

FILED WITH LRC
TIME: 11:50 am
JAN 04 2024
Emily B Caudill
REGULATIONS COMPILER

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of the Secretary

3 (New Administrative Regulation)

4 915 KAR 1:060. Safety Compliance Facility.

5 RELATES TO: KRS Chapter 218B

6 STATUTORY AUTHORITY: KRS 218B.140

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet
8 for Health and Family Services to promulgate administrative regulations establishing requirements
9 and procedures for safety compliance facilities that provide testing services to medicinal cannabis

10 businesses in the commonwealth. This administrative regulation sets out those requirements and
11 procedures.

12 Section 1. General requirements.

13 (1) A safety compliance facility shall not collect, handle, receive, or conduct tests on
14 medicinal cannabis samples unless it has been issued a license by the cabinet. Prior to
15 conducting any testing of a sample at the request of a cannabis business, a safety compliance
16 facility shall enter into a written contract with the cannabis business for testing services. A
17 safety compliance facility shall provide a copy of their contracts with cannabis businesses to the
18 cabinet within two (2) business days of receipt of the request.

19 (2) The cabinet shall post a list of licensed safety compliance facilities on the website for
20 the Kentucky Medical Cannabis Program, <https://kymedcan.ky.gov>.

1 (3) A safety compliance facility shall employ at least one (1) director to oversee and be
2 responsible for the testing operations of the facility. A director shall have earned, from a college
3 or university accredited by a national or regional accrediting authority, at least one of the
4 following:

5 (a) A doctorate of science or an equivalent degree in chemistry, biology, or a
6 subdiscipline of chemistry or biology;

7 (b) A master's level degree in a chemical or biological science and a minimum of two (2)
8 years post-degree experience related to laboratory testing of medicinal or pharmaceutical
9 products; or

10 (c) A bachelor's degree in a biological science and a minimum of four (4) years post-
11 degree experience related to laboratory testing of medicinal or pharmaceutical products.

12 (4) A principal officer, board member, employee, volunteer, or agent of a cultivator,
13 processor, producer, or dispensary shall not be employed by or affiliated with a safety
14 compliance facility that has a contract with that respective cannabis business.

15 (5) A license issued by the cabinet to a safety compliance facility is valid only for the
16 specific site licensed and identified on the license.

17 (6) A safety compliance facility shall:

18 (a) Conduct a criminal background check into the criminal history of each person seeking
19 to become a principal officer, board member, agent, volunteer, or employee before that person
20 begins work and shall retain records of these background checks for five (5) years and provide
21 same to the cabinet during subsequent inspections or upon request;

22 (b) Maintain and adhere to proper standards of accuracy for testing and comply with the
23 testing requirements contained in 915 KAR 1:110;

1 (c) Comply with all required analytes standards for the relevant test methods of
2 cannabinoids, terpenoids, residual solvents and processing chemicals, residual pesticides, heavy
3 metals, microbial impurities, mycotoxins, water activity, yeast, mold, and vitamin E acetate;

4 (d) Accurately and honestly report all medicinal cannabis test results;

5 (e) Only allow authorized individuals to perform medicinal cannabis testing and sign
6 reports;

7 (f) Only accept a sample or test sample from a cannabis business employee or agent or an
8 authorized representative of the cabinet;

9 (g) Maintain a certificate of accreditation in good standing from an accreditation body
10 and provide a copy to the cabinet during subsequent inspections or upon request. The certificate
11 of accreditation shall attest to the safety compliance facility's competence to perform testing,
12 including all the required analytes for the relevant test methods required, and shall be obtained
13 by the safety compliance facility prior to collecting, receiving, or testing any medicinal cannabis
14 sample or test sample;

15 (h) Develop and maintain standard operating procedures for a laboratory approved by the
16 accreditation body that issued the certificate of accreditation to the safety compliance facility and
17 provide copies to the cabinet during subsequent inspections or upon request;

18 (i) Properly enter medicinal cannabis test results into the commonwealth's designated
19 electronic monitoring system and seed to sale tracking system as required by the cabinet and in
20 accordance with written instructions provided by the cabinet; and

21 (j) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS
22 218B.095 and 218B.125, and 915 KAR Chapter 1.

1 (7) A safety compliance facility shall not employ, take on as a volunteer, or have as a
2 board member, principal officer, or agent any person who was convicted of a disqualifying
3 felony offense or is younger than twenty-one (21) years of age.

4 (8) The qualifications that a safety compliance facility shall meet to receive a license are
5 continuing qualifications to maintain the license throughout the licensure period.

6 Section 2. Selecting and collecting samples for testing.

7 (1) A sampler is an employee or agent of a cultivator, processor, producer, safety
8 compliance facility, or dispensary that is authorized by his or her employer to collect samples or
9 test samples in accordance with the contracted safety compliance facility's standard operating
10 procedures and this administrative regulation. A sampler shall obtain an amount for a sample or
11 test sample on behalf of his or her employer sufficient to be aliquoted into a primary sample and
12 a reserve sample, which shall be equal in amount. The primary sample and reserve sample shall
13 be in the amounts specified in the safety compliance facility's standard operating procedures.

14 (2) A safety compliance facility shall ensure that samples and test samples are selected
15 and collected in accordance with standard operating procedures established by the safety
16 compliance facility and required by this administrative regulation. The standard operating
17 procedures for sampling shall be written and provided to the cabinet and each cannabis business
18 that the safety compliance facility contracts with for testing prior to collecting, receiving, or
19 testing any medicinal cannabis. These standard operating procedures shall be in place prior to
20 the first day that the safety compliance facility collects, receives, or tests a sample.

21 (3) Samples shall consist of enough samples from a harvest batch or production batch to
22 ensure that the required attributes in the products are homogenous and consistent with the safety
23 compliance facility's standard operating procedures for selecting and collecting samples. Test

1 samples shall consist of enough samples of the item identified for testing to ensure any required
2 testing can be accomplished in accordance with the safety compliance facility's standard
3 operating procedures.

4 (4) The sampling policies and procedures shall include:

5 (a) A step-by-step guide for obtaining samples and test samples;

6 (b) Random taking of samples or test samples throughout the harvest batch or production
7 batch;

8 (c) Using appropriate sampling equipment, including protocols relating to the sanitizing
9 of equipment and tools, protective garb, and sampling containers;

10 (d) Using consistent collection procedures for samples and test samples;

11 (e) Transporting samples in a manner that does not endanger the integrity of the samples
12 and that is in accordance with transportation requirements for samples contained in 915 KAR
13 1:080;

14 (f) Creating a unique sample identification number that will be linked to the harvest batch
15 or production batch number assigned by the cultivator, processor, or producer in the
16 commonwealth's designated electronic monitoring system and seed to sale tracking system; and

17 (g) The process for properly documenting a chain of custody for each sample or test
18 sample and retaining those records for a minimum of two (2) years.

19 (5) An employee or agent of a safety compliance facility shall only enter a facility
20 operated by a cultivator, processor, producer, or dispensary for the purpose of:

21 (a) Selecting and collecting samples and test samples and shall have access to limited
22 access areas in the facility for these purposes; and

23 (b) Providing training to cannabis business agents as provided in KRS 218B.125(7).

1 (6) An employee or agent of a safety compliance facility shall comply with all visitor
2 requirements for entry into the cultivator, processor, producer, or dispensary's facility.

3 (7) An authorized cannabis business employee collecting any samples for testing shall
4 follow the standard operating procedures established by the contracted safety compliance facility
5 conducting the testing for sampling and documenting the chain of custody.

6 Section 3. Standards for testing. A safety compliance facility shall follow:

7 (1) The methodologies and parameters that are contained in the scope of the certificate of
8 accreditation issued to the safety compliance facility; and

9 (2) The testing requirements contained in 915 KAR 1:110.

10 Section 4. Quality assurance program.

11 (1) Prior to its first day of collecting or receiving samples or test samples in the
12 commonwealth, a safety compliance facility shall establish and implement a written quality
13 assurance program to ensure that measurements are accurate, errors are controlled, and
14 equipment, devices, or instruments used for testing are routinely and properly calibrated in
15 accordance with the equipment, device, or instrument manufacturer recommendations regarding
16 calibration and frequency.

17 (2) The quality assurance program required under this section shall include the following
18 components:

19 (a) An organizational chart that includes the testing responsibilities of employees;

20 (b) A description of sampling procedures to be utilized;

21 (c) Appropriate chain of custody protocols;

22 (d) Analytical procedures;

23 (e) Data reduction and validation procedures; and

1 (f) A plan for implementing corrective action, when necessary.

2 (3) A safety compliance facility shall provide a copy of its written quality assurance
3 program to the cabinet upon request or during subsequent inspections or investigations.

4 Section 5. Cabinet request for testing. If the cabinet requests that a safety compliance
5 facility conduct tests on any samples or test samples collected by the cabinet, the safety
6 compliance facility shall comply with the request and directions of the cabinet and provide the
7 cabinet with a written report of the results from a sample tested under this section within seven
8 (7) calendar days of receipt of the sample, or sooner if requested by the cabinet.

9 Section 6. Ownership prohibition. The following individuals shall not have a
10 management or a direct or indirect financial or other ownership interest in a safety compliance
11 facility:

12 (1) An owner, principal officer, board member, financial backer, employee, volunteer, or
13 agent of a cultivator, processor, producer, or dispensary; and

14 (2) A medicinal cannabis practitioner.

15 Section 7. Plans of operation.

16 (1) In addition to any other standard operating procedures required by this administrative
17 regulation, a safety compliance facility shall establish standard operating procedures for the
18 following prior to its first day of collecting or receiving samples or test samples in the
19 commonwealth:

20 (a) Employment policies and procedures;

21 (b) Security, including:

22 1. Staff identification measures and use of employee identification badges;

23 2. Monitoring of attendance of staff and visitors;

- 1 3. Alarm systems;
- 2 4. Video surveillance;
- 3 5. Monitoring and tracking samples and test results, including use of the commonwealth's
- 4 electronic monitoring system and seed to sale tracking system established pursuant to KRS
- 5 218B.140;
- 6 6. Personnel security;
- 7 7. Transportation of medicinal cannabis;
- 8 8. Cash management and anti-fraud procedures;
- 9 9. Measures to prevent loitering, which shall include signage; and
- 10 10. Storage of medicinal cannabis and medicinal cannabis products;
- 11 (c) Recordkeeping;
- 12 (d) The process for receiving, handling, packaging, labeling, storing, transporting, and
- 13 disposing of medicinal cannabis samples;
- 14 (e) Employee qualifications, supervision, and training;
- 15 (f) Workplace safety;
- 16 (g) Waste disposal and sanitation;
- 17 (h) Inventory management, including intake, labeling, and storage of samples and test
- 18 samples;
- 19 (i) Contamination;
- 20 (j) Maintenance, cleaning, and sanitation of equipment used to test samples;
- 21 (k) Maintenance, cleaning, and sanitation of the safety compliance facility;
- 22 (l) Proper handling and storage of any chemical or substance used in testing medicinal
- 23 cannabis;

1 (m) Investigation of complaints and potential adverse events received from other
2 cannabis businesses, registered qualified patients, designated caregivers, or medicinal cannabis
3 practitioners regarding the safety compliance facility's operations;

4 (n) Preventing unlawful diversion of medicinal cannabis; and

5 (o) Any other standard operating procedures required for all cannabis businesses in KRS
6 Chapter 218B and 915 KAR Chapter 1.

7 (2) A safety compliance facility shall make its standard operation procedures available to
8 the cabinet upon request and during any inspection or investigation.

9 Section 8. Facilities.

10 (1) A safety compliance facility shall only test samples in a facility on the specific site
11 licensed by the cabinet and identified on its license issued by the cabinet. The facility shall meet
12 all applicable state and local building codes and specifications in addition to the following:

13 (a) Has a complete roof enclosure supported by connecting permanent walls, constructed
14 of solid materials extending from the ground to the roof;

15 (b) Is secure against unauthorized entry;

16 (c) Has a foundation, slab, or equivalent base to which the floor is securely attached;

17 (d) Has commercial grade door locks on all external doors that are locked at all times;

18 (e) Restricts access to only authorized personnel to limited access areas identified with
19 signage and daily records of entry and exit;

20 (f) Contains adequate plumbing to carry sufficient quantities of water to locations
21 throughout the facility and convey sewage and waste from the facility without cross
22 contamination of potable water and waste;

1 (g) Stores toxic cleaning compounds, sanitizing agents, and substances used in testing
2 samples in a manner that is in accordance with applicable local, state, and federal laws and
3 regulations;

4 (h) Maintains proper ventilation;

5 (i) Maintains pest control;

6 (j) Maintains adequate indoor and exterior lighting to facilitate video surveillance at all
7 times; and

8 (k) Maintains adequate on-site parking for employees, agents, visitors, transporters of
9 medicinal cannabis, or cabinet staff.

10 (2) A safety compliance facility shall clearly mark all limited access areas on its premises
11 with proper signage. All areas of ingress and egress to a limited access area shall be clearly
12 identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long,
13 composed of letters not less than one-half inch in height, which shall state: "Do Not Enter.
14 Limited Access Area. Access Limited to Authorized Personnel and Escorted Visitors."

15 (3) A safety compliance facility shall have a secure area for the loading and unloading of
16 medicinal cannabis samples into and from a transport vehicle.

17 Section 9. Employee records and identification.

18 (1) A safety compliance facility shall keep an individual employment record for all
19 employees, including:

20 (a) Full legal name;

21 (b) Detailed job description;

22 (c) Documentation of completed criminal background check;

23 (d) Record of all training received or acquired by the employee;

- 1 (e) Dates of employment;
- 2 (f) Records of days and hours worked; and
- 3 (g) Any disciplinary actions taken by the safety compliance facility.

4 (2) Employment records shall be maintained, either electronically or in hard copy, for at
5 least five (5) years after the employee's last date of employment with the safety compliance
6 facility.

7 (3) A safety compliance facility shall create an identification badge for each employee,
8 agent, or volunteer. This badge shall be conspicuously worn by employees or agents at all times
9 that they are on the licensed premises or during transport of samples or test samples. The badge
10 shall contain:

- 11 (a) The individual's name, photo, and employee identification number;
- 12 (b) A phone number and email address for the safety compliance facility; and
- 13 (c) A phone number and email address for the Kentucky Medical Cannabis Program.

14 Section 10. Visitors to safety compliance facilities.

15 (1) A safety compliance facility shall not be open to the general public.

16 (2) A safety compliance facility shall complete the following steps when admitting a
17 visitor to its site and facility:

- 18 (a) Require the visitor to sign a visitor log upon entering and leaving the facility;
- 19 (b) Check the visitor's government-issued identification to verify that the name on the
20 identification provided matches the name in the visitor log;

21 (c) Issue a visitor identification badge with the visitor's name and company, if applicable,
22 and a badge number;

1 (d) Escort the visitor while the visitor remains in the facility keeping a record of the areas
2 of the facility visited; and

3 (e) Ensure that the visitor does not touch any medicinal cannabis located in a limited
4 access area.

5 (3) No one under the age of eighteen (18) shall be permitted to enter a safety compliance
6 facility. A person who is at least eighteen (18) years of age may enter and remain on the
7 premises if that person is present to perform contract work, including electrical, plumbing, or
8 security maintenance, that does not involve handling medicinal cannabis or is a government
9 employee and is at the facility in the course of his or her official duties.

10 (4) A safety compliance facility shall post a sign in a conspicuous location at each
11 entrance of its facility that states “THESE PREMISES ARE UNDER CONSTANT VIDEO
12 SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.”

13 (5) A safety compliance facility shall maintain the visitor log required under this section
14 for five (5) years and make the visitor log available to the cabinet, law enforcement, and other
15 federal or state government officials upon request to perform the government officials' functions
16 and duties. The visitor log shall include the date, the full name of each visitor, the visitor
17 identification badge number, the time of arrival, the time of departure, and the purpose of the
18 visit, including the areas of the site and the facility visited.

19 (6) This section does not limit the right of the cabinet or its authorized agents, or other
20 federal, state, or local government officials from entering any area of a safety compliance facility
21 if necessary to perform the governmental officials' functions and duties.

1 (7) A principal officer, board member, agent, financial backer, or employee of a safety
2 compliance facility may not receive any type of consideration or compensation for allowing a
3 visitor to enter a limited access area.

4 Section 11. Security and surveillance.

5 (1) A safety compliance facility shall have security and surveillance systems, utilizing
6 commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse
7 loss. The security and surveillance systems shall include the following:

8 (a) A professionally monitored security alarm system that includes:

9 1. Coverage of all facility entrances and exits, storage rooms, including those that contain
10 medicinal cannabis and safes, and the perimeter of the facility;

11 2. Smoke and fire alarms;

12 3. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours
13 following a power outage;

14 4. The ability to ensure all access doors are not solely controlled by an electronic access
15 panel to prevent locks from becoming released during a power outage; and

16 5. Motion detectors for exterior lighting.

17 (b) A professionally monitored security surveillance system that is operational twenty-
18 four (24) hours a day, seven (7) days a week, and records all activity in images capable of clearly
19 revealing facial detail. The security and surveillance system shall include:

20 1. Fixed camera placement that allows for a clear image of all individuals and activities in
21 and around the following:

22 a. All limited access areas;

1 b. A room or area containing a security alarm and surveillance system storage device or
2 equipment;

3 c. Entrances to and exits from the facility; and

4 d. Twenty (20) feet from the exterior of the perimeter of the facility.

5 2. Ability to operate under the normal lighting conditions of each area under surveillance;

6 3. Ability to immediately produce a clear, color, still photograph in a digital format that is
7 easily accessible;

8 4. Ability to display the date and time clearly and accurately. The date and time shall be
9 synchronized and set correctly and may not significantly obscure the picture; and

10 5. Ability to record all images captured by each surveillance camera in a format that may
11 be easily accessed for a minimum of thirty (30) days, unless otherwise required for investigative
12 or litigation purposes. The recordings shall be kept:

13 a. At the safety compliance facility:

14 (i) In a locked cabinet, closet or other secure place to protect it from tampering or theft;

15 and

16 (ii) In a limited access area or other room to which access is limited to authorized
17 individuals; or

18 b. At a secure location other than the location of the safety compliance facility if
19 approved by the cabinet.

20 (2) The following requirements apply to the inspection, servicing or alteration of, and any
21 upgrade to, the security alarm and surveillance systems:

22 (a) The systems shall be inspected and all devices tested once every year by a qualified
23 alarm system vendor and a qualified surveillance system vendor;

1 (b) A safety compliance facility shall conduct maintenance inspections once every month
2 to ensure that any repairs, alterations, or upgrades to the security alarm and surveillance systems
3 are made for the proper operation of the systems;

4 (c) A safety compliance facility shall retain at the facility, for at least five (5) years,
5 records of all inspections, servicing, alterations, and upgrades performed on the security alarm
6 and surveillance systems and shall make the records available to the cabinet and its authorized
7 agents within two (2) business days following a request; and

8 (d) In the event of a mechanical malfunction of the security alarm or surveillance system
9 that a safety compliance facility anticipates will exceed an eight (8) hour period, the safety
10 compliance facility shall notify the cabinet immediately via electronic mail to
11 kymedcanreporting@ky.gov, with cabinet approval, provide alternative security measures that
12 may include closure of the facility.

13 (3) A safety compliance facility shall meet the following requirements regarding records
14 retention:

15 (a) Have a secure electronic back-up system for all electronic records;

16 (b) Within three (3) business days following a request for records under this paragraph,
17 provide up to four (4) screen captures of an unaltered copy of a video surveillance recording to
18 the cabinet or its authorized agents, law enforcement, or other federal, state, or local government
19 officials if necessary to perform the governmental officials' functions and duties; and

20 (c) If a safety compliance facility has been notified in writing by the cabinet or its
21 authorized agents, law enforcement, or other federal, state, or local government officials of a
22 pending criminal or administrative investigation for which a recording may contain relevant
23 information, retain an unaltered copy of the recording for two (2) years or until the investigation

1 or proceeding is closed or the entity conducting the investigation or proceeding notifies the
2 cultivator that it is not necessary to retain the recording, whichever is later.

3 (4) During all non-working hours, all entrances to and exits from the safety compliance
4 facility shall be securely locked.

5 (5) A safety compliance facility shall install lighting to ensure proper surveillance inside
6 and outside of the facility.

7 (6) A safety compliance facility shall limit access to a room containing the equipment
8 operating the security alarm and surveillance monitoring systems to:

9 (a) Persons who are essential to maintaining security and surveillance operations;

10 (b) Federal, state, and local law enforcement;

11 (c) Security alarm and surveillance system service employees;

12 (d) The cabinet or its authorized agents; and

13 (e) Other persons with the prior written approval of the cabinet.

14 (7) A safety compliance facility shall make available to the cabinet or its authorized
15 agents, upon request, a current list of authorized employees and service employees or contractors
16 who have access to areas containing the equipment operating the security alarm and surveillance
17 monitoring systems.

18 (8) A safety compliance facility shall keep rooms housing the equipment operating the
19 security alarm and surveillance monitoring systems locked at all times and may not use these
20 rooms for any other purpose or function.

21 Section 12. Electronic monitoring system and seed to sale tracking system. A safety
22 compliance facility shall use the electronic monitoring system and seed to sale tracking system
23 prescribed by the cabinet containing the requirements in KRS Chapter 218B, specifically KRS

1 218B.140. A safety compliance facility shall use the electronic monitoring system and send to
2 sale tracking system in accordance with written instructions provided by the cabinet.

3 Section 13. Equipment, operation, and maintenance.

4 (1) A safety compliance facility shall have a written process in place to maintain the
5 sanitation and operation of equipment that comes into contact with samples to prevent
6 contamination. A safety compliance facility shall provide a copy of the written process to the
7 cabinet upon request.

8 (2) As part of the written process required under this section, a safety compliance facility
9 shall:

10 (a) Routinely check and inspect automatic, mechanical, or electronic equipment as well
11 as any measurement devices used in the safety compliance facility's operations to ensure
12 accuracy; and

13 (b) Maintain an accurate log recording the:

- 14 1. Maintenance of equipment;
- 15 2. Cleaning of equipment; and
- 16 3. Calibration of equipment.

17 Section 14. Sanitation and safety in a safety compliance facility.

18 (1) A safety compliance facility shall maintain its site and facility in a sanitary condition
19 to limit the potential for contamination of samples. The following requirements shall apply:

20 (a) Equipment and surfaces, including floors, counters, walls, and ceilings, shall be
21 cleaned and sanitized as frequently as necessary to protect against contamination, using a
22 sanitizing agent registered by the United States Environmental Protection Agency, in accordance

1 with the instructions printed on the label. All equipment and utensils used by a safety
2 compliance facility shall be capable of being adequately cleaned;
3 (b) Trash shall be properly and routinely removed;
4 (c) Floors, walls, and ceilings shall be kept in good repair;
5 (d) Adequate protection against pests shall be provided; and
6 (e) Toxic cleaning compounds, sanitizing agents, and other chemicals shall be labeled
7 and stored in a manner that prevents contamination of samples, and in a manner that otherwise
8 complies with other applicable laws, rules, and regulations.

9 (2) All employees shall conform to sanitary practices while on duty, including:

10 (a) Maintaining adequate personal cleanliness;

11 (b) Washing hands thoroughly in an adequate hand-washing area before starting work
12 and at any other time when hands may have become soiled or contaminated;

13 (c) Wearing proper clothing, including gloves, hair nets, headbands, caps, beard covers,
14 or other effective hair restraints where appropriate;

15 (d) Removing all unsecured jewelry and other objects that might fall into medicinal
16 cannabis, equipment, or containers, and removing hand jewelry that cannot be adequately
17 sanitized during periods in which medicinal cannabis is manipulated by hand. If such hand
18 jewelry cannot be removed, it may be covered by material which can be maintained in an intact,
19 clean, and sanitary condition and which effectively protects the medicinal cannabis from
20 contamination by these objects;

21 (e) Storing clothing or other personal belongings in areas other than where medicinal
22 cannabis is exposed or where equipment is cleaned;

1 (f) Confining the following to areas other than where medicinal cannabis may be exposed
2 or where equipment is cleaned: eating food, chewing gum, drinking beverages, or using tobacco;
3 and

4 (g) Taking any other necessary precautions to protect against contamination of medicinal
5 cannabis with microorganisms or foreign substances including perspiration, hair, cosmetics,
6 tobacco, chemicals, and medicines applied to the skin.

7 (3) A safety compliance facility shall provide its employees and visitors with adequate
8 and convenient hand-washing facilities furnished with running water at a temperature suitable for
9 sanitizing hands. Effective nontoxic sanitizing cleansers and sanitary towel service or suitable
10 drying devices shall also be provided.

11 (4) A safety compliance facility shall provide its employees and visitors with adequate,
12 readily accessible restrooms that are maintained in a sanitary condition and in good repair.

13 (5) A safety compliance facility shall ensure that its facility is provided with a water
14 supply sufficient for its operations, which shall be derived from a source that is a public water
15 system, or a nonpublic system that is capable of providing a safe, potable, and adequate supply
16 of water to meet the operational needs of the facility.

17 (6) A safety compliance facility shall comply with all other applicable federal, state, and
18 local building code requirements and occupational safety and health requirements.

19 Section 15. Storage requirements.

20 (1) A safety compliance facility shall have separate locked limited access areas for
21 storage of all samples and test samples until they can be tested and destroyed or otherwise
22 disposed of as required under Section 16 of this administrative regulation.

1 (2) A safety compliance facility shall maintain all storage areas in a clean and orderly
2 condition and free from infestation by insects, rodents, birds, and pests.

3 Section 16. Management and disposal of medicinal cannabis waste.

4 (1) A safety compliance facility shall dispose of samples in such a manner as to render
5 the medicinal cannabis unusable. A safety compliance facility shall record medicinal cannabis
6 waste as required in the commonwealth's designated electronic monitoring system and seed to
7 sale tracking system.

8 (2) Medicinal cannabis that is rendered unusable shall be discarded into a locked
9 dumpster or other approved, locked container for removal from the facility by a waste removal
10 company selected by the safety compliance facility. Medicinal cannabis shall be rendered
11 unusable by:

12 (a) Controlled incineration; or

13 (b) Grinding and incorporating the medicinal cannabis with one (1) or more of the non-
14 consumable, solid wastes listed below, such that the resulting mixture is majority non-cannabis
15 waste:

16 1. Paper waste;

17 2. Cardboard waste;

18 3. Food waste;

19 4. Yard or garden waste;

20 5. Grease or other compostable oil waste; or

21 6. Soil or other used growth media.

1 (3) The disposal of medicinal cannabis shall be performed under video surveillance from
2 the time the destruction begins to when it is placed in a locked dumpster or other approved,
3 locked container and removed from the safety compliance facility location.

4 (4) The employee overseeing the disposal of medicinal cannabis shall maintain and make
5 available a separate record of every disposal indicating the following:

6 (a) The date and time of disposal;

7 (b) The manner of disposal;

8 (c) The unique identification codes associated with the medicinal cannabis scheduled for
9 destruction;

10 (d) The reasoning for and description of the disposal;

11 (e) The name, employee identification number, and signature of the employee overseeing
12 the disposal of the medicinal cannabis; and

13 (f) The harvest batch or production batch number and weight of the plant material being
14 disposed of.

15 (5) The disposal of other waste from the safety compliance facility that does not include
16 medicinal cannabis, including hazardous waste and liquid waste, shall be performed in a manner
17 consistent with applicable federal, state, and local requirements.

18 Section 17. Duty to report.

19 (1) At the time a safety compliance facility submits a license renewal application to the
20 cabinet, a safety compliance facility shall report to the cabinet via electronic mail to
21 kymedcanreporting@ky.gov the following:

22 (a) A list of the cannabis businesses that the safety compliance facility has contracted
23 with for sample testing;

- 1 (b) A list of non-testing activities allowed under KRS 218B.125 that the safety
2 compliance facility engaged in during the licensure period, a list of its customers for each
3 activity, and the compensation received for each activity. If the safety compliance facility
4 produced and sold educational materials related to the use of medicinal cannabis, the safety
5 compliance facility shall provide copies of those educational materials to the cabinet upon
6 request;
- 7 (c) Any issues with accomplishing sample testing in a timely manner; and
- 8 (d) The number of current employees, their respective job titles, and hourly wage.
- 9 (2) A safety compliance facility shall participate in surveys distributed by the cabinet
10 throughout a licensure period and provide full and complete responses.

915 KAR 1:060

REVIEWED:

<small>DocuSigned by:</small> <i>Sam Flynn</i> <small>7226208BA436414...</small>	1/2/2024
<hr/>	
Sam Flynn Executive Director Kentucky Medical Cannabis Program Cabinet for Health and Family Services	Date

APPROVED:

<small>DocuSigned by:</small> <i>Eric Friedlander</i> <small>0A2A1D6C15D6431...</small>	1/2/2024
<hr/>	
Eric C. Friedlander Secretary Cabinet for Health and Family Services	Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on March 25, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by March 18, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

Contact Person: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 915 KAR 1:060
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements and procedures for safety compliance facilities that provide testing services to medicinal cannabis businesses in the commonwealth.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to carry out the requirements of KRS Chapter 218B, specifically KRS 218B.140.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 218B.140 authorizes the Cabinet for Health and Family Services to promulgate administrative regulations establishing requirements and procedures for safety compliance facilities that provide testing services to medicinal cannabis businesses in the commonwealth. This administrative regulation sets out those requirements and procedures.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides the requirements and procedures for safety compliance facilities to operate in the commonwealth.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Not applicable. This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: Not applicable. This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: Not applicable. This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: Not applicable. This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects safety compliance facilities that have applied for and subsequently received licenses to provide testing services to medicinal cannabis businesses in the commonwealth.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The requirements to operate as a safety compliance facility and remain in good standing throughout the licensure period are provided in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Safety compliance facilities will have to pay an initial application fee, and if approved for a license, an initial license fee and then a renewal license fee if it desires to continue operating as a cannabis business following the expiration of its initial license.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): A safety compliance facility that receives a license from the Cabinet for Health and Family Services is authorized to provide testing and other services to medicinal cannabis businesses in the commonwealth for the term of the license (i.e., 1 year from the date of license issuance).

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: \$1,200,000

(b) On a continuing basis: \$1,200,000

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds provided by the commonwealth.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: It is anticipated that an increase in funding will be necessary to implement this regulation as additional staff and resources are necessary to administer and enforce licensure of safety compliance facilities.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied. All safety compliance facilities will be treated equally.

FISCAL NOTE

Administrative Regulation: 915 KAR 1:060
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218B.010, 218B.080, 218B.085, 218B.090, 218B.095, 218B.100, 218B.125, 218B.140.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The cabinet will receive initial application fees and initial license fees paid by safety compliance facilities during the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The cabinet will receive annual renewal license fees from safety compliance facilities that desire to continue operating in the commonwealth following the expiration of their existing license.

(c) How much will it cost to administer this program for the first year? The cabinet estimates that it will cost \$1,200,000 to license and regulate cultivators in the first year.

(d) How much will it cost to administer this program for subsequent years? The cabinet estimates that it will cost \$1,200,000 to regulate licensed cultivators in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: It is anticipated that an increase in funding will be necessary to implement this regulation as additional staff and resources are necessary to administer and enforce licensure of safety compliance facilities.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? The cabinet does not anticipate any cost savings in the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? The cabinet does not anticipate any cost savings in subsequent years.

(c) How much will it cost the regulated entities for the first year? Safety compliance facilities will pay an initial application fee and, if issued a license, an initial license fee in order to conduct testing and other activities in the commonwealth.

(d) How much will it cost the regulated entities for subsequent years? If it desires to continue cannabis business operations in the commonwealth, a safety compliance facility will pay an annual renewal license fee. The renewal license fee is refundable if the renewal application is denied.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings(+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]* The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward licensing and enforcement of cannabis businesses operating in the commonwealth, including safety compliance facilities, as well implementation and continued operation of the electronic monitoring system and seed to sale tracking system required by KRS 218B.140. The Kentucky Medical Cannabis Program will have a major economic impact on the Cabinet for Health and Family Services, and it is anticipated that an increase in funding will be necessary to administer all of the administrative regulations contained in 915 KAR Chapter 1 related to cannabis businesses.