Guidance on Recall Plans

Quality Management Systems Subcommittee
Science & Policy Workgroup

NOTE: This guidance is not legal advice. It is intended to assist licensed marijuana businesses to better understand elements of a recall plan. Please consult an attorney or quality management professional if you have any questions regarding the requirements that apply to licensed marijuana businesses.

What is a recall plan?
A recall plan is a written procedure that is designed to prevent unsafe or potentially harmful products from reaching consumers. All organizations, regardless of size, should have a recall plan in place. A strong recall plan may prevent illness or injury to consumers and could reduce a company's liability. Conversely, a poor or nonexistent recall plan could lead to an adverse health event resulting in legal, financial, or regulatory liability.

What is included in a recall plan?
A written recall plan may include many parts, all of which should be tested with mock recalls. A recall plan should include the following parts:

- A primary individual responsible for the plan (i.e. recall coordinator) and a recall team.
- Evaluation of the complaint or condition; collecting information, determining the need for a recall.
- Written traceability procedures - Identification of affected Marijuana Businesses, distribution list and product information
- Notification of parties impacted and regulatory agencies - this includes a recall notice
- Removal of affected products
- Effectiveness Check
- Termination of Recall

The recall plan should be periodically tested through random mock recalls. These events will test the ability of the plan to trace, locate and recapture products. This will evaluate the effectiveness of the plan and identify areas where improvement is needed.

Recall Plan:
<u>Create a recall team:</u>

1. Recall Coordinator: Oversees all activities relating to the recall and manages the recall team.
2. Other team members may include:
    a. Compliance Person or Quality Manager to help determine the root cause of the complaint.
    b. Communications personnel
    c. Sales and marketing personnel
    d. Administrative support
    e. Accounting
    f. Legal Counsel

<u>Evaluation of a Complaint or Condition:</u> Once a nonconformity is found or a complaint is received, the marijuana business shall start a file to collect information. All complaints shall be recorded if they impact health or cause an adverse reaction. Complaint records must contain:

1. The name of the complainant
2. The purchase date
3. The location, name, and license number of the business where the product was purchased

4. The date the complaint was received
5. The nature of the complaint
6. The steps taken to investigate the complaint
7. The response to the complaint
8. The name and Production or Harvest Batch number for the Regulated Marijuana subject to the complaint.

Determine the Need for a Recall:
Initiating a recall can be voluntary or be requested by the Division (MED). If a recall is deemed necessary the Regulated Marijuana Business shall contact the MED to notify them.

If a recall is not necessary, document on the records why not. If an initial assessment indicates a recall may be necessary, the Regulated Marijuana Business shall take the following measures:

1. Determine the hazard and evaluate the safety concerns with the product;
2. Undertake necessary product quarantine measures for any affected Regulated Marijuana in the Licensee's possession or control; and
3. Determine the product removal strategy appropriate to the threat and location in commerce.

Identification of Affected Regulated Marijuana:
A recall plan must establish a process for identifying affected Regulated Marijuana subject to a recall, which shall include the following:

1. Distribution List. When identifying Regulated Marijuana subject to a recall, the Licensee shall create a distribution list that includes the following information:
    a. The name, license number, and address of the Regulated Marijuana Business(es) that received the Regulated Marijuana subject to the recall
    b. Ship or Transfer date(s) for the Regulated Marijuana subject to the recall;
    c. Business contact information for each Regulated Marijuana Business that received Regulated Marijuana subject to the recall, including names and telephone numbers.

Product Information:
When identifying Regulated Marijuana subject to a recall, the Licensee shall document the following product information:

1. The category of Regulated Marijuana (e.g. Medical Marijuana flower; Medical Marijuana Concentrate; Medical Marijuana Product; Retail Marijuana flower; Retail Marijuana Concentrate, Retail Marijuana Product);
2. Product description;
3. Net contents;
4. Production or Harvest Batch number;
5. The license number(s) for the Regulated Marijuana Business(es) that cultivated or manufactured the product(s) subject to the recall; and
6. To the extent known after reasonable diligence to ascertain the information, the recall plan must also include the following additional product information:
    a. The amount of affected Regulated Marijuana returned in response to the recall
    b. The amount of affected Regulated Marijuana that remains in the marketplace.

Notification to Affected Parties:

1. A Licensee initiating a recall pursuant to this rule shall issue a recall notice to Regulated Marijuana Businesses identified on the Licensee's distribution list no later than 48 hours from issuing a recall notice to Regulated Marijuana Businesses on the Licensee's distribution list.
2. The Licensee shall issue the following additional notifications:

a. The Licensee shall notify the Division and the Colorado Department of Public Health and Environment
b. The Licensee shall notify the Local Licensing Authority or Local Jurisdiction in which the Licensee issuing the recall is located
c. The Licensee shall notify patients or consumers using the most effective method available, which may include any of the following methods: an email to the patient or customer list serve, an alert on the Regulated Marijuana Business' website, a warning that is clearly and visibly posted on the Regulated Marijuana Business' Licensed Premise, or a press release to notify patients or consumers.

Recall Notice:

A recall notice issued by a Regulated Marijuana Business pursuant to this rule shall include at least the following information:

1. The reason for recall and related hazards, if any.
2. If the Regulated Marijuana is being removed for quality rather than health reasons, the notice may state that the Regulated Marijuana does not meet internal company specifications and is being removed from distribution
3. The category of Regulated Marijuana (e.g. Medical Marijuana flower; Medical Marijuana Concentrate; Medical Marijuana Product; Retail Marijuana flower; Retail Marijuana Concentrate, Retail Marijuana Product);
4. Regulated Marijuana Businesses that received the Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana Concentrate or Retail Marijuana Product;
5. The license number(s) and name(s), including trade name(s), of the Regulated Marijuana Business(es) that cultivated or manufactured the product(s) subject to the recall
6. Product description(s) for Regulated Marijuana subject to the recall
7. Production or Harvest Batch number(s) for the Regulated Marijuana subject to the recall
8. Expiration date(s) for the Regulated Marijuana subject to the recall, if applicable
9. Ship or Transfer date(s) for the Regulated Marijuana subject to the recall
10. Instructions regarding the disposition of the Regulated Marijuana subject to the recall.

Removal of Affected Regulated Marijuana:

1. A Regulated Marijuana Business subject to this Rule 3-336 shall make all reasonable efforts to remove the affected Regulated Marijuana from commerce.
2. Affected Regulated Marijuana that is either still in control of the originating Regulated Marijuana Business or in commerce shall be, secured, segregated, clearly labeled not for sale or distribution and separated from any other Medical Marijuana Concentrate, Medical Marijuana Product(s), Retail Marijuana Concentrate, or Retail Marijuana Product(s).
3. Final Product Disposition. At the discretion of the Regulated Marijuana Business
4. contaminated product must be disposed by either:
    i. Destroying and documenting the destruction of the affected Regulated Marijuana pursuant to Rule 3-230; or
    ii. If possible, Decontaminating the affected Regulated Marijuana pursuant to Rule 4-135(B)(2). If the Regulated Marijuana cannot be decontaminated, it must be destroyed pursuant to Rule 4-135(B)(3)(c) and 3-230.

Recall Effectiveness:

1. A Regulated Marijuana Business initiating a recall pursuant to this rule is responsible for determining whether the recall is effective.
2. The Licensee shall complete recall effectiveness checks to verify that all receiving Licensees have been notified and have taken the appropriate action.
3. Effectiveness checks shall determine:

a. If the receiving Licensee received the recall notification;
b. If the recalled Regulated Marijuana was handled as instructed in the recall notification; and
c. If the Regulated Marijuana was further distributed or sold by the receiving Licensee before receipt of the recall notification, and if so, were these additional Licensees notified.

4. If 100 percent of the affected Regulated Marijuana has been accounted for, then no effectiveness checks are required.

Termination of Recall:

1. A Regulated Marijuana Business initiating a recall pursuant to this rule may terminate the recall when the Licensee determines that all reasonable efforts have been made to remove or correct the affected Regulated Marijuana in accordance with the recall plan, and when it is reasonable to assume that the Regulated Marijuana subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled Regulated Marijuana.
2. Upon termination of the recall, the Regulated Marijuana Business shall provide notice to the Division with a recall status report and a description of the disposition of the recalled Regulated Marijuana. The recall status report shall contain the following information:
    a. Number of receiving Licensees notified of the recall, the date and method of notification
    b. Number of receiving Licensees who responded to the recall notice and both the quantity of affected Regulated Marijuana in the possession of the Licensee at the time of response, and quantity of affected Regulated Marijuana returned or corrected
    c. Number and results of the effectiveness checks that were made\Estimated time frame for completion of the recall.

Mock Recall

It is recommended that businesses conduct a mock recall twice a year. Mock recalls prepare a facility for an actual recall and provide an opportunity to identify and address any deficiencies in the current procedure. Mock recalls can help to:

1. Test the traceability system by tracing a product's journey within the supply chain.
2. Verify communication systems – personnel, suppliers, consumers, etc.
3. Determine and modify portions of the plan that prove problematic or challenging.

Conducting a Mock Recall

1. Choose a product(s) for the mock recall.
2. Use your internal Recall Plan and go through the recall process.
3. Document the mock recall actions and findings.
4. Discuss any gaps or deficiencies, and update the recall plan if needed.

Where can I learn more about recall plans?

1. U.S. Consumer Product Safety Commission's article on Recall Planning. https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Be-Prepared-Recall-Planning
2. California Department of Public Health Sample Recall Plan. https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/FoodRecalls/SampleRecallPlan.pdf
3. U.S. Food and Drug Administration Drug Recalls. https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls