

ADVISORY BULLETIN

March 22, 2018

SAFETY COMPLIANCE FACILITIES PRE-LICENSURE INSPECTION REMINDERS

Please note the following excerpts from the <u>Emergency Rules</u> and from the <u>Medical</u> <u>Marihuana Facilities Licensing Act</u>, in preparation for pre-licensure inspections. This list is not all-inclusive yet highlights key areas to consider when navigating the application and inspection process.

A safety compliance facility shall use analytical testing methodologies for the required quality assurance tests in sub rule (2) of Rule 31 that are validated and may be monitored on an ongoing basis by the department or third party. The methodologies shall include either the most current version of the Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia or an alternative testing methodology approved by the department and validated by an independent third party that the methodology followed by the laboratory produces scientifically accurate results as quality assurance for each test it conducts.

A safety compliance facility shall become fully accredited by the International Organization for Standardization (ISO), ISO/IEC 17025:2005, or by an entity approved by the department within one year after the date the license is issued and agree to have the inspections and reports of the International Organization for Standardization made available to the department. A safety compliance facility must become provisionally accredited within six months from the issuance of a license and may be ordered to cease operations if provisional accreditation is not received within six months.

A safety compliance facility shall test samples per the Michigan medical marihuana act and the emergency rules and shall collect the samples of marihuana product from another marihuana facility per the guidelines in the rules (refer to Emergency Rules for details).

In addition to transfer and testing authorized in section 203, a safety compliance facility license authorizes the safety compliance facility to take marihuana from, test marihuana for, and return marihuana to only a marihuana facility and to collect a random sample of marihuana at the marihuana facility of a grower, processor, or provisioning center for testing – without using a secure transporter:

A safety compliance facility must be accredited by an entity approved by the board by 1 year after the date the license is issued or have previously provided drug testing services to this state or this state's court system and be a vendor in good standing in regard to those services. The board may grant a variance from this requirement upon a finding that the variance is necessary to protect and preserve the public health, safety, or welfare.



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A grower shall uniquely identify each immature plant batch in the statewide monitoring system. Each immature plant batch must not consist of more than 100 immature plants. A grower shall tag each plant that is greater than 8 inches in height or more than 8 inches in width with an individual plant tag and record the identification information in the statewide monitoring system.

A grower shall delineate or separate the plants as the plants go through different growth stages and ensure that the plant tag is always identified with the plant throughout the growth span so that all plants can be easily identified and inspected pursuant to the act and these rules. A grower shall ensure that identification information is recorded in the statewide monitoring system in accordance with the act, the marihuana tracking act, and these rules.

After a tagged plant is harvested, it is part of a harvest batch so that a sample of the harvest batch can be tested by a safety compliance facility. A grower shall isolate a harvest batch from other plants or batches that has test results pending. A harvest batch must be easily distinguishable from other harvest batches until the batch is broken down into packages.

Before the marihuana product can leave the grower facility, a sample of the harvest batch must be tested by a licensed safety compliance facility as provided in Rule 32, and test results must indicate a passed test result in the statewide monitoring system before the marihuana can be packaged. Marihuana product from harvest batches must not be transferred or sold until tested, packaged, and tagged.

After test results show a passed test, the grower shall destroy the individual plant tags and the harvest batch is packaged. Each package must have a package tag attached. A grower shall ensure this information is placed in the statewide monitoring system in accordance with the act, the marihuana tracking act, and these rules.

A grower shall not transfer or sell any marihuana product that has not been packaged with a package tag attached and recorded in the statewide monitoring system in accordance with the act, the marihuana tracking act, and these rules.

After a processor receives or purchases a package in the statewide monitoring system, and the processor proceeds to process the marihuana product in accordance with the scope of a processor license, the act, and these rules, the processor must give the marihuana product a new package tag anytime it changes state or is incorporated into something else.

Once a package is created by a processor of the marihuana product in its final state, the processor shall have the sample tested pursuant to Rule 32. The processor shall not transfer or sell a final package until after test results indicate a passed test.



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After a provisioning center receives or purchases marihuana product in the statewide monitoring system, a licensee may sell or transfer marihuana product only to a registered qualifying patient or registered primary caregiver after the marihuana product has received passing test results in the statewide monitoring system and bears the label required for retail sale under the act and these rules. If the test results cannot be confirmed, the marihuana product must be tested by a safety compliance facility and receive passing test results prior to sale or transfer.