(c), 1253, 1254, 1255, and 1271.

An applicant or other person shown in the AVS in an ownership or control link to any person cited in a state violation notice may challenge the status of the violation in that notice under the state program equivalents to proposed 30 CFR 773.24(b)–(d) and 773.26. See proposed 30 CFR 773.24(a)(3), 56 FR 45800 (Sept. 6, 1991). Similarly, decisions by a state regulatory authority to suspend or rescind a permit are reviewed by the State program equivalent of proposed 43 CFR 4.1370–4.1377. See proposed 30 CFR 773.20(c)(2), 56 FR 45799 (Sept. 6, 1991). The fact that challenges to ownerships and control links and to the status of violations are made to OSM by applicants or other persons shown in the AVS under proposed 30 CFR 773.24(a)(1) and (a)(2), and that OSM's decisions are reviewed under proposed 43 CFR 4.1380–4.1387, is a function of OSM's maintenance of the data in AVS and its responsibility to keep that data accurate and up-to-date. But OSM's role in deciding on the accuracy of the data and OHA's role in reviewing those decisions do not subvert the authority of the state regulatory authority in a primacy state to make decisions on applications for permits.

Burden of Proof

NCA/AMC object to OHA's proposed 43 CFR 4.1374(b) and 4.1384(b), which place the ultimate burden of persuasion on a permittee that seeks review of a notice of proposed suspension or rescission and on an applicant or other persons that seeks review of an OSM decision on a challenge to an ownership and control link or status of a violation shown in the AVS. In proposed §§ 4.1374(a) and 4.1384(a), OSM has the burden of going forward to present a prima facie case of the validity of the notice or decision. NCA/AMC state that when OSM seeks to overturn a permit as improvidently issued, it should bear the ultimate burden of proving its case. "All permits, once issued, should be accorded some presumption that they were issued in accordance and compliance with applicable law. * * * [I]t is the party seeking to set aside the permitting decision who should bear both the burden of going forward to establish a prima facie case and the ultimate burden of persuasion, "NCA/AMC state.

Allocation of the burdens of proof in proposed 43 CFR 4.1374 and 4.1384 is consistent with other OHA regulations governing review of OSM decisions. See 43 CFR 4.1171, 4.1193, 4.1366. OSM's burden of going forward to support a prima facie case of the validity of its notice or decision means it must present "sufficient evidence * * * to establish the essential facts * * * which evidence will remain sufficient if not contradicted. It is evidence that will justify but not compel a finding in favor of the one presenting it." *James Moore*, 1 IBSMA 216, 223 n.7, 86 I.D. 369, 373 n.7 (1979). It is the permittee, applicant, or other person shown in the AVS who will have access to information that would overcome OSM's prima facie case. *Harry Smith Construction Co.* v. *OSM*, 78 IBLA 27, 31 (1983). Under the Administrative Procedure Act, 5 U.S.C. 556(d) (1988), OSM properly bears only the burden of going forward with proof, not the ultimate burden of persuasion. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 548 F.2d 998, 1012–13 (D.C. Cir. 1976).

Right of Appeals From OSM Decisions for Adversely Affected Persons; Notice of Appeals to Adversely Affected Persons

The NWF comments criticized proposed 43 CFR 4.1371 for its failure to incorporate the rights of citizens to challenge decisions by OSM regarding improvidently issued permits under 30

CFR 773.20. As explained above, 30 CFR 773.20 provides that a permit has been improvidently issued if, under the violations review criteria at the time the permit was issued, the regulatory authority should not have issued the permit. Proposed 43 CFR 4.1371 grants a right of review to a "permittee that is served with a notice of suspension under 30 CFR 773.20(c)(2) or a notice of proposed suspension and rescission under 30 CFR 773.21." The rights of citizens to appeal similar decisions have been completely overlooked, NWF states.

Similarly, NWF objects to proposed 43 CFR 4.1381, which authorizes "[a]ny person who receives a written decision from OSM" pursuant to proposed 30 CFR 773.24(d)(2) or 773.25(c)(2) to file a request for review of OSM's finding that such person is in an ownership or control link to any person cited in a violation notice within the scope of 30 CFR 773.5 and 773.15(b). No provision for citizen-initiated appeals of these decisions exists under the proposed rules, NWF states. "Decisions by OSM not to act on the information provided by citizens, or decisions to issue permits in the face of information that indicates an ownership or control link to a violation, should be subject to review by the Office of Hearings and Appeals," NWF comments.

NWF also criticizes lack of notice to affected citizens. Although proposed 43 CFR 4.1372(b) provides to "OSM and all interested parties" the right to file an answer to a request for review of a decision to suspend or rescind a permit as improvidently issued and to request an evidentiary hearing even if the person requesting review does not, it is silent as to how interested parties other than OSM are to know that a request for review has been filed, NWF states. Only counsel for OSM would be served with a copy of a request for review under 43 CFR 4.1109, NWF observes. Similarly, the rules proposed in 43 CFR 4.1380–4.1387 for review of OSM decisions concerning ownership and control links provide "no notice to citizens who may be substantially and adversely affected by a reversal of a determination of ownership and control linkage," NWF comments. Specific provisions for notice to all affected persons of appeals of both kinds of OSM decisions should be adopted, NWF urges.

OHA agrees that provisions for notice to citizens of appeals of OSM decisions concerning permit suspension and rescission and concerning ownership and control links and for rights of appeal of such OSM decisions were not included in the proposed rules. Adding such provisions to the final rules on the basis of NWF's comments, however, without providing an opportunity for notice and comment, might be regarded as inconsistent with the requirements of the Administrative Procedure Act. See *American Federation of Labor* v. *Donovan*, 757 F.2d 330, 338–40 (D.C. Cir. 1985). After consultation with OSM, OHA may propose rules concerning these issues in the future. Meanwhile, no right of appeal by citizens from OSM decisions not to find an ownership or control link is available under these rules. Citizens may of course avail themselves of existing procedures, e.g., 30 CFR 773.13, 842.11, 842.12, 842.15, and 843.21, and petition for leave to intervene in proceedings under §§ 4.1370–4.1377 and 4.1380–4.1387 in accordance with 43 CFR 4.1110.

Changes in the Final Rules From the Proposed Rules

OHA believes no revisions to proposed 43 CFR 4.1370–4.1377 and 4.1380–4.1387 are required in response to the comments. However, OHA has made the following changes to the proposed rules to improve their clarity and to remove references to section numbers of the rules proposed by OSM:

1. 43 CFR 4.1373(a): The phrase "If a hearing is requested" has been added at the beginning of the first sentence, and the remainder of the sentence revised, to account for the possibility that a hearing might not be requested.

2. 43 CFR 4.1373(b): "of the date of the hearing" has been added at the end of the sentence to make clear that notice shall be given at least 10 days in advance of the hearing.

3. 43 CFR 4.1375: An alternative deadline is provided for issuance of an initial decision when no hearing is held.

4. 43 CFR 4.1380: The language concerning the kind of OSM decisions from which a request for review may be filed has been revised to replace references to 30 CFR 773.5 and 773.15(b) with a more general description, i.e., decisions on challenges by an applicant or other person shown in the AVS to an ownership or control link or the status of a violation.

5. 43 CFR 4.1381(a): The specific references to proposed 30 CFR 773.24(d)(2) and 773.25(c)(2) and to 30 CFR 773.5 and 773.15(b) have been replaced with language describing the kind of OSM decision from which a request for review may be filed, i.e., a written decision by OSM, in response to a challenge from an applicant or other person shown in the AVS, on whether or not the ownership or control link has been shown to be erroneous or has been rebutted and/or whether the violation covered by the notice remains outstanding, has been corrected, or is the subject of a good faith appeal.

6. 43 CFR 4.1383(a): The phrase "If a hearing is requested" has been added at the beginning of the first sentence, and the remainder of the sentence revised, to account for the possibility that a hearing might not be requested.

7. 43 CFR 4.1383(b): "of the date of the hearing" has been added at the end of the sentence to make clear that notice shall be given at least 10 days in advance of the hearing.

8. 43 CFR 4.1385: An alternative deadline is provided for issuance of an initial decision when no hearing is held.

In addition, in order to implement the Administrative Dispute Resolution Act, OHA has added rules (§§ 4.1371(c), 4.1381(c)) providing the parties an opportunity to employ alternatives means of dispute resolution, as defined in 5 U.S.C. 571(3) (1988), before the hearing and appeals procedures set forth in the following rules. Any party could decline this opportunity, in its discretion, at any time. Because no new obligations are imposed and this voluntary procedure does not affect substantive rights, its adoption does not require separate notice under the Administrative Procedure Act.

Determination of Effects

The Department has determined that these rules will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

Executive Order 12866

These rules were not subject to OMB review under Executive Order 12866.

National Environmental Policy Act

The Department has determined that these rules will not significantly affect the quality of the human environment on the basis of the categorical exclusion of regulations of a procedural nature set forth in 516 DM 2, Appendix 1, section 1.10.

Paperwork Reduction Act

These rules contain no information collection requirement requiring Office of Management and Budget approval under 44 U.S.C. 3501 *et seq.*

Takings Implication Assessment

These rules do not pose any takings implications requiring preparation of a Takings Implication Assessment under Executive Order No. 12630 of March 18, 1988.

Drafting Information

The primary author of these regulations is Will A. Irwin,

Administrative Judge, Interior Board of Land Appeals, Office of Hearings and Appeals, U.S. Department of the Interior.

List of Subjects in 43 CFR Part 4

Administrative practice and procedure, Mines, Public lands, Surface mining.

For the reasons set forth in the preamble, subpart L of part 4 of title 43 of the Code of Federal Regulations is amended as set forth below:

Dated: August 18, 1994.

Bonnie R. Cohen,

Assistant Secretary—Policy, Management and Budget.

43 CFR part 4 is amended as follows:

PART 4—[AMENDED]

Subpart L—Special Rules Applicable to Surface Coal Mining Hearings and Appeals

1. The authority citation for part 4, subpart L, continues to read as follows:

Authority: 30 U.S.C. 1256, 1260, 1261, 1264, 1268, 1271, 1272, 1275, 1293; 5 U.S.C. 301.

2. Section 4.1105 is amended by revising paragraph (a)(2) introductory text to read:

§ 4.1105 Parties.

(a) * * *

(2) In a review proceeding under §§ 4.1160 through 4.1171, 4.1180 through 4.1187, 4.1300 through 4.1309, 4.1350 through 4.1356, 4.1360 through 4.1369, 4.1370 through 4.1377, 4.1380 through 4.1387 or 4.1390 through 4.1394 of this part, OSM, as represented by the Office of the Solicitor, Department of the Interior, and—

* * * * *

3. New §§ 4.1370 through 4.1377 and a new undesignated heading preceding them are added to read:

Review of Decisions of the Office of Surface Mining Suspending or Rescinding Improvidently Issued Permits

Sec.

Review of Decisions of the Office of Surface Mining Suspending or Rescinding Improvidently Issued Permits

§ 4.1370 Scope.

Sections 4.1370 through 4.1377 govern the procedures for review of notices from OSM of suspension of improvidently issued permits issued under 30 CFR 773.20(c) or of notices of proposed suspension and rescission of improvidently issued permits issued under 30 CFR 773.21.

§ 4.1371 Who may file, where to file, when to file.

(a) A permittee that is served with a notice of suspension under 30 CFR 773.20(c)(2) or a notice of proposed suspension and rescission under 30 CFR 773.21 may file a request for review with the Hearings Division, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203 (Telephone 703–235–3800) within 30 days of service of the notice.

(b) Failure to file a request for review within 30 days of service of the notice shall constitute a waiver of review of the notice. An untimely request for review shall be dismissed.

(c) Where appropriate under the Administrative Dispute Resolution Act, 5 U.S.C. §§ 571–583, the Hearings Division may use a dispute resolution proceeding, if the parties agree to such proceeding, before the procedures set forth in §§ 4.1373 through 4.1377.

§ 4.1372 Contents of requests for review, response to request, amendment of request.

(a) The request for review shall include:

(1) A copy of the notice of suspension or the notice of proposed suspension and rescission;

(2) Documentary proof, or, where appropriate, offers of proof, concerning the matters set forth in 30 CFR 773.20(b) or 773.21(a)(1) through (4) showing that the person requesting review is entitled to administrative relief;

(3) A statement whether the person requesting review wishes an evidentiary hearing or waives the opportunity for such a hearing;

(4) A request for specific relief; and

(5) Any other relevant information.

(b) Within 20 days of service of the request for review by the permittee in accordance with 43 CFR 4.1109, OSM and all interested parties shall file an answer to the request for review or a motion in response to the request or a statement that no answer or motion will be filed. OSM or any interested party may request an evidentiary hearing even if the person requesting review has waived the opportunity for such a hearing.

(c) The permittee may amend the request for review once as a matter of right before a response in accordance with paragraph (b) of this section is required to be filed. After the period for filing such a response, the permittee may file a motion for leave to amend the request for review with the administrative law judge. If the administrative law judge grants a motion for leave to amend, he shall provide OSM and any other party that filed a response in accordance with paragraph (b) not less than 10 days to file an amended response.

§ 4.1373 Hearing.

(a) If a hearing is requested, the administrative law judge shall convene the hearing within 90 days of receipt of the responses under § 4.1372(a). The 90-day deadline for convening the hearing may be waived for a definite time by the written agreement of all parties, filed with the administrative law judge, or may be extended by the administrative law judge, in response to a motion setting forth good cause to do so, if no other party is prejudiced by the extension.

(b) The administrative law judge shall give notice of the hearing at least 10 days in advance of the date of the hearing.

§ 4.1374 Burdens of proof.

(a) OSM shall have the burden of going forward to present a prima facie case of the validity of the notice of suspension or the notice of proposed suspension and rescission.

(b) The permittee shall have the ultimate burden of persuasion by a preponderance of the evidence that the notice is invalid.

§ 4.1375 Time for initial decision.

The administrative law judge shall issue an initial decision within 30 days of the date the record of the hearing is closed, or, if no hearing is held, within 30 days of the deadline for filing responses under § 4.1372(b).

§ 4.1376 Petition for temporary relief from notice of suspension or notice of proposed suspension and rescission: appeals from decisions granting or denying temporary relief.

(a) Any party may file a petition for temporary relief from the notice of suspension or the notice of proposed suspension and rescission in conjunction with the filing of the request for review or at any time before an initial decision is issued by the administrative law judge.

(b) The petition for temporary relief shall be filed with the administrative law judge to whom the request for review has been assigned. If none has been assigned, the petition shall be filed with the Hearings Division, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203 (Telephone 703–235–3800).

(c) The petition for temporary relief shall include:

(1) A statement of the specific relief requested;

(2) A detailed statement of why temporary relief should be granted, including—

(i) A showing that there is a substantial likelihood that petitioner will prevail on the merits, and

(ii) A showing that the relief sought will not adversely affect the public health or safety or cause significant, imminent environmental harm to land, air or water resources;

(3) A statement whether the petitioner requests an evidentiary hearing.

(d) Any party may file a response to the petition no later than 5 days after it was served and may request a hearing even if the petitioner has not done so.

(e) The administrative law judge may hold a hearing on any issue raised by the petition within 10 days of the filing of responses to the petition, and shall do so if a hearing is requested by any party.

(f) The administrative law judge shall issue an order or decision granting or denying the petition for temporary relief within 5 days of the date of a hearing on the petition or, if no hearing is held, of service of the responses to the petition on all parties.

(g) The administrative law judge may only grant temporary relief if:

(1) All parties to the proceeding have been notified of the petition and have had an opportunity to respond and a hearing has been held if requested;

(2) The petitioner has demonstrated a substantial likelihood of prevailing on the merits; and

(3) Temporary relief will not adversely affect public health or safety or cause significant, imminent harm to land, air or water resources.

(h) Any party may file an appeal of an order or decision granting or denying temporary relief with the Board within 30 days of receipt of the order or decision or, in the alternative, may seek judicial review within 30 days in accordance with section 526(a) of the Act, 30 U.S.C. 1276(a). If an appeal is filed with the Board, the Board shall issue an expedited briefing schedule and shall decide the appeal expeditiously.

§ 4.1377 Petition for discretionary review of initial decision.

(a) Any party may file a petition for discretionary review of an initial decision of an administrative law judge issued under § 4.1375 with the Board within 30 days of receipt of the decision. An untimely petition shall be dismissed.

(b) The petition for discretionary review shall set forth specifically the alleged errors in the initial decision, with supporting argument, and shall attach a copy of the decision.

(c) Any party may file a response to the petition for discretionary review within 30 days of its service.

(d) The Board shall issue a decision denying the petition or granting the petition and deciding the merits within 60 days of the deadline for filing responses.

4. New §§ 4.1380 through 4.1387 and a new undesignated heading preceding them are added to read:

Review of Office of Surface Mining Written Decisions Concerning Ownership and Control

Sec.

Review of Office of Surface Mining Written Decisions Concerning Ownership and Control

§ 4.1380 Scope.

Sections 4.1380 through 4.1387 govern the procedures for review of written decisions of OSM on challenges by an applicant or other person shown in the Applicant Violator System to an ownership or control link or the status of a violation.

§ 4.1381 Who may file; when to file; where to file.

(a) An applicant or any other person shown in the Applicant Violator System who receives a written decision by OSM, in response to a challenge to an ownership or control link or the status of a violation, on whether or not the ownership or control link has been shown to be erroneous or has been rebutted and/or whether the violation covered by a federal violation notice remains outstanding, has been corrected, or is the subject of a good faith appeal may file a request for review with the Hearings Division, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203 (Telephone 703–235–3800) within 30 days of service of the decision.

(b) Failure to file a request for review within 30 days of service of the decision constitutes a waiver of review of the decision. An untimely request for review shall be dismissed.

(c) Where appropriate under the Administrative Dispute Resolution Act, 5 U.S.C. §§ 571–583, the Hearings Division may use a dispute resolution proceeding, if the parties agree to such proceeding, before the procedures set forth in §§ 4.1383 through 4.1387.

§ 4.1382 Contents of request for review; response to request; amendment of request.

(a) The request for review shall include:

(1) A copy of the decision of OSM;

(2) A statement of the alleged errors in the decision and the facts that entitle the person requesting review to administrative relief;

(3) A statement whether the person requesting review wishes an evidentiary hearing or waives the opportunity for such a hearing;

(4) A request for specific relief; and

(5) Any other relevant information.

(b) Within 20 days of service of the request for review in accordance with 43 CFR 4.1109, OSM and all interested parties shall file an answer to the request for review or a motion in response to the request or a statement that no answer or motion will be filed. OSM or any interested party may request an evidentiary hearing even if the person requesting review has waived the opportunity for a hearing.

(c) The person filing the request for review may amend it once as a matter of right before the response in accordance with paragraph (b) of this section is required to be filed. After the period for filing such a response, the person may file a motion for leave to amend the request with the administrative law judge. If the administrative law judge grants a motion for leave to amend, he shall provide OSM and any other party that filed a response in accordance with paragraph (b) not less than 10 days to file an amended response.

§ 4.1383 Hearing.

(a) If a hearing is requested, the administrative law judge shall convene the hearing within 90 days of receipt of responses under § 4.1382(b). The 90-day deadline for convening the hearing may

be waived for a definite time by the written agreement of all parties, filed with the administrative law judge, or may be extended by the administrative law judge, in response to a motion setting forth good cause to do so, if no other party is prejudiced by the extension.

(b) The administrative law judge shall give notice of the hearing at least 10 days in advance of the date of the hearing.

§ 4.1384 Burdens of proof.

(a) OSM shall have the burden of going forward to present a prima facie case of the validity of the decision.

(b) The person filing the request for review shall have the ultimate burden of persuasion by a preponderance of the evidence that the decision is in error.

§ 4.1385 Time for initial decision.

The administrative law judge shall issue an initial decision within 30 days of the date the record of the hearing is closed, or, if no hearing is held, within 30 days of the deadline for filing responses under § 4.1382(b).

§ 4.1386 Petition for temporary relief from decision; appeals from decisions granting or denying temporary relief.

(a) Any party may file a petition for temporary relief from the decision of OSM in conjunction with the filing of the request for review or at any time before an initial decision is issued by the administrative law judge.

(b) The petition for temporary relief shall be filed with the administrative law judge to whom the request for review has been assigned. If none has been assigned, the petition shall be filed with the Hearings Division, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203 (Telephone 703–235–3800).

(c) The petition for temporary relief shall include:

(1) A statement of the specific relief requested:

(2) A detailed statement of why temporary relief should be granted, including:

(i) A showing that there is a substantial likelihood that petitioner will prevail on the merits, and

(ii) A showing that granting the relief requested will not adversely affect the public health or safety or cause significant, imminent environmental harm to land, air or water resources;

(3) A statement whether the petitioner requests an evidentiary hearing.

(d) Any party may file a response to the petition no later than 5 days after it was served and may request a hearing even if the petitioner has not done so.

(e) The administrative law judge may hold a hearing on any issue raised by the petition within 10 days of the filing of responses to the petition, and shall do so if a hearing is requested by any party.

(f) The administrative law judge shall issue an order or decision granting or denying the petition for temporary relief within 5 days of the date of a hearing on the petition or, if no hearing is held, of service of the responses to the petition on all parties.

(g) The administrative law judge may only grant temporary relief if:

(1) All parties to the proceeding have been notified of the petition and have had an opportunity to respond and a hearing has been held if requested;

(2) The petitioner has demonstrated a substantial likelihood of prevailing on the merits; and

(3) Temporary relief will not adversely affect public health or safety or cause significant, imminent environmental harm to land, air or water resources.

(h) Any party may file an appeal of an order or decision granting or denying temporary relief with the Board within 30 days of receipt of the order or decision or, in the alternative, may seek judicial review within 30 days in accordance with section 526(a) of the Act, 30 U.S.C. 1276(a). If an appeal is filed with the Board, the Board shall issue an expedited briefing schedule and shall decide the appeal expeditiously.

§ 4.1387 Petition for discretionary review of initial decisions.

(a) Any party may file a petition for discretionary review of an initial decision of an administrative law judge issued under § 4.1385 with the Board within 30 days of receipt of the decision. An untimely petition shall be dismissed.

(b) The petition for discretionary review shall set forth specifically the alleged errors in the initial decision, with supporting argument, and shall attach a copy of the decision.

(c) Any party may file a response to the petition for discretionary review within 30 days of its service.

(d) The Board shall issue a decision denying the petition or granting the petition and deciding the merits within 60 days of the deadline for filing responses.

[FR Doc. 94–26553 Filed 10–27–94; 8:45 am]

BILLING CODE 4310–79–M