

Recalls & Adverse Events

Alabama

Cannabis has been consumed by humans for thousands of years. The medicinal use of it originated in central Asia or western China as far back as 2800 B.C.

Cannabis may be generally considered to be safe, and serious adverse events can and have occurred.

One of our top goals in the cannabis industry is to **cultivate, process, and dispense cannabis in a responsible, safe manner** so we can continue to grow the industry and provide safe access for patients.

Consumer safety is dependent upon our industry ensuring that only safe cannabis products are sold. If a licensee becomes aware that unsafe products have been distributed, activate your **recall plan, ensure no additional affected products are sold, and promptly notify all potentially affected parties.**

Application Requirements

A detailed **Recall Plan** is required within Alabama Medical Cannabis Commission (AMCC) license applications. This document must be maintained and made available to the AMCC upon request. Licensees are required to notify the AMCC if and when there are “Material Breaches,” or instances when operations differ from those that were submitted within license applications:

The Recall Plan will be followed in the event of required recalls. The plan must include, but is not limited to:

- Provisions for notifying the all affected licensees of an adverse event;
- Factors about an adverse event that would likely necessitate a recall, and any potential for retesting or remediation;
- Responsible individuals or positions who will oversee the recall process;
- Notification protocols to other licensees and the AMCC through Metrc;
- Processes to ensure that the recalled product is returned, remediated (and deemed safe,) or destroyed;
- Processes to report to the AMCC and any other appropriate agencies regarding crisis response and steps taken to mitigate or avoid danger to the public;
- Steps to be taken to avoid further contamination, to preserve and protect uncontaminated medical cannabis, and to ensure access to said products by those who depend on it; and
- Investigation and analysis of the factors that led to the unsafe condition requiring the recall, and any adjustments to SOPs to avoid recurrence.

Additional Required SOPs

In addition to the above, Dispensaries must have and maintain a **Contamination and Recall Plan**. Operations must match those outlined in applicable SOPs, which should be reviewed and updated at least annually. All SOPs must be readily accessed from the physical site of operations upon the request of the AMCC.

The Contamination and Recall Plan must detail the steps to be undertaken in the event of discovery of contamination of medical cannabis. The plan must account for the safety of employees and others on the premises, notification of proper authorities, exploring the possibility of retesting or remediation, proper disposal of contaminated medical cannabis, steps to be taken for the preservation of medical cannabis, and the reasonable efforts to maintain access to those who depend on it.

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538-X-8-.05 Applications And Licensing Procedures As To Dispensaries Generally.

(3) Procedure for Filing Application - Exhibits to Dispensary's Application. Exhibits to the Dispensary Applicant's application information shall include all those as provided in subparagraphs 3.m.(1) through 3.m.(16) of Rule 538-X-3-.05 of Chapter 3 of these Rules, unless specifically provided otherwise as follows:

(1) Dispensary applicants must provide a detailed recall plan that will be followed in the event one or more of the products offered for sale at its dispensing sites, including any lots or batches thereof, is determined to require recall. The plan must include, but is not limited to, the following:

1. Provisions for notifying the originating Processor or Integrated Facility and any other licensee in the chain of custody of an adverse event;
2. Factors about an adverse event that would likely necessitate a recall, and any potential for retesting or remediation;
3. Responsible individuals or positions within the Dispensary's organization who will oversee the recall process;
4. Notification protocols to other licensees and the Commission through the Statewide Seed-to-Sale Tracking System;
5. Processes to ensure that the recalled product is returned, remediated (and ultimately approved as safe), or destroyed; processes to report to the Commission and any other appropriate regulatory body regarding crisis response and steps taken to mitigate or avoid danger to the public;
6. Steps to be taken to avoid further contamination, to preserve and protect uncontaminated cannabis or medical cannabis products, and to ensure access to said products by those who depend on it; and
7. Investigation and analysis of the factors that led to the unsafe condition requiring the recall, and any adjustments to internal protocols and processes to avoid recurrence.

538-X-4-.07 Duty To Meet And Maintain Standards, Policies, Procedures and Operations Per Application.

A licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended by the licensee from time to time in accordance with Rules 538-X-4-.08 and 538-X-4-.19. Specifically, at the time of the licensee's pre commencement inspection and at each inspection thereafter, a licensee must meet and/or maintain the following, in the manner previously provided at the time of licensing, as updated (i.e., current to within 30 days, unless otherwise required):

(12) The following documents, labeled, and in the following order:

(o) The licensee's verified Standard Operating Plan and Procedures. The licensees must demonstrate and maintain standard operating procedures regarding the following subjects in such a way that they can be readily accessed from the physical site of operations upon the request of inspectors, the Commission, or Commission staff, including, at a minimum, the following:

4. Contamination and Recall Plan. Licensees must maintain at all times and review at least annually a clear written contamination and recall plan, detailing the steps to be undertaken in the event of discovery of contamination of cannabis or medical cannabis within the possession and control of the licensee. The plan must account for the safety of employees and others on the premises, notification of proper authorities, exploring the possibility of retesting or remediation, proper disposal of contaminated cannabis and medical cannabis, steps to be taken for the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it.