

Safety Compliance Facility Inspection (MMFLA)

Sec./Rule Order

Rule 9
Facility Plan on File

R 333.209 Marihuana facility plan.

Rule 9. (1) An applicant shall submit a marihuana facility plan for the proposed marihuana facility as required in R 333.207 and upon request by the department. Upon the request of the department, an applicant or licensee may be required to submit a revised marihuana facility plan.

(2) The marihuana facility plan must include, but is not limited to, all of the following:

(a) The type of proposed marihuana facility, the location of the marihuana facility, a description of the municipality where the marihuana facility will be located, and any of the following, if applicable:

(i) A statement in the marihuana facility plan that a combination of state operating licenses will operate as separate marihuana facilities at the same location, as provided under R 333.232.

(ii) A statement in the marihuana facility plan that the applicant has or intends to apply to stack a license at the proposed marihuana facility as provided under R 333.220.

(b) A diagram of the marihuana facility including, but not limited to, all of the following:

(i) The proposed facility's size and dimensions.

(ii) Specifications of the marihuana facility.

(iii) Physical address.

(iv) Location of common entryways, doorways, or passageways.

(v) Means of public entry or exit.

(vi) Limited-access areas within the marihuana facility.

(vii) An indication of the distinct areas or structures for separate marihuana facilities at the same location as provided in R 333.232.

(c) A detailed floor plan and layout that includes all of the following:

(i) Dimensions of the marihuana facility including interior and exterior rooms.

(ii) Maximum storage capabilities.

(iii) Number of rooms.

(iv) Dividing structures.

(v) Fire walls.

(vi) Entrances and exits.

(vii) Locations of hazardous material storage.

(viii) Quantities of hazardous materials, such as chemical, flammable/combustible liquids and gases, and the expected daily consumption of the hazardous materials.

(d) Means of egress, including, but not limited to, delivery and transfer points.

(e) Construction details for structures and fire-rated construction for required walls.

(f) Building structure information, including but not limited to, new, pre-existing, freestanding, or fixed.

(g) Building type information, including but not limited to, commercial, warehouse, industrial, retail, converted property, house, building, mercantile building, pole barn, greenhouse, laboratory, or center.

(h) Zoning classification and zoning information.

(i) If the proposed marihuana facility is in a location that contains multiple tenants and any applicable occupancy restrictions.

(j) A proposed security plan that demonstrates the proposed marihuana facility meets the security requirements specified in R 333.235.

(k) Any other information required by the department if not inconsistent with the act and these rules.

(3) Any changes or modifications to the marihuana facility plan under this rule must be reported to the department and may require preapproval by the department.

(4) The department may provide a copy of the marihuana facility plan to the BFS, local fire department, and local law enforcement for use in pre-incident review and planning.

(5) The department may reinspect the marihuana facility to verify the plan at any time and may require that the plan be resubmitted upon renewal.

<p style="text-align: center;">R 17 Inspection Authority</p>	<p>R 333.217 Inspection; investigation.</p> <p>Rule 17. (1) The department shall do all of the following with respect to inspections and investigations of applicants, licensees, proposed marihuana facilities, and marihuana facility operations:</p> <p>(a) Oversee and conduct inspections through its investigators, agents, auditors, or the state police of proposed marihuana facilities and marihuana facilities as provided in section 303 of the act, MCL 333.27303, to ensure compliance with the act and these rules.</p> <p>(b) Investigate individuals employed by marihuana facilities.</p> <p>(c) Inspect and examine marihuana facilities and proposed marihuana facilities.</p> <p>(d) Inspect, examine, and audit records of the licensee.</p> <p>(2) The department may at any time, through its investigators, agents, auditors, or the state police, without a warrant and without notice to the licensee, enter the proposed marihuana facility or marihuana facility, offices, or other places of business of a licensee, if evidence of compliance or noncompliance is likely to be found in accordance with the act and these rules.</p> <p>(3) The department, through its investigators, agents, auditors, or the state police, may place an administrative hold on a marihuana product and order that no sales or transfers occur during an investigation for an alleged violation or violation of the act or these rules.</p> <p>(4) The department, through its investigators, agents, auditors, or the state police, may inspect, examine, and audit relevant records of the licensee. If a licensee fails to cooperate with an investigation, the department through its investigators, agents, auditors, or the state police may impound, seize, assume physical control of, or summarily remove records from a proposed marihuana facility or marihuana facility.</p> <p>(5) The department through its investigators, agents, auditors, or the state police may eject or exclude, or authorize the ejection or exclusion of, an individual from a proposed marihuana facility or marihuana facility if that individual violates the act, a final order, or these rules.</p> <p>(6) The department through its investigators, agents, auditors, or the state police may take any reasonable or appropriate action to enforce the act and rules.</p> <p>(7) This rule does not limit the application of any other remedies or sanctions that are available through local, state, and federal laws, the act, and these rules.</p> <p>(8) For purposes of this rule, the term “record” means books, ledgers, documents, writings, photocopies, correspondence, electronic records, videotapes, surveillance footage, electronic storage media, electronically stored records, money receptacles, equipment in which records are stored, including data or information in the statewidemonitoring system, or any other document that is used for recording information.</p>
<p style="text-align: center;">§303(f) Records maintained onsite</p>	<p>Sec. 303 Require all relevant records of licensees, including financial or other statements, to be kept on the premises authorized for operation of the marihuana facility of the licensee or in the manner prescribed by the board.</p>
<p style="text-align: center;">R 10 Inspections: C of O, BFS Compliance</p>	<p>R 333.210 Prelicensure investigation; proposed marihuana facility inspection.</p> <p>Rule 10. (1) An applicant for a state operating license shall submit to a prelicensure physical inspection of a proposed marihuana facility, as determined by the department.</p> <p>(2) The department shall establish an inspection process to confirm that the applicants and proposed marihuana facilities meet the requirements of the act and these rules.</p> <p>(3) The department shall investigate an applicant in accordance with the act and these rules.</p> <p>(4) The department, through its investigators, agents, auditors, or the state police, shall conduct inspections and examinations of an applicant and a proposed marihuana facility in accordance with the act and these rules.</p> <p>(5) An applicant shall submit proof to the department of both of the following:</p> <p>(a) A certificate of use and occupancy as required pursuant to section 13 of the Stille- DeRossett-Hale single state construction code act, 1972 PA 230, MCL 125.1513, and these rules.</p> <p>(b) A fire safety inspection as specified in R 333.234.</p>

R 333.215 Notification and reporting.

Rule 15. (1) Applicants and licensees have a continuing duty to provide the department with up-to-date contact information and shall notify the department in writing of any changes to the mailing addresses, phone numbers, electronic mail addresses, and other contact information they provide the department.

(2) Applicants and licensees shall report any changes to the marihuana facility operations that are required in R 333.231 to R 333.238 and as required in the act and these rules, as applicable.

(3) Applicants and licensees shall report material changes to the department before making a material change that may require prior authorization by the department. Material changes, include, but are not limited to, the following:

(a) Change in owners, officers, members, or managers.

(b) Change of location. Upon notification of a change in location, the department may determine that a new license and new inspection are required for the change of location.

(c) A description of a violation of an ordinance or a zoning regulation adopted pursuant to section 205 of the act, MCL 333.27205, committed by the licensee, but only if the violation relates to activities licensed under the act, the Michigan medical marihuana act, and these rules.

(d) The addition or removal of persons named in the application or disclosed.

(e) Change in entity name.

(f) Any attempted transfer, sale, or other conveyance of an interest in a license.

12

(g) Any change or modification to the marihuana facility for prelicensure or postlicensure that was not preinspected, inspected, or part of the marihuana facility plan or final inspection including, but not limited to, operational or method changes requiring inspection under these rules, additions or reductions in equipment or processors at a marihuana facility, increase or decrease in the size or capacity of the marihuana facility, alterations of ingress or egress, and changes that impact security, fire and building safety.

(4) An applicant or licensee shall notify the department within 1 business day of becoming aware of or should have been aware of all the following:

(a) Adverse reactions to a marihuana product sold or transferred by any licensee.

(b) Criminal convictions, charges, or civil judgements against an applicant or licensee in this state or any other state.

(c) Regulatory disciplinary action taken or determined against an applicant or licensee by this state or any other state, including any pending action.

(5) Failure to report material changes pursuant to subrule (3) of this rule or notifications under subrule (4) of this rule may result in sanctions or fines, or both.

§ 406ADHERENCE TO:

Each license is exclusive to the licensee, and a licensee or any other person must apply for and receive the board's approval before a license is transferred, sold, or purchased.

(No, means - The attempted transfer, sale, or other conveyance of an interest of more than 1% in a license without prior board approval).

**R 15, § 406
Notification &
Reporting:
Changes in -
ownership,
facility plan, or
criminal and
regulatory
discipline**

<p style="text-align: center;">§505 Safety Compliance Facility Authorization Information</p>	<p>333.27505 Safety compliance facility license.</p> <p>Sec. 505. (1) In addition to transfer and testing authorized in section 203, a safety compliance facility license authorizes the safety compliance facility to do all of the following without using a secure transporter:</p> <p>(a) Take marihuana from, test marihuana for, and return marihuana to only a marihuana facility.</p> <p>(b) Collect a random sample of marihuana at the marihuana facility of a grower, processor, or provisioning center for testing.</p> <p>(2) 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.</p> <p>(3) To be eligible for a safety compliance facility license, the applicant and each investor with any interest in the safety compliance facility must not have an interest in a grower, secure transporter, processor, or provisioning center.</p> <p>(4) A safety compliance facility shall comply with all of the following:</p> <p>(a) Perform tests to certify that marihuana is reasonably free of chemical residues such as fungicides and insecticides.</p> <p>(b) Use validated test methods to determine tetrahydrocannabinol, tetrahydrocannabinol acid, cannabidiol, and cannabidiol acid levels.</p> <p>(c) Perform tests that determine whether marihuana complies with the standards the board establishes for microbial and mycotoxin contents.</p> <p>(d) Perform other tests necessary to determine compliance with any other good manufacturing practices as prescribed in rules.</p> <p>(e) Enter all transactions, current inventory, and other information into the statewide monitoring system as required in this act, rules, and the marihuana tracking act.</p> <p>(f) Have a secured laboratory space that cannot be accessed by the general public.</p> <p>(g) Retain and employ at least 1 staff member with a relevant advanced degree in a medical or laboratory science.</p>
<p style="text-align: center;">R 16 Diversion, Theft, Loss, or Criminal Activity Contact Info</p>	<p>ADHERENCE TO: R 333.216 Notifications of diversion, theft, loss, or criminal activity pertaining to marihuana product.</p> <p>Rule 16. (1) A licensee and an applicant shall notify the department, state police, and local law enforcement authorities within 24 hours of becoming aware of or should have been aware of the theft or loss of any marihuana product or criminal activity at the marihuana facility.</p> <p>(2) Failure to notify as required under subrule (1) of this rule may result in sanctions or fines, or both.</p> <p>MSP 517-284-3388, mti@michigan.gov</p> <p>LARA 517-284-8599, lara-medicalmarihuana@michigan.gov</p>

OPERATIONS

R 333.231 State operating licenses; licensees; operations; general.

Rule 31. (1) A state operating license and a stacked license as described in R 333.220 are limited to the scope of the state operating license issued for that type of marihuana facility that is located within the municipal boundaries connected with the license.

(2) A licensee shall comply with all of the following:

(a) Marihuana facilities shall be partitioned from any other marihuana facility, activity, business, or dwelling.

Marihuana facilities shall not allow onsite or as part of the marihuana facility any of the following:

(i) Sale, consumption, or serving of food except for as provided in R 333.281.

(ii) Sale, consumption, or use of alcohol or tobacco products.

(iii) Consumption, use, or inhalation of a marihuana product.

(b) A marihuana facility shall have distinct and identifiable areas with designated structures that are contiguous and specific to the state operating license.

(c) A marihuana facility shall have separate entrances and exits, inventory, record keeping, and point of sale operations, if applicable.

(d) Access to the marihuana facility is restricted to the licensee; employees of the licensee; and, the department through its investigators, agents, auditors, or the state police. A provisioning center may grant access as provided in R 333.233(3) to registered qualifying patients and registered primary caregivers with valid registry cards to a dedicated point of sale area. A separate waiting area may be created for visitors not authorized to enter the marihuana facility. The licensee shall maintain a log tracking all visitors to a marihuana facility. The visitor log must be available at all times for inspection by the department through its investigators, agents, auditors, or the state police to determine compliance with the act and these rules.

(e) Licensee records must be maintained and made available to the department upon request.

(f) The marihuana facility must be at a fixed location. Mobile marihuana facilities and drive through operations are prohibited. Any sales or transfers of marihuana product by internet or mail order, consignment, or at wholesale are prohibited.

(g) A state operating license issued under the act must be framed under a transparent material and prominently displayed in the marihuana facility.

(3) A marihuana facility must comply with any other operational measures requested by the department that are not inconsistent with the act and these rules.

R 31

General:

Partitioning,
Food, alcohol,
tobacco, use of
marihuana onsite,
Restricted access,
Visitor log,
License Posting

<p style="text-align: center;">R 32 Same Location Operations</p>	<p>R 333.232 Operation at same location. Rule 32. (1) A licensee that has any combination of state operating licenses may operate separate marihuana facilities at the same location. For purposes of this rule, a stacked license is considered a single marihuana facility. (2) To operate at the same location subject to subrule (1) of this rule, all of the following requirements must be met: (a) The department has authorized the proposed operation at the same location. (b) The operation at the same location is not in violation of any local ordinances or regulations. 16 (c) The operation at the same location does not circumvent a municipal ordinance or zoning regulation that limits the type or number of marihuana facilities under section 205 of the act, MCL 333.27205, or prohibits the operation at the same location. (d) The licensee of each marihuana facility operating at the same location under this rule shall do all the following: (i) Apply for and be granted separate state operating licenses and pay a separate regulatory assessment for each state operating license. (ii) Have distinct and identifiable areas with designated structures that are contiguous and specific to the state operating license. (iii) Have separate entrances and exits, inventory, record keeping, and point of sale operations, if applicable. (iv) Post the state operating license on the wall in its distinct area and as provided in these rules. (v) Obtain any additional inspections and permits required for local or state building inspection, fire services, and public health standards. (vi) Comply with the provisions in the act and these rules. (3) Operation of a state operating license at the same location that includes a licensed provisioning center shall have the entrance and exit to the licensed provisioning center marihuana facility and entire inventory physically separated from any of the other licensed marihuana facility or facilities so that individuals can clearly identify the retail entrance and exit.</p>
<p style="text-align: center;">R 33 SCF Requirements</p>	<p>R 333.233 Marihuana facilities; requirements. Rule 33.(4) A marihuana facility shall ensure that the handling of marihuana product is done in compliance with current good manufacturing practice in manufacturing, packing, or holding human food, 21 CFR part 110. (5) A marihuana facility shall enter in the statewide monitoring system all transactions including, but not limited to, current inventory. These records must be maintained and made available to the department upon request.</p>

207, 501(8c)
3rd Party P.O.S.
and Tracking

Sec. 207. A licensee shall adopt and use a third-party inventory control and tracking system that is capable of interfacing with the statewide monitoring system to allow the licensee to enter or access information in the statewide monitoring system as required under this act and rules. The third-party inventory control and tracking system must have all of the following capabilities necessary for the licensee to comply with the requirements applicable to the licensee's license type:

- (a) Tracking all marihuana plants, products, packages, patient and primary caregiver purchase totals, waste, transfers, conversions, sales, and returns that are linked to unique identification numbers.
- (b) Tracking lot and batch information throughout the entire chain of custody.
- (c) Tracking all products, conversions, and derivatives throughout the entire chain of custody.
- (d) Tracking marihuana plant, batch, and product destruction.
- (e) Tracking transportation of product.
- (f) Performing complete batch recall tracking that clearly identifies all of the following details relating to the specific batch subject to the recall:
 - (i) Sold product.
 - (ii) Product inventory that is finished and available for sale.
 - (iii) Product that is in the process of transfer.
 - (iv) Product being processed into another form.
 - (v) Postharvest raw product, such as product that is in the drying, trimming, or curing process.
 - (g) Reporting and tracking loss, theft, or diversion of product containing marihuana.
 - (h) Reporting and tracking all inventory discrepancies.
 - (i) Reporting and tracking adverse patient responses or dose-related efficacy issues.
 - (j) Reporting and tracking all sales and refunds.
 - (k) Electronically receiving and transmitting information as required under this act, the Michigan medical marihuana act, 2008 IL 1, MCL 333.26421 to 333.26430, and the marihuana tracking act.

(l) Receiving testing results electronically from a safety compliance facility via a secured application program interface into the system and directly linking the testing results to each applicable source batch and sample.

(m) Identifying test results that may have been altered.

(n) Providing the licensee with access to information in the tracking system that is necessary to verify that the licensee is carrying out the marihuana transactions authorized under the licensee's license in accordance with this act.

(o) Providing information to cross-check that product sales are made to a registered qualifying patient or a registered primary caregiver on behalf of a registered qualifying patient and that the product received the required testing.

(p) Providing the department and state agencies with access to information in the database that they are authorized to access.

(q) Providing law enforcement agencies with access to only the information in the database that is necessary to verify that an individual possesses a valid and current registry identification card.

(r) Providing licensees with access only to the information in the system that they are required to receive before a sale, transfer, transport, or other activity authorized under a license issued under this act.

(s) Securing the confidentiality of information in the database by preventing access by a person who is not authorized to access the statewide monitoring system or is not authorized to access the particular information.

(t) Providing analytics to the department regarding key performance indicators such as the following:

- (i) Total daily sales.
- (ii) Total marihuana plants in production.
- (iii) Total marihuana plants destroyed.
- (iv) Total inventory adjustments.

Sec. 501(8c)

Enter all transactions, current inventory, and other information into the statewide monitoring system as required in this act, rules, and the marihuana tracking act.

R 34
Building & Fire
Safety

Handled by BFS

R 35
Security &
Surveillance:
Alarm,
Escort required,
Door locks,
Video w/ printer,
30 day storage,
Failure notification

R 333.235 Security measures; required plan; video surveillance system.

Rule 35. (1) An applicant for a license to operate a proposed marijuana facility shall submit a security plan that demonstrates, at a minimum, the ability to meet the requirements of this rule.

(2) A licensee shall ensure that any person at the marijuana facility, except for employees of the licensee, are escorted at all times by the licensee or an employee of the licensee when in the limited-access areas at the marijuana facility.

(3) A licensee shall securely lock the marijuana facility, including all interior rooms, windows, and points of entry and exits, with commercial-grade, nonresidential door locks. Locks on doors that are required for egress shall meet the requirements of NFPA 1, local fire codes, and the Michigan building code.

(4) A licensee shall maintain an alarm system at the marijuana facility. Upon request, a licensee shall make available to the department all information related to the alarm system, monitoring, and alarm activity.

(5) A licensee shall have a video surveillance system that, at a minimum, consists of digital or network video recorders, cameras capable of meeting the recording requirements in this rule, video monitors, digital archiving devices, and a color printer capable of delivering still photos.

(6) A licensee shall ensure the video surveillance system does all the following:

(a) Records, at a minimum, the following areas:

(i) Any areas where marijuana products are weighed, packed, stored, loaded, and unloaded for transportation, prepared, or moved within the marijuana facility.

(ii) Limited-access areas and security rooms. Transfers between rooms must be recorded.

(iii) Areas storing a surveillance system storage device with not less than 1 camera recording the access points to the secured surveillance recording area.

(iv) The entrances and exits to the building must be recorded from both indoor and outdoor vantage points. The areas of entrance and exit between marijuana facilities at the same location if applicable, including any transfers between marijuana facilities.

(v) Point of sale areas where marijuana products are sold and displayed for sale.

(b) Records at all times images effectively and efficiently of the area under surveillance with a minimum of 720p resolution.

21

(7) A licensee shall install each camera so that it is permanently mounted and in a fixed location. Each camera must be placed in a location that allows the camera to clearly record activity occurring within 20 feet of all points of entry and exit on the marijuana facility and allows for the clear and certain identification of any person, including facial features, and activities, including sales or transfers, in all areas required to be recorded under these rules.

(8) A licensee shall have cameras that record continuously 24 hours per day and recorded images must clearly and accurately display the time and date.

(9) A licensee shall secure the physical media or storage device on which surveillance recordings are stored in a manner to protect the recording from tampering or theft.

(10) A licensee shall keep surveillance recordings for a minimum of 30 days, except in instances of investigation or inspection by the department, through its investigators, agents, auditors, or the state police, in which case the licensee shall retain the recordings until the time as the department notifies the licensee that the recordings may be destroyed.

(11) Surveillance recordings of the licensee are subject to inspection by the department, through its investigators, agents, auditors, or the state police, and must be kept in a manner that allows the department to view and obtain copies of the recordings at the marijuana facility immediately upon request. The licensee shall also send or otherwise provide copies of the recordings to the department upon request within the time specified by the department.

(12) A licensee shall maintain a video surveillance system equipped with a failure notification system that provides notification to the licensee of any interruption or failure of the video surveillance system or video surveillance system storage device.

(13) A licensee shall maintain a log of the recordings, which includes all of the following:

(a) The identities of the employee or employees responsible for monitoring the video surveillance system.

(b) The identity of the employee who removed the recording from the video surveillance system storage device and the time and date removed.

(c) The identity of the employee who destroyed any recording.

<p>R 37 Waste Management</p>	<p>R 333.237 Marihuana product destruction and waste management. Rule 37. (1) A marihuana product that is to be destroyed or is considered waste must be rendered into an unusable and unrecognizable form through grinding and incorporating the 22 marihuana product waste with the non-consumable solid waste specified in subdivisions (a) to (h) of this subrule so that the resulting mixture is not less than 50% non-marihuana product waste: (a) Paper waste. (b) Plastic waste. (c) Cardboard waste. (d) Food waste. (e) Grease or other compostable oil waste. (f) Fermented organic matter or other compost activators. (g) Other wastes approved by the department that will render the marihuana product waste unusable and unrecognizable. (h) Soil. (2) A marihuana product rendered unusable and unrecognizable and, therefore, considered waste, must be recorded in the statewide monitoring system. (3) A licensee shall not sell marihuana waste or marihuana products that are to be destroyed, or that the department orders destroyed. (4) A licensee shall manage all waste that is hazardous waste pursuant to part 111 of the natural resources and environmental protection act, 1994 PA 451, MCL 324.11101 to 324.11153. (5) A licensee shall dispose of marihuana product waste in a secured waste receptacle using 1 or more of the following methods that complies with applicable state and local laws and regulations: (a) A manned and permitted solid waste landfill. (b) A manned compostable materials operation or facility. (c) An in-vessel digester. (d) An incineration method approved by state and local laws and regulations. (6) A licensee shall dispose of wastewater generated during the cultivation of marihuana and the processing of marihuana products in a manner that complies with applicable state and local laws and regulations. (7) A licensee shall maintain accurate and comprehensive records regarding marihuana product waste that accounts for, reconciles, and evidences all waste activity related to the disposal. The department may publish guidance on marihuana product waste management. (8) For the purposes of this rule, “unrecognizable” means marihuana product rendered indistinguishable from any other plant material.</p>
----------------------------------	--

<p style="text-align: center;">R 38 Storage</p>	<p>R 333.238 Storage of marihuana product. Rule 38. (1) All inventories of marihuana products must be stored at a marihuana facility in a secured limited access area or restricted access area and must be identified and tracked consistently in the statewide monitoring system under the act, the marihuana tracking act, or these rules. (2) All containers used to store marihuana products for transfer or sale between marihuana facilities must be clearly marked, labeled, or tagged, if applicable, and enclosed on all sides in secured containers. The secured containers must be latched or locked in a manner to keep all contents secured within. Each secured container must be identified and tracked in accordance with the act, the marihuana tracking act, and these rules. (3) All chemicals or solvents must be stored separately from marihuana products and kept in locked storage areas. (4) Marihuana-infused products, edible marihuana products, or materials used in direct contact with such marihuana-infused products or edible marihuana products, must have separate storage areas from toxic or flammable materials. (5) Edible marihuana products must be stored in compliance with current good manufacturing practice in manufacturing, packing, or holding human food, 21 CFR part 110. Edible marihuana products not in final packaging must be stored separately from other types of marihuana product in compliance with these rules. (6) A provisioning center shall store all marihuana products for transfer or sale behind a counter or other barrier separated from stock rooms. (7) A safety compliance facility shall establish an adequate chain of custody and instructions for sample and storage requirements. (8) A licensee shall ensure that any stock or storage room meets the security requirements of these rules and any other applicable requirements in the act and these rules.</p>
<p style="text-align: center;">R 36 Prohibitions</p>	<p>R 333.236 Prohibitions. Rule 36. (1) Marihuana products not identified and recorded in the statewide monitoring system pursuant to the act, the marihuana tracking act, or these rules must not be at a marihuana facility. A licensee shall not transfer or sell a marihuana product that is not identified in the statewide monitoring system pursuant to the act or these rules. (2) Any marihuana product without a batch number or identification tag or label pursuant to these rules must not be at a marihuana facility. A licensee shall immediately tag, identify, or record as part of a batch in the statewide monitoring system any marihuana product as provided in these rules. (3) A violation of these rules may result in sanctions or fines, or both, in accordance with the act or these rules.</p>
TESTING	
<p style="text-align: center;">R 47 SCF Testing</p>	<p>Addressed on addendum checklist</p>

<p>R 48 Sampling</p>	<p>R 333.248 Sampling. Rule 48. (1) A safety compliance facility shall test samples as provided in the act, the Michigan medical marihuana act, and these rules. (2) A safety compliance facility shall collect samples of a marihuana product from another marihuana facility according to the following requirements: (a) The safety compliance facility shall physically collect samples of a marihuana product from another marihuana facility to be tested at the safety compliance facility. The safety compliance facility shall ensure that samples of the marihuana product are placed in secured, sealed containers that bear the labeling information as required under these rules. (b) The safety compliance facility shall collect a sample size sufficient to complete all analyses required, but the sample shall not be less than 0.5% of the weight of the batch. The maximum batch size must be 15 pounds. The department may publish recommendations for this subdivision based on the type of marihuana product being tested. (c) The safety compliance facility shall enter in the statewide monitoring system the marihuana product sample that was collected from a grower, processor, or provisioning center, including the date and time the marihuana product is collected, transferred, tested, and recorded. (d) If a testing sample is collected from a marihuana facility for testing in the statewide monitoring system, that marihuana facility shall quarantine the marihuana product that is undergoing the testing from any other marihuana product at the marihuana facility. The marihuana facility shall indicate the sample being tested in the statewide monitoring system. The quarantined marihuana product must not be transferred or sold until testing results pass as provided under these rules. (e) Any marihuana product that a safety compliance facility collects for testing from a licensee under this rule must not be transferred or sold to any other marihuana facility other than the licensee from whom the sample was collected. (f) A safety compliance facility may request additional sample material from the same licensee from which the sample was collected for the purposes of completing the required safety tests as long as the requirements of this rule are met.</p>
SALE OR TRANSFER	
<p>R 71 Labeling</p>	<p>R 333.271 Tracking identification; labeling requirements; general. Rule 71. (1) All marihuana products sold or transferred between marihuana facilities must have the tracking identification numbers that are assigned by the statewide monitoring system affixed, tagged, or labeled and recorded, and any other information required by the department, the act, and these rules. (2) To ensure access to safe sources of marihuana products, the department, if alerted in the statewide monitoring system, may recall any marihuana products, issue safety warnings, and require a marihuana facility to provide information material or notifications to a registered qualifying patient or registered primary caregiver at the point of sale.</p>

<p style="text-align: center;">R 72 Plant Tracking R 73 Product Tracking</p>	<p>R 333.272 Marihuana plant; tracking requirements. Rule 72. Before a marihuana plant is sold or transferred, a package tag must be affixed to the plant or plant container and enclosed with a tamper proof seal that includes all of the following information: (a) Business or trade name, licensee number, and the RFID package tag assigned by the statewide monitoring system that is visible. (b) Name of the strain. (c) Date of harvest, if applicable. (d) Seed strain, if applicable. (e) Universal symbol, if applicable.</p> <p>R 333.273 Marihuana product sale or transfer; labeling and packaging requirements. Rule 73. (1) Before a marihuana product is sold or transferred to or by a provisioning center, the container, bag, or product holding the marihuana product must have a label and be sealed with all of the following information: (a) The name of the licensee and the license number of the producer, including business or trade name, and tag or source number as assigned by the statewide monitoring system. (b) The name of the licensee and the license number including business or trade name of licensee that packaged the product, if different from the processor of the marihuana product. (c) The unique identification number for the package or the harvest, if applicable. (d) Date of harvest, if applicable. (e) Name of strain, if applicable. (f) Net weight in United States customary and metric units. (g) Concentration of THC and cannabidiol (CBD). (h) Activation time expressed in words or through a pictogram. (i) Name of the safety compliance facility that performed any test, any associated test batch number, and any test analysis date. (j) The universal symbol for marihuana product published on the department’s website. (k) A warning that states all the following: (i) "For use by registered qualifying patients only. Keep out of reach of children." (ii) "It is illegal to drive a motor vehicle while under the influence of marihuana." (iii) "National Poison Control Center 1-800-222-1222." (2) An edible marihuana product sold by a provisioning center must comply with R 333.261(7).</p>
<p style="text-align: center;">R 76 Marketing & Advertising</p>	<p>R 333.276 Marketing and advertising restrictions. Rule 76. (1) A marihuana facility shall comply with all municipal ordinances, state law, and these rules that regulate signs and advertising. (2) A licensee shall not engage in advertising that is deceptive, false, or misleading. A licensee shall not make any deceptive, false, or misleading assertions or statements on any marihuana product, any sign, or any document provided. (3) A licensee shall not advertise a marihuana product where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place. A licensee shall not advertise or market a marihuana product to members of the public unless the licensee has reliable evidence that no more than 30 percent of the audience or readership for the television program, radio program, internet web site, or print publication, is reasonably expected to be aged 17 years or younger. Any marihuana product advertised or marketed under this rule shall include the warnings listed in R 333.273(1)(k). (4) A marihuana product must be marketed or advertised as “medical marihuana” for use only by registered qualifying patients or registered primary caregivers. (5) A marihuana product must not be marketed or advertised to minors aged 17 years or younger. Sponsorships targeted to members aged 17 years or younger are prohibited.</p>

EMPLOYEES

R 333.281 Employees; requirements.

Rule 81. (1) A licensee shall conduct a criminal history background check on any prospective employee before hiring that individual pursuant to section 405 of the act, MCL 333.27405. A licensee shall keep records of the results of the criminal history background checks. A licensee shall record confirmation of criminal history background checks and make the confirmation available for inspection upon request by the department through its investigators, agents, auditors, or the state police.

(2) A licensee shall comply with all of the following:

(a) Have a policy in place that requires employees to report any new or pending charges or convictions. If an employee is charged or convicted for a controlled substance-related felony or any other felony, the licensee shall report it immediately to the department.

(b) Enter in the statewide monitoring system the employee's information and level of statewide monitoring system access within 7 business days of hiring for the system to assign an employee identification number. The licensee shall update in the statewide monitoring system employee information and changes in status or access within 7 business days.

(c) If an employee is no longer employed by a licensee, the licensee shall remove that employee's access and permissions to the marihuana facility and the statewide monitoring system.

(d) Train employees and have an employee training manual that includes, but is not limited to, employee safety procedures, employee guidelines, security protocol, and educational training, including, but not limited to, marihuana product information, dosage and purchasing limits if applicable, or educational materials.

(e) Establish point of sale or transfer procedures for employees at provisioning centers performing any transfers or sales to registered qualifying patients and registered primary caregivers. The point of sale or transfer procedures must include, but are not limited to, training in dosage, marihuana product information, health or educational materials, point of sale training, purchasing limits, CBD and THC information, serving size, and consumption information including any warnings.

(f) Screen prospective employees against a list of excluded employees based on a report or investigation maintained by the department.

(g) When a registered primary caregiver is hired as an employee of a grower, processor, or secure transporter, the licensee or the individual shall withdraw registration as a registered primary caregiver in a manner established by the department.

(h) A licensee shall ensure that employees handle marihuana product in compliance with current good manufacturing process in manufacturing, packing, or holding human food, 21 CFR part 110, as specified in R. 333.233.

(3) If an individual is present at a marihuana facility or in a secure transporter vehicle who is not identified as a licensee or an employee of the licensee in the statewide 34 monitoring system or is in violation of the act or these rules, the department, through its investigators, agents, auditors, or the state police may take any action permitted under the act and these rules.

(4) Employee records are subject to inspection or examination by the department, through its investigators, agents, auditors, or the state police to determine compliance with the act or these rules.

(5) Consumption of food by employees is prohibited where marihuana product is stored, processed or packaged or where hazardous materials are used, handled or stored unless the marihuana facility has an employee designated area that includes, but is not limited to, a room with floor to ceiling walls and a door that separates the room from any marihuana product.

(6) As used in this rule "employee" includes, but is not limited to, hourly employees, contract employees, trainees, or any other person given any type of employee credentials or authorized access to the marihuana facility. Trade services provided by individuals not normally engaged in the operation of a marihuana facility, except for those individuals required to have employee credentials under this rule, must be reasonably monitored, logged in as a visitor, and escorted through any limited access areas.

§ 405

Before hiring a prospective employee, the holder of a license shall conduct a background check of the prospective employee. If the background check indicates a pending charge or conviction within the past 10 years for a controlled substance-related felony, a licensee shall not hire the prospective employee without written permission of the board.

R 81, § 405
Employees
General:
Criminal Hx,
Employee
reporting,
Training,
Restriction on food
consumption

EXIT INTERVIEW

Review violations identified during inspection.

Review informational points regarding facility plan accuracy, floor plan accuracy, and inspector accessed all areas of marihuana facility.

Discuss timeline for next inspection.

Facility _____ Evaluator _____

Location _____ Date _____

Test	Method used, ISO accredited etc.
Potency Analysis: 1. Tetrahydrocannabinol level (THC) 2. Tetrahydrocannabinol acid level (THC-A) 3. Cannabidiol level (CBD) 4. Cannabidiol acid level (CBD-A)	
Foreign matter inspection: 1. Pests 2. Mold 3. other organic or inorganic materials	
Microbial Screening: 1. Total Viable Aerobic Bacteria 2. Total Coliform 3. Total Yeast & Mold 4. Bile-tolerant gram-negative bacteria 5. E. coli 6. Salmonella 7. Aspergillus Spp.	
Chemical Residue: 1. Pesticides, Fungicides, Insecticides 2. Banned published list of chemicals and action limits	

Facility _____ Evaluator _____

Location _____ Date _____

Metals: 1. Mercury 2. Inorganic Arsenic 3. Cadmium 4. Lead 5. Total Chromium	
Residual solvents levels 1. Published list of solvents and action limits	
Water activity including moisture content	
Homogeneity	

Personnel

Position/Title 333.27505 (2)(g) Retain and employ at least 1 staff member with a relevant advanced degree in a medical or laboratory science.	Name	Education Level Degree/Major*	Experience in yrs.
Laboratory Director			
Chemistry			

Facility _____ Evaluator _____

Location _____ Date _____

Microbiology			
Quality Assurance Officer			

***If the major is not in medical or laboratory science, list hours of college level courses in medical or laboratory sciences**

TESTS AND METHODS

TESTS AND METHODS		Satisfactory Yes or No Comments <i>*for educational compliance only</i>
Has a written Standard Operating Procedure (SOP) Manual been established?	R47 (R 333.247)1 (b)(9)(c)	
Is the SOP Manual readily available to all analysts?*	R47 (R 333.247)1 (b)(9)(c)	
Does the SOP Manual include criteria for identifying and rejecting unacceptable samples?*	R47 (R 333.247)1 (b)(9)(c)	
Does the SOP Manual include criteria for security of samples, aliquots, extracts, and records?*	R47 (R 333.247)1 (b)(9)(c)	
Does the SOP Manual include criteria for sample retention to assure stability?*	R47 (R 333.247)1 (b)(9)(c)	

Facility _____ Evaluator _____

Location _____ Date _____

<p>Does the laboratory document all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the Standard Operating Procedure?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Does the SOP Manual include criteria, for the validation of new or revised methods, where applicable, prior to testing samples?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Does the SOP Manual include criteria establishing a documented system for reviewing the results of testing calibrators, controls, standards, and test results; as well as reviewing for clerical errors, analytical errors, and any unusual analytical results?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Does the SOP Manual include criteria for sample disposal?</p>	<p>R47 (R 333.247)3</p>	
<p>Does the SOP Manual include criteria for the preparation and identification of reagents, solutions, standards, calibrators, and controls?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Does the SOP Manual include criteria for the frequency and number of control and calibration materials?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Does the SOP Manual include criteria for recording and reporting assay results?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	
<p>Do laboratory SOPs include step-by-step instructions with sufficient detail to perform the assay, to include equipment operation and any abbreviated versions used by a testing analyst?*</p>	<p>R47 (R 333.247)1 (b)(9)(c)(d)</p>	

Facility _____ Evaluator _____

Location _____ Date _____

Does the SOP Manual include acceptability criteria for the results of controls?*	R47 (R 333.247)1 (b)(9)(c)(d)	
--	--	--

QUALITY ASSURANCE AND DATA REPORTING

Item	Reference	Satisfactory Yes or No Comments
Does the laboratory have a quality control and quality assurance program that conforms to ISO/IEC 17025:2005 or 17025:2017 standards?	R47 (R 333.247) (9)(d)	
Does the laboratory perform and document instrument preventative maintenance and repair as required by the manufacturer?	R47 (R 333.247) (9)(d)	
Does the laboratory evaluate and document the performance of instruments after routine and preventative maintenance and prior to analyzing samples?	R47 (R 333.247) (9)(d)	
Does the laboratory perform and document instrument troubleshooting and corrective actions when performance does not meet established levels of quality?	R47 (R 333.247) (9)(d)	
Has the laboratory established and continuously monitored and documented the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory's pre-analytic, analytic, and post-analytic systems when they occur?	R47 (R 333.247) (9)(d)	

Facility _____ Evaluator _____

Location _____ Date _____

<p>Has the laboratory established, continuously monitored, and documented the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of SOPs, and accuracy of results reported?</p>	<p>R47 (R 333.247) (9)(d)</p>	
<p>Does the laboratory annually verify the calibration of analytical balances using certified weights to include; three or more NIST traceable weights, bracketing the ranges of measurement used by the laboratory?</p>	<p>R47 (R 333.247) (9)(d)</p>	
<p>Does the laboratory properly label and track in-house prepared solutions that identify: solution contents, the concentration, date of preparation, storage conditions, lot number (if applicable), expiration date, and the identity of the preparer?</p>	<p>R47 (R 333.247) (9)(d)</p>	
<p>Is the Marijuana Testing Facility accredited under the International Organization for Standardization/ International Electrotechnical Commission ISO/IEC17025:2005, or any subsequent superseding ISO/IEC 17025 standard?</p>	<p>R47 (R 333.247) (9)(b)</p>	
<p>Does the ISO 17025:2005 scope of accreditation specify each particular testing category?</p>	<p>R47 (R 333.247) (9)(b)</p>	
<p>A safety compliance facility shall analyze proficiency test samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used for marihuana product testing. A safety compliance facility shall successfully analyze a set of proficiency testing samples not less than annually.</p>	<p>R47 (R 333.247) (10)</p>	

