NOTICE OF INTENT Louisiana Department of Agriculture and Forestry Part XLIX. Chapters 1 – 31. Medical Marijuana

(LAC 7:XLIX.Chapters 1-31)

In accordance with the Administrative Procedure Act, R.S. 49:950, et seq., notice is hereby given that the Department of Agriculture and Forestry ("Department"), intends to adopt LAC 7:XLIX.Chapters 1 - 31 regarding the growing and production of medical marijuana. The proposed rules are being adopted pursuant to R.S. 40:1046. Chapter 1 of the proposed rules sets forth definitions used in the medical marijuana rules. Chapter 3 sets for the department's authority to adopt the rules and addresses administrative matters, such as rules of construction for the proposed regulations. Chapter 5 addresses the license issued by the department to the grower and permits issued by the department to employees of the licensee. Chapter 5 includes rules regarding the form, content and information required in applications. Chapter 5 also addresses suitability standards, the ownership and transferability of the license and requires permits for employees. Chapter 7 addresses fees charged by the department to the licensee. Chapter 9 addresses compliance by the licensee and permitees and inspections by the department. Chapter 9 further sets forth a procedure for the licensee to request waivers from certain rules in emergency situations. Chapter 11 requires the licensee to establish internal controls for the production facility and sets forth the areas that must be covered by the internal controls. Chapter 13 sets forth record keeping and reporting requirements for the licensee and requires the licensee to submit an annual report to the department. The department, in turn, is required by law to submit an annual report to the legislature. Chapter 15 governs the production facility, including requiring certain areas of the facility be restricted. Chapter 15 also addresses the use of pesticides on medical marijuana plants. Chapter 17 addresses surveillance and security requirements that the licensee must follow at the production facility. Chapter 19 requires the licensee to use a tracking system for inventory. Chapter 21 addresses quality control of the medical marijuana products produced by the licensee and requires the licensee to conduct quality assurance tests. Chapter 23 sets forth the requirements for laboratory testing, including which tests must be run. Chapter 23 sets forth requirements on the licensee and its employees when transporting medical marijuana or medical marijuana infused products to laboratories, pharmacies or research facilities. Chapter 27 sets forth sanitation requirements for the production facility and provides rules for the disposal of waste. Chapter 29 addresses labeling of medical marijuana or medical marijuana infused products and also addresses advertising by the licensee. Finally, Chapter 31 sets forth the procedures for the department to take enforcement action against the licensee.

Title 7 AGRICULTURE AND ANIMALS Part XLIX. Medical Marijuana

Chapter 1. General Provisions §101. Definitions

A. The provisions of the Act, R.S. 40:1046 and 1047, relating to definitions, words and terms are hereby incorporated by reference and made a part hereof and will therefore apply and govern the interpretation of these rules, unless the context otherwise requires or unless specifically redefined in a particular Section. Any word or term not defined in these rules shall have the same meaning ascribed to it in the Act. Any word not defined by the Act or these regulations shall be construed in accordance with its plain and ordinary meaning.

B. The following words and terms shall have the following meanings.

Act—R.S. 40:1046, et. seq.

Applicant—any person or legal entity who has submitted an application or bid to the department for a license, permit, registration, contract, certificate or other finding of suitability or approval, or renewal thereof, authorized by the Act or rule.

Applicant Records—those records which contain information and data pertaining to an applicant's criminal record, background, and financial records, furnished to or obtained by the department from any source incidental to an investigation for licensing or permitting, findings of suitability, registration, the continuing obligation to maintain suitability, or other approval.

Application—the documentation, forms and schedules prescribed by the department upon which an applicant seeks a license, permit, registration, contract, certificate or other finding of suitability or approval, or renewal

thereof, authorized by the Act or rule. Application also includes questionnaires, information, disclosure statements, financial statements, affidavits, and all documents incorporated in, attached to, or submitted by an applicant or requested by the department.

Architectural Plans and Specifications or Architectural Plans or Plans or Specifications—all of the plans, drawings, and specifications for the construction, furnishing, and equipping of the facility including, but not limited to, detailed specifications and illustrative drawings or models depicting the proposed size, layout and configuration of the production facility, including electrical and plumbing systems, engineering, structure, and aesthetic interior and exterior design as are prepared by one or more licensed professional architects and engineers.

Background Investigation—all efforts, whether prior to or subsequent to the filing of an application, designed to discover information about an applicant, affiliate, licensee, permittee, registrant, or other person required to be found suitable and includes, without time limitations, any additional or deferred efforts to fully develop the understanding of information which was provided or should have been provided or obtained during the application process.

Batch—the established segregation of a group of plants at the time of planting for the control of quantity, traceability and/or strain. A batch number will be assigned a specific unit or finite set of marijuana plants, therapeutic marijuana or therapeutic chemicals identifiable by a unique number or other unique designation, every portion or package of which is uniform, within recognized characteristics or tolerances for factors specific to the production stage. This unique identification follows each specific unit or finite set throughout growing, production, laboratory testing and product packaging and labelling.

Business Entity or Legal Entity—a natural person, a corporation, limited liability company, partnership, joint stock association, sole proprietorship, joint venture, business association, cooperative association, professional corporation or any other legal entity or organization through which business is conducted.

Consent to Administrative Supervision—a confidential legal agreement signed by the department and an individual, business, or other entity through which the violator agrees to pay for correction of violations, take the required corrective actions, or refrain from an activity while under the department's supervision.

Department—the Louisiana Department of Agriculture and Forestry.

Department Agent—any employee of the department designated by the Commissioner of Agriculture and Forestry.

Economic Interest—any interest in a license from which a person receives or is entitled to receive, by agreement or otherwise, a profit, gain, thing of value, loss, credit, security interest, ownership interest or other benefit. Economic interest includes voting shares of stock or otherwise exercising control of the day-to-day operations through a management agreement or similar contract. Economic interest does not include a debt unless upon review of the instrument, contract, or other evidence of indebtedness, the department determines a finding of suitability is required based upon the economic relationship with the licensee.

Employee Permit—the permit issued by the department authorizing a person to work for the licensee.

Financial Interest—any actual or future right to ownership, investment, or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent or child, in the licensee. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national securities exchange or over-the-counter market in the United States, provided the investment securities held by the person and the person's spouse, parent or child, in the aggregate, do not exceed one percent ownership in the licensee.

Financial Statements or Financial Records—both summaries of financial matters of any sort and any source documents or records from which summaries are or may be derived. Those statements and the information contained therein which relate to balance sheets, profit and loss statements, mortgages, debt instruments, ledgers, journals, invoices, and any other document bearing on the financial status of an entity, whether historical or current.

Geographic Location—a single location in the control of a licensee, which by definition is the premises, that has contiguous boundaries and is located within a parish in Louisiana.

Internal Controls—internal procedures and administration and accounting controls designed by the licensee for the purpose of exercising control over the licensee's operations as approved by the department.

License—the authorization by the department to produce medical marijuana and medical marijuana-infused product in accordance with the Act.

Licensed Dispensary Pharmacy or Dispensary—a pharmacy licensed by the Louisiana Board of Pharmacy to dispense medical marijuana-infused product.

Licensee—a person or legal entity holding the specialty license issued by the department authorizing the holder to operate a medical marijuana production facility.

Louisiana Medical Marijuana Tracking System (LMMTS)— the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the product is sold to a dispensary or is destroyed.

LMMTS Tracking System User—a licensee or authorized employee who is granted LMMTS user account access for the purpose of conducting inventory tracking functions in the LMMTS, who has been successfully trained by LMMTS Trained Administrator(s) in the proper and lawful use of LMMTS, and who has completed any additional training required by the department.

LMMTS Trained Administrator—a licensee or authorized employee who has attended and successfully completed LMMTS training and who has completed any additional training required by the department.

Medical Marijuana—substances which are identified as including any parts of the plant Cannabis sativa, and all derivatives or subspecies of all strains of cannabis, whether growing or not, the seeds thereof; the resin extracted from any part of such plant; and any compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin, including tetrahydrocannabinol (THC), Cannabidiol (CBD) and all other naturally occurring cannabinol derivatives, whether produced directly or indirectly by extraction. This term shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination.

Medical Marijuana Concentrate—a product derived from medical marijuana that is produced by extracting cannabinoids from the plant through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats; water, ice or dry ice; or butane, propane, CO2, ethanol or isopropanol. The use of any other solvent as is expressly prohibited unless and until it is approved by the department.

Medical Marijuana-Infused Product or *Product*—a product infused with medical marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures.

Medical Marijuana Waste—medical marijuana or medical marijuana-infused product that is not usable or cannot be processed.

Monitoring—the continuous and uninterrupted video surveillance of cultivation activities and oversight for potential suspicious actions. The department or law enforcement agencies designated by the department shall have the ability to access the licensee's monitoring system in real-time via a secure web-based portal.

Permit—authorization issued from the department to a natural person to work for, or on behalf of, the licensee.

Permittee—a principle officer or board member of the licensee, or a person employed in the operation or supervision of the licensee's operation, including any individual whose employment duties directly relate to the growing, cultivating, harvesting, processing, weighing, packing, transportation and selling of product.

Permittee Identification Card—a document approved by the department that identifies a person as a production facility permittee.

Premises—land, together with all buildings, improvements, and personal property located thereon, wherein medical marijuana or product is produced.

Produce or *Production*—the growing, compounding, conversion, processing or manufacturing of medical marijuana and medical marijuana-infused product, by extraction from substances of natural origin including any packaging or repackaging of the products or the labeling or relabeling of these products or their containers.

Producer—the licensee or a person or entity under contract, memorandum of understanding, or cooperative endeavor agreement with the licensee for services to grow or produce medical marijuana and medical marijuana-infused product.

Production Facility—a permanent, secured, indoor space designed and located in one geographic location, operated solely for the production of medical marijuana and product by the licensee to perform necessary activities to provide licensed dispensary pharmacies with usable product.

Production Facility Agent-In-Charge or Agent-In-Charge—the production facility permittee who has been designated by the licensee to have control and management over the day to day operations of the production facility. The licensee may designate more than one agent-in-charge to cover varying operational work shifts, but may only have one per work shift as approved by the department.

Records—all books, records, writings, accounts, letters and letter books, maps, drawings, photographs, cards, tapes, recordings, memoranda, and papers, and all copies, duplicates, photographs, or other reproductions thereof, or any other documentary materials, regardless of physical form or characteristics, including information contained in electronic data processing equipment, having been used, being in use, or prepared, possessed, or retained for use in the conduct, transaction, or performance of any business, transaction, work, duty, or function which was conducted, transacted, or performed by or under the authority of a license or permit issued by the department.

Restricted Access Area—a building, room or other area in the production facility where medical marijuana is grown, cultivated, harvested, stored, weighed, packaged, sold or processed for sale to a licensed dispensary pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 3. Administrative Procedures and Authority

§301. Policy

A. It is the declared policy of the department that production of medical marijuana in Louisiana be strictly regulated and controlled through administrative rules to protect the public welfare of the inhabitants of the state of Louisiana.

- B. Marijuana is classified as a Schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.
- 1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any Schedule I controlled substance, including marijuana, is a violation of federal law.
- 2. Neither Louisiana law nor these rules can preempt federal law. Therefore, the provisions of this chapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§303. Construction of Regulations and Administrative Matters

A. Nothing contained in these regulations shall be so construed as to conflict with any provision of the Act, any other applicable statute. If any regulation is held invalid by a final order of a court of competent jurisdiction at the state or federal level, such provision shall be deemed severed and the court's finding shall not be construed to invalidate any other regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§305. Louisiana State University Agricultural Center and/or Southern University Agricultural Center Is Licensee

A. These regulations, subject to any rights in the Act, intend for the term licensee to apply to Louisiana State University Agricultural Center, Southern University Agricultural Center, either separately or jointly, to any of their subordinate contractors, or to the recipient of the license pursuant to R.S. 40:1046.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 5. License and Permits

§501. Procedure for Issuing the License

- A. The department shall issue the license pursuant to the Act.
- B. Louisiana Revised Statute 40:1046 entitles the Louisiana State University Agricultural Center and the Southern University Agricultural Center the right of first refusal to be licensed as the production facility. This entitlement carries a presumption of suitability and accordingly, the following administrative rules pertaining to licensing shall not apply to the Louisiana State University Agricultural Center and the Southern University Agricultural Center: 505, 507, 509, 513(A), 515, 517, 519(A)(3), 521, 701(A).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§503. General Authority of the Department

- A. The department shall have the authority to call forth any person who, in their opinion, has the ability to exercise significant influence over an applicant or licensee, and such person shall be subject to all suitability requirements.
- B. In the event a person is found unsuitable, then the applicant or licensee shall have no association or connection with such person.

C. The department may grant variances in writing from certain licensing requirements for Louisiana State University Agricultural Center and Southern University Agricultural Center.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§505. Applications in General

- A. The license and any permit issued by the department is deemed to be a revocable privilege, and no person or legal entity holding such a license or permit is deemed to have acquired any vested rights therein.
- B. An applicant for a license or permit authorized by the Act or rule is seeking the granting of a privilege, and the burden of proving qualification and suitability to receive the license or permit is at all times on the applicant.
- C. The securing of the license, permit or approval required under the Act or these rules is a prerequisite for conducting, operating, or performing any activity regulated by the Act or these rules. Each applicant must file a complete application as prescribed by the department.
- D. The filing of an application under the Act or these rules constitutes a request for a decision upon the applicant's general suitability, character, integrity, and ability to participate or engage in or be associated with the licensee or permittee. By filing an application, the applicant specifically consents to the making of such a decision by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§507. Investigations; Scope

A. The department shall investigate all applications for the license or permit or other matters requiring department approval. The department may investigate, without limitation, the background of the applicant, the suitability of the applicant's finances, the applicant's business integrity, the suitability of the proposed premises for the facility, the suitability of a person with an ownership or economic interest in the applicant for a license of 5 percent or more, the suitability of any person who in the opinion of the department has the ability to exercise significant influence over the activities of an applicant for a license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§509. Ownership of License and Permits

A. The license and all permits issued by the department as provided in the Act or by rule, are and shall remain the property of the department at all times.

B. The license shall be issued in the name of the licensee. One license will be issued even though multiple individuals may file or be required to file applications related thereto.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§511. Transfer of License or Permits

A. The license and all permits are not transferable or assignable. If the status of the licensee or permittee should change such that the person no longer needs or is entitled to the license or permit, then the license or permit shall be cancelled and any tangible item which evidences such a license or permit shall be surrendered to the department within five days of the change of status.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§513. Eligibility Suitability Standards

- A. No person shall be eligible to apply for the license unless he meets all of the following requirements:
 - 1. is in compliance with all requirements provided by the act; and
- 2. is properly registered and in good standing with the Louisiana Secretary of State and Department of Revenue.
- B. No person shall be eligible to obtain a license or permit or obtain any other approval pursuant to the provisions of the Act or these rules unless the applicant has demonstrated by clear and convincing evidence to the department, where applicable, that he is suitable. Suitable means the applicant, licensee, permittee, or other person is:
 - 1. a person of good character, honesty, and integrity;

- 2. a person whose prior activities, criminal record, if any, reputation, habits, and associations do not pose a threat to the public interest of this state or to the effective regulation and control of the production of medical marijuana or product or enhance the dangers of unsuitable, unfair, or illegal practices, methods, and activities in the production of medical marijuana or product or carrying on of the business and financial arrangements incidental thereto;
- 3. capable of and likely to conduct the activities for which the applicant, licensee, permittee, is licensed, permitted, or approved pursuant to the provisions of the Act or these rules; and
 - 4. not disqualified pursuant to the provisions Subsection B of this Section.
- C. The department, where applicable, shall not grant a license or permit, or issue any other approval pursuant to the provisions of the Act or these rules to any person who is disqualified on the basis of the following criteria:
- 1. the conviction or a plea of guilty or nolo contendere by the applicant or any person required to be suitable under the provisions of the Act or these rules for any of the following:
 - a. Any offense punishable by imprisonment of more than one year;
- b. Theft or attempted theft, illegal possession of stolen things, or any offense or attempt involving the misappropriation of property or funds;
 - c. Any offense involving fraud or attempted fraud, false statements or declarations;
 - d. A crime of violence as defined in R.S.14:2(B); and
 - e. Any offense involving Schedule I narcotics.
- 2. there is a current prosecution or pending charge against the person in any jurisdiction for any offense listed in Paragraph (1) of this Subsection; and
- 3. the failure to provide information and documentation to reveal any fact material to a suitability determination, or the supplying of information which is untrue or misleading as to a material fact pertaining to the suitability criteria.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§515. Suitability Determination

A. An applicant and officers, directors, and any person having a 5 percent or more economic interest in the licensee shall be required to submit to an investigation to determine suitability.

- B. Any person, who in the opinion of the department, has the ability to exercise significant influence over the activities of an applicant for license or licensee shall be required to submit to an investigation to determine suitability.
- C. All costs associated with conducting an investigation for suitability shall be borne by the applicant, licensee, or permittee or the person who is the subject of the investigation.
- D. Failure to submit to a suitability determination as required by this Section may constitute grounds for delaying consideration of the application or for denial of the application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§517. Form of Application

A. An application for a license, permit, or finding of suitability shall be filed by way of forms prescribed by and obtained from the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§519. Information Required from an Applicant for a License

A. An application for the license shall contain the following information including but not limited to:

- 1. information required by the Act;
- 2. one copy of detailed plans of design of the facility, including the projected use of each area;
- 3. an estimated timetable for the proposed financing arrangements through completion of construction;
- 4. the construction schedule proposed for completion of the production facility including therein projected dates for completion of construction and commencement of operations and indicating whether the construction contract includes a performance bond;
 - 5. explanation and identification of the source or sources of funds for the construction of the facility;
 - 6. description of the production facility size;

- 7. a detailed plan of surveillance and surveillance equipment to be installed;
- 8. proposed hours of operation;
- 9. the proposed management plan, management personnel by function and organizational chart by position; and
- 10. a list of employees which the applicant anticipates employing in the production facility operation, including job classifications.
- B. An applicant for the license shall provide a copy of proposed internal controls which shall include:
- 1. accounting and financial controls including procedures to be utilized in counting, banking, storage and handling of cash;
- 2. job descriptions and the systems of personnel and chain-of-command, establishing a diversity of responsibility among employees engaged in production facility operations and identifying primary and secondary supervisor positions for areas of responsibility, which areas shall not be so extensive as to be impractical for an individual to monitor;
- 3. procedures for the inventory control and tracking, security, storage, and recordation of inventory; and
 - 4. procedures and security standards for total operation of the facility;
- C. In addition, the department may require an applicant to provide such other information and details as it needs to discharge its duties properly.
- D. Failure to comply with the provisions of this Section may constitute grounds for delaying consideration or for denial of the application.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§521. Fingerprinting

A. An initial application is not complete unless all persons required by the department have submitted to fingerprinting at the direction of the department.

B. Failure to submit to fingerprinting may constitute grounds for delaying consideration of the application or for denial of the application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§523. Employee Permits Required

A. A person employed in the operation or supervision of the licensee's operation including any individual whose employment duties require or authorize access to the premises on a regular basis, or a principle officer or board member of the licensee, shall be permitted by the department annually. A permit is valid for one year from the date of issuance.

B. The licensee shall not employ an individual in a capacity which requires an employee permit unless such individual is the holder of a valid employee permit issued by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§525. Display of Identification Badge

A. Every employee required to be permitted shall be issued a permittee identification badge, which shall be on his person and displayed at all times when on the production facility premises or when transporting product.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§527. Permit Renewal Applications

A. Applications for renewal of permits shall be made in such a manner and by way of forms prescribed by the department and shall contain all information requested by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 7. Fees

§701. Fees

A. The license fee of \$100,000 shall be payable to the department upon issuance of the license and annually

thereafter.

- B. The fee for a permit shall be \$100 annually.
- C. A fee of 7% of gross sales shall be paid quarterly to the department.
- D. All fees collected by the department shall be used to fund expenses relating to the regulation and control of the medical marijuana program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 9. Compliance and Inspections

§901. Applicability and Resources

A. This Chapter is applicable to inspections relative to compliance with the Act and the rules. The department is empowered to employ such personnel as may be necessary for such inspections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§903. Code of Conduct of Licensee and Permittees

A. General Provisions

- 1. all licensees and permittees shall comply with all applicable federal, state, and local laws and regulations. For purposes of this Chapter, applicable federal law shall not mean the growing, sale, possession, or distribution of medical marijuana; and
 - 2. all notifications to the department required by this Section shall be in writing.

B. Unsuitable Conduct

- 1. a licensee or permittee shall not engage in unsuitable conduct or practices and shall not employ or have a business association with any person, natural or juridical, that engages in unsuitable conduct or practices; and
- 2. for purposes of this section, unsuitable conduct or practices shall include, but not be limited to, the following:
- a. employment of, in a managerial or other significant capacity as determined by the department, business association with, or participation in any enterprise or business with a person disqualified pursuant to Section 513 of Chapter 5 of these rules or declared unsuitable by the department;
- b. failure to provide information or documentation of any material fact or information to the department;
 - c. misrepresentation of any material fact or information to the department;
- d. engaging in, furtherance of, or profit from any illegal activity or practice, or any violation of these rules or the Act;
 - e. obstructing or impeding the lawful activities of the department; or
 - f. persistent or repeated failure to pay amounts due or to be remitted to the state.
- 3. the licensee or permittee shall not engage in, participate in, facilitate, or assist another person in any violation of these rules or the Act; or
- 4. any person required to be found suitable or approved in connection with the license, or permitted by the department, shall have a continuing duty to notify the department of his arrest, summons, citation or charge for any criminal offense or violation that would deem him unsuitable in accordance with these rules. The notification required by this Paragraph shall be made within 15 calendar days of the arrest, summons, citation, charge, fact, event, occurrence, matter or action.
- C. Responsibility for the employment and maintenance of suitable methods of operation rests with the licensee. Willful or persistent use or toleration of methods of operation deemed unsuitable is cause for administrative action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§905. Compliance with Laws

A. Acceptance of a license or permit or renewal thereof constitutes an agreement on the part of the licensee or permittee to be bound by all of the applicable provisions of the Act and the regulations. It is the responsibility of the licensee or permittee to keep informed of the content of all such laws, and ignorance thereof shall not excuse violations. Violation of any applicable provision of the Act or the rules by a licensee or its agent, or permitte, employee or representative, is contrary to the public health, safety, morals, good order and general welfare of the inhabitants of the state of Louisiana and constitutes cause for administrative action.

B. In the event the licensee subcontracts services in the production of medical marijuana or product, the subcontractor's acts or omissions shall be considered the acts or omissions of the licensee. All obligations, duties, and responsibilities imposed on the licensee by these regulations shall be the obligations, duties and responsibilities of the subcontractor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§907. Inspections and Observations

- A. The department and its representatives shall have complete, immediate and unrestricted access at all times and without notice or demand to the licensee, permittee or any other person, to enter and:
 - 1. inspect the entire production facility and its ancillary facilities, including all restricted areas;
 - 2. observe production activities; or
 - 3. observe the transportation of product.
- B. A licensee shall, upon request, immediately make available for inspection by the department all papers, documents, books and records used in the licensed operations.
- C. Such inspections and observations may or may not be made known to the licensee.
- D. All requests for access to the production facility and production of records and documents in connection with any inspection shall be granted in accordance with the provisions of the Act and these regulations.
- E. In conducting an inspection, the department is empowered to:
- 1. inspect and examine the entire production facility wherein production activities are conducted or proposed to be conducted, wherein inventory, equipment or supplies are maintained, and wherein all papers, books, records, documents and electronically stored media are maintained;
- 2. summarily seize and remove product, inventory, supplies, and equipment from such premises for the purpose of examination and inspection;
- 3. have access to inspect, examine, photocopy and, if necessary seize all papers, books, records, documents, information and electronically stored media of an applicant, licensee, or permittee pertaining to the licensed operation or activity, on all premises where such information is maintained;
 - 4. review all papers, books, records, and documents pertaining to the licensed operation; and
- 5. conduct audits to determine compliance with all laws, rules and operations authorized by the Act under the department's jurisdiction;

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§909. Production Facility Agent-In-Charge

A. The licensee shall designate a permittee as production facility agent-in-charge. A production facility agent-in-charge shall be on the licensee's premises during hours of operation and shall have authority to immediately act in any matter or concern of the department. A description of the duties and responsibilities of the production facility agent-in-charge shall be included in the written system of internal controls.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§911. Waivers and Authorizations

- A. All requests to the department for waivers, approvals, or authorizations, except matters concerning emergency situations, shall be submitted in writing no less than 30 days prior to the licensee's planned implementation date, unless a shorter time is approved by the department.
- B. No waiver, approval, or authorization is valid until such time as the licensee receives written authorization from the department.
- C. The department, in its sole discretion, may determine what constitutes an emergency situation. Such determinations will be made on a case by case basis.
- D. A licensee shall adhere to all the requirements and provisions of the authorization. Violation of the terms of a written authorization may be cause for administrative action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 11. Internal Controls

§1101. Internal Control for Production Facility

- A. The licensee shall establish administrative and accounting procedures for the purpose of exercising effective control over the licensee's internal fiscal affairs. The procedures must be designed to reasonably ensure that:
 - 1. assets are safeguarded;
 - 2. financial records are accurate and reliable;
- 3. transactions are performed only in accordance with management's general or specific authorization;
- 4. transactions are recorded adequately to permit proper reporting of sales and maintain accountability for inventory and assets;
 - 5. access to assets is permitted only in accordance with management's specific authorization; and
- 6. functions, duties, and responsibilities are appropriately segregated and performed in accordance with sound practices by competent, qualified personnel.
- B. The licensee shall describe, in such manner as the department may approve or require, its administrative and accounting procedures in detail in a written system of internal control. The licensee shall submit for approval a copy of its written system to the department. Each written system shall include:
 - an organizational chart depicting segregation of functions and responsibilities;
 - 2. a description of the duties and responsibilities of each position shown on the organizational chart;
- 3. a detailed, narrative description of the administrative, accounting, and operational procedures designed to satisfy the requirements of Subsection A. This description shall address operational and management practices, including but not limited to:
 - a. record keeping;
 - b. security measures to deter and prevent theft of medical marijuana and product;
 - c. authorized entrance into areas containing medical marijuana or product;
- d. types and quantities of medical marijuana or products that are produced at the manufacturing facility;
 - e. methods of planting, harvesting, drying, batching, and storage of medical marijuana;
 - f. estimated quantity of all crop inputs used in production;
 - g. estimated quantity of waste material to be generated;
 - h. disposal methods for all waste materials;
 - i. inventory storage procedures;
 - j. employee training methods for the specific phases of production;
 - k. biosecurity measures used in production and manufacturing;
 - 1. strategies for reconciling discrepancies in plant material, medical marijuana or product;
 - m. sampling strategy and quality testing for labeling purposes;
 - n. medical marijuana and product packaging and labeling procedures;
 - o. procedures for the mandatory and voluntary recall of medical marijuana and product;
- p. plans for responding to a security breach at a production facility, or while medical marijuana or product is in transit to another approved facility;
 - q. business continuity plan;
 - r. procedures and records relating to all transport activities; and
 - s. other information requested by the department.
- 4. a written statement signed by the licensee's chief financial officer and either the licensee's chief executive officer or a licensed owner attesting that the system satisfies the requirements of this section; and
 - 5. such other items as the department may require.
- C. The licensee's system of internal control procedures shall meet, at a minimum, the requirements set forth in the Act and administrative rules. If the department determines that a licensee's administrative or accounting procedures or its written system does not meet the standards, the department shall so notify the licensee in writing. Within 30 days after receiving the notification, the licensee shall amend its procedures and written system accordingly, and shall submit a copy of the written system as amended and a description of any other remedial measures taken.
- D. The licensee shall promptly report any amendments to the licensee's system of internal control procedures. The report must include either a copy of the written system of internal control procedures as amended or a copy of each amended page of the written system of internal control procedures, and a written description of the amendments signed by the licensee's chief financial officer. The department may also request the licensee to submit a copy of the written system of internal control procedures at any time.

E. The licensee shall comply with its written system of internal control procedures submitted pursuant to Subsection B as it relates to compliance with the requirements set forth in these regulations. Failure to comply is an unsuitable method of operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1103. Application Control

- A. The licensee shall establish application control procedures for the purpose of exercising effective control over the licensee's management information systems to include the LMMTS, and to provide for a stable operation of the IT environment. The licensee shall comply with its system of application control as it relates to compliance with the requirements set forth in these regulations. The application procedures shall include a business continuity plan, an organizational chart depicting segregation of functions and responsibilities, and a description of the duties and responsibilities of each position shown on the organizational chart.
- B. The procedures must be designed to reasonably ensure that:
- 1. information is safeguarded and logically secured through the use of passwords, biometrics, or other means as approved by the department;
 - 2. electronic records are accurate and reliable;
- 3. controls assure the accuracy of the data input, the integrity of the processing performed, and the verification and distribution of the output generated by the system. Examples of these controls include:
 - a. proper authorization prior to data input, for example, passwords;
 - b. use of parameters or reasonableness checks; and
 - c. use of control totals on reports and comparison of them to amounts input.
 - 4. transactions are performed only in accordance with control procedures; and
- 5. transactions are recorded adequately to permit proper reporting of data, and to maintain accountability for processing tracking, inventory, sales, and assets.
- C. Data server equipment and system storage shall be housed in a secured environment equipped with a non-water based fire suppression system, redundant power supply and UPS battery backup, redundant HVAC system, and protected by surveillance and security alarm systems. Only authorized personnel shall have physical access to the computer software and hardware.
- D. Backup and Recovery
- 1. the licensee shall perform a backup to the system data daily. Backup and recovery procedures shall be written and distributed to all applicable personnel. These policies shall include information and procedures, which includes, at a minimum, a description of the system and system manual(s) that ensure the timely restoration of data in order to resume operations after a hardware or software failure;
- 2. the licensee shall maintain copies of system-generated edit reports, exception reports and transaction logs for a minimum of five years; and
- 3. the licensee shall maintain either printed or electronic copies of system-generated edit reports, exception reports, and transaction logs.
- E. Access to Software and Hardware
- 1. the licensee shall establish security groups based on job requirements and access level of employees. This information shall be maintained by the licensee and include the employee's name, position, identification number, and the date authorization is granted. These files shall be updated as employees or the functions they perform change;
- 2. the licensee shall print and review the computer security access report monthly. Discrepancies shall be investigated, documented, and maintained for five years;
 - 3. only authorized personnel shall have physical access to the computer software and hardware;
- 4. all changes to the system and the name of the individual who made the change shall be documented; and
- 5. reports and other output generated by the system shall be available and distributed to authorized personnel only.
- F. Computer Records
- 1. at a minimum, the licensee shall generate, review, document this review, and maintain reports on a daily basis for the respective system(s) utilized in their operation.
- G. The licensee may not implement application control procedures that do not satisfy the requirements set forth in these regulations unless the department approves otherwise in writing. If the department determines that the licensee's application control procedures do not comply with the requirements of the Act or administrative rules, the

department shall so notify the licensee in writing. Within 30 days after receiving the notification, the licensee shall amend its application controls, and shall submit a copy of the amended application controls and a description of any other remedial measures taken.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 13. Reporting and Record Keeping

§1301. Reporting & Record Keeping

- A. The licensee shall keep and maintain all of the true, accurate, complete, legible and current books upon the licensed premises for a five-year period and made available for inspection if requested by the department. Electronic records may be maintained in other locations if access to the records is available on computers located at the production facility or other location approved by the department.
- B. The licensee shall conduct a complete system data backup to an off-site location a minimum of once a month. For purposes of this Section, the licensee shall submit the name, location, and security controls of the off-site storage facility to the department.
- C. The licensee shall have a written contingency plan in the event of a system failure or other event resulting in the loss of system data. The plan shall address backup and recovery procedures and shall be sufficiently detailed to ensure the timely restoration of data in order to resume operations after a hardware or software failure or other event that results in the loss of data.
- D. The licensee is responsible for keeping and maintaining all of the production facility's records that clearly reflect all financial transactions and the financial condition of the business. The following records shall be kept and maintained on the licensed premises for a five-year period and shall be made available for inspection if requested by the department:
- 1. purchase invoices, bills of lading, manifests, sales records, copies of bills of sale and any supporting documents, including the items and/or services purchased, from whom the items were purchased, and the date of purchase;
 - 2. bank statements and cancelled checks for all accounts relating to the production facility;
 - 3. accounting and tax records related to the production facility and each producer backer;
- 4. records of all financial transactions related to the production facility, including contracts and/or agreements for services performed or received that relate to the production facility;
 - 5. all permittee records, including training, education, discipline, etc.;
- 6. soil amendment, fertilizers, pesticides, or other crop production aids applied to the growing medium or plants or used in the process of growing medical marijuana;
 - 7. production records, including:
- a. planting, harvest and curing, weighing, destruction of medical marijuana, creating batches of products, and packaging and labeling; and
 - b. disposal of medical marijuana, products and waste materials associated with production.
- 8. records of each batch of medical marijuana concentrate or products made, including, at a minimum, the usable medical marijuana or trim, leaves, and other plant matter used (including the total weight of the base product used), any solvents or other compounds utilized, and the product type and the total weight of the end product produced;
 - 9. transportation records;
 - 10. inventory records;
- 11. records of all samples sent to an independent testing lab and/or the department's lab and the quality assurance test results;
 - 12. all samples provided to anyone or any entity for any purpose; and
- 13. records of any theft, loss or other unaccountability of any medical marijuana seedlings, clones, plants, trim or other plant material, extracts, products, or other items containing medical marijuana.
- E. The records required by this section shall include the following:
 - 1. the amount of plants being grown at the production facility on a daily basis;
- 2. the quantity and form of medical marijuana and product maintained at the production facility on a daily basis;
 - 3. the date of each sale, transporting or disposing of any product;
- 4. the name, address and registration number of the dispensary facility to which the product was sold;
 - 5. the item number, product name (description), and quantity of products registered by the

department and sold or otherwise distributed to the dispensary;

- 6. the name of the dispensary facility and dispensary employee who took custody of the product;
- 7. the price charged and the amount received for the products from the dispensary;
- 8. name of production facility employee(s) transporting the product; and
- 9. if the distribution was for a purpose other than sale, the reason for the distribution.
- F. A record of all approved products that have been distributed shall be filed electronically with the department, utilizing a transmission format acceptable to the department, not later than 24 hours after the product was transported to a dispensary or disposed of by the production facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1303. Annual Report

A. The licensee shall prepare an annual report detailing all of the following:

- 1. the amount of gross medical marijuana and product produced by the licensee during each calendar year;
- 2. the details of all production costs including but not limited to seed, fertilizer, labor, advisory services, construction, and irrigation;
- 3. the details of any items or services for which the licensee subcontracted and the costs of each subcontractor directly or indirectly working for the contractor;
 - 4. the amount of products produced resulting from the medical marijuana grown;
- 5. the amounts paid each year to the licensee related to the licensee's production of medical marijuana and product; and
- 6. the amount of medical marijuana and product distributed to each pharmacy licensed to dispense medical marijuana in this state during each calendar year.
- B. The report shall cover the previous calendar year and be received by the department no later than January 15th.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 15. Production Facility

§1501. Production Facility and Areas

A. The production facility shall be compartmentalized based on function, and access shall be restricted between areas or compartments. The licensee shall develop, establish, maintain and comply with its written system of internal controls approved by the department regarding best practices for the secure and proper production of medical marijuana or products. These practices shall include, but not be limited to, policies and procedures that:

- 1. restrict movement between production areas or compartments;
- 2. ensure that only those personnel necessary for a production function have access to that area or compartment of the production facility;
- 3. require pocket-less clothing for all production facility employees working in an area containing medical marijuana or products;
 - 4. document the chain of custody of all medical marijuana or products;
- 5. require the storage of all medical marijuana or products in the process of production, manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion, theft or loss;
- 6. make all medical marijuana or products accessible only to the minimum number of specifically authorized employees essential for efficient operation;
- 7. require the return of all medical marijuana or products to their designated, secure locations immediately after completion of the process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the licensee shall securely lock the medical marijuana or products, or tanks, vessels, bins, or bulk containers containing any such materials inside a processing area or compartment that affords adequate security;
- 8. address mandatory and voluntary recalls of medical marijuana or products in a manner that adequately deals with recalls due to any action initiated at the request of the department and any voluntary action by the licensee to remove defective or potentially defective products from the market, or any action undertaken to promote public health and safety by replacing existing medical marijuana or products with improved products or packaging; and

- 9. prepare for, protect against, and handle any crises that affect the security or operation of the production facility in the event of fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
- B. Each production area or compartment within a production facility shall:
- 1. develop, establish, maintain and comply with policies and procedures contained in the written system of internal controls for each production area, as approved by the department;
 - 2. be maintained free of debris and kept clean and orderly;
- 3. be kept free from infestation by insects, rodents, birds or vermin of any kind, including the use of adequate screening or other protection against the entry of pests;
 - 4. implement and maintain biosecurity measures at all times;
- 5. allow access on all sides of each medical marijuana plant group to allow for unobstructed movement of personnel and materials, for plant observation and for inventory of each plant group;
- 6. maintain production and storage areas, including areas where equipment or utensils are cleaned, with adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions for the production of medical marijuana or products;
- 7. prevent the growth of undesirable microorganisms that can occur on medical marijuana plants by holding the plants in a manner that prevents such growth;
- 8. move medical marijuana or products that are outdated, damaged, deteriorated, misbranded or adulterated, or whose containers or packaging have been opened or breached, into a separate storage room, in a quarantined area, until the medical marijuana or products are destroyed pursuant to Chapter 27;
- 9. ensure that the oldest stock of medical marijuana or products is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;
 - 10. not produce any products other than medical marijuana or products;
- 11. maintain a record of all crop inputs for at least five years at the production facility. The record shall include the following (see Section 1507 for additional requirements for the use of pesticides):
 - a. the date of crop input application;
 - b. the name and title of the individual making the application;
 - c. the product that was applied;
- d. the section, including the square footage, that received the application (by group designation or number);
 - e. the amount of product that was applied; and
 - f. a copy of the label of the product applied.
- 12. Hold and store toxic cleaning compounds, sanitizing agents, solvents used in the production of any products, and pesticide chemicals in a manner that protects against contamination of medical marijuana or products, and in a manner that is in accordance with any applicable local, State or federal law, rule, regulation or ordinance;
- 13. ensure that the water supply to the production areas or compartments is sufficient for the operations intended and is derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable and adequate supply of water to meet the production facility's needs (see Chapter 27); and
 - 14. ensure that plumbing complies with all applicable plumbing codes.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1503. Age Restrictions

A. No persons under the age of 21 shall:

- 1. enter any restricted area of the facility; or
- 2. be licensed or permitted by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1505. Restricted Areas

- A. Only permittees as provided in these rules, or in the internal controls may enter restricted areas. The licensee shall implement procedures to ensure compliance with this Section.
- B. All non-permitted employees and visitors shall be accompanied by an authorized permittee.
- C. All access to the production area of the facility, any area where product is located, and the vault shall be documented on a log maintained by the licensee. The logs shall contain entries with the following information:

- 1. the identity of each person entering the restricted area;
- 2. for non-permitted employees and visitors authorized by the department, the reason each person entered the restricted area:
 - 3. the date and time each person enters and exits the restricted area;
 - 4. a description of any unusual events occurring in the restricted area; and
 - 5. such other information required in the internal controls.
- D. The logs shall be made available to the department upon request.
- E. Only transparent trash bags shall be utilized in restricted areas.
- F. All authorized persons working in any restricted area when product is present shall wear clothing without any pockets or other compartments, unless otherwise authorized by the department.
- G. Employees shall not bring purses, handbags, briefcases, bags or any other similar item into the restricted area.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1507. Pesticide Usage on Medical Marijuana Plants

- A. Only pesticides approved by the department may be applied by the licensee to the medical marijuana plant. The department's approved pesticide list shall be published in the potpourri section of the Louisiana Register and on the department's website. Updates to the approved list shall be posted in the same manner.
- B. All pesticide products shall be registered with the department, including those products classified by the United States Environmental Protection Agency as 25(b) "minimum risk" products.
- C. No application of pesticides shall be made after the budding/flowering of the cannabis plant.
- D. All permittees applying pesticides shall adhere fully to product label requirements and shall employ all personal protective equipment prescribed by the label.
- E. A record of all pesticide applications shall be maintained at the production facility for at least five years and shall be made available to the department. The application record shall include the following information:
 - 1. owner/operator name, address, and license number;
 - 2. certified applicator, name, address and certification number;
 - 3. product/brand name;
 - 4. LDAF product registration number (if applicable);
 - 5. application date;
 - 6. crop/type of application;
 - 7. location of application;
 - 8. size of area treated acres, square feet, or minutes of spraying;
 - 9. rate of application;
 - 10. total amount of pesticide product (concentrate) applied; and
 - 11. applicator name (working under the supervision of a certified applicator).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 17. Surveillance and Security

§ 1701. Required Surveillance Equipment

- A. The licensee shall install a surveillance system on the entire premises which meets or exceeds specifications established by the department and provide access to the department at all times.
- B. Cameras, as approved by the department, shall monitor in detail, from various vantage points, the following:
- 1. the entire premises to include all areas within and outside the production facility excluding restrooms and private offices where product is not located;
 - 2. the movement of medical marijuana and product on the premises;
 - 3. the entrance and exits to the production facility;
 - 4. inside of the vault area and restricted areas; and
 - 5. such other areas as designated by the department.
- C. All cameras shall be equipped with lenses of sufficient magnification to allow the operator to clearly distinguish product identifiers and ID tags.
- D. All date and time generators shall be based on a synchronized, central or master clock, recorded and visible on any monitor when recorded.

- E. The surveillance system and power wiring shall be tamper resistant.
- F. The system shall be supplemented with a back-up gas or diesel generator power source which is automatically engaged in case of a power outage and capable of returning to full power within 7 to 10 seconds.
- G. The system shall have an additional uninterrupted power supply system so that time and date generators remain active and accurate.
- H. Video switchers shall be capable of both manual and automatic sequential switching for the appropriate cameras.
- I. Recorders, as approved by the department, shall be capable of producing high quality first generation pictures and recording with high speed scanning and flicker-less playback capabilities in real time, or other medium approved by the department. Such recorders must possess time and date insertion capabilities for recording what is being viewed by any camera in the system.
- J. The system shall have audio capability in certain areas as required by the department.
- K. The facility shall have adequate lighting in all areas where camera coverage is required. The lighting shall be of sufficient intensity to produce clear recording and still picture production, and correct color correction where color camera recording is required. The video must demonstrate a clear picture, in existing light under normal operating conditions.
- L. Adequate back-up replacement equipment shall be maintained on the premises to ensure prompt replacement in the event of failure.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1703. Surveillance System Plans

A. The licensee shall submit to the department for approval a surveillance system plan prior to the commencement of operations. The surveillance system plan shall include a floor plan indicating the placement of all surveillance equipment and a detailed description of the surveillance system and its equipment. The plan shall also include a detailed description of the configuration of the monitoring equipment. The plan may include other information that evidences compliance with this Subsection by the licensee including, but not limited to, a configuration detailing the location of all production equipment.

B. Any changes to the surveillance system shall require prior approval by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§1705. Surveillance Personnel Employment Provisions

A. The licensee shall designate at a minimum one permittee responsible in the use, monitoring, and administration of the surveillance system. This employee is prohibited from having duties in the production process.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1707. Storage and Retrieval

A. All video recordings shall be retained for at least thirty days, unless otherwise provided for in these rules or required by the department.

B. Any video recording of illegal or suspected illegal activity shall, upon completion of the recording, be duplicated and the copy shall be preserved until the department notifies the licensee otherwise.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1709. Security Plan Requirements

A. The licensee shall submit to the department a security plan prior to commencement of operations to include, at a minimum, the following:

- 1. a detailed description of all security solutions for the facility and transportation of product to and from the facility to be implemented by the licensee;
 - 2. security training requirements and procedures; and
- 3. other information required by the department that evidences compliance with the Act and these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

§1711. Security Alarm System

A. The licensee shall install and maintain in good working order a professionally installed and monitored security alarm system as approved by the department. This system shall provide intrusion and fire detection for all buildings and areas within the premises. The alarm system shall be able to operate in the event of a power outage.

- B. The security system shall be able to summon law enforcement personnel during, or as a result of, an alarm condition. The security system must be equipped with the following components or features:
 - 1. motion detectors;
 - 2. a duress alarm
 - 3. a panic alarm;
 - 4. a holdup alarm;
 - 5. an automatic voice dialer; and
- 6. a failure alert system that provides an audio, text, or visual notification of any failure in the alarm system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1713. Security of Premises and Production Facility

A. The licensee shall:

- 1. erect fencing or other barriers as approved by the department of adequate type and height to prevent unauthorized persons from entering the premises. Ingress and egress to the premises shall be controlled by use of a gate or other approved device;
- 2. install locks or locking mechanisms of adequate type to securely lock and protect the premises and production facility from unauthorized entry at all times. The licensee shall safeguard all keys, combinations, passwords, and other security sensitive measures in a manner that prevents accessibility from unauthorized persons;
- 3. install exterior lighting sufficient to illuminate all areas of the premises to facilitate surveillance and deter unauthorized activity;
- 4. load the medical marijuana or product for transportation to dispensaries in a locked, secured area within the perimeter protected by fence or other approved barrier. This area shall be considered a restricted area obscured from public view; and
- 5. post a sign at all entryways into the premises and production facility which shall be a minimum of twelve inches in height and twelve inches in width which shall state: "DO NOT ENTER RESTRICTED ACCESS AREA ACCESS LIMITED TO AUTHORIZED PERSONNEL ONLY" or other wording approved by the department. The lettering shall be no smaller than one-half inch in height.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1715. Security Log/Notification/Reports

A. The licensee shall maintain a security log of all visitors to the production facility and unusual incidents. Each incident without regard to materiality shall be entered in the log containing, at a minimum, the following information:

- 1. the assignment number;
- 2. the date;
- 3. the time;
- 4. the description of the incident;
- 5. the person involved in the incident; and
- 6. the permittee assigned.
- B. The security logs required by this Section shall be retained and stored by month and year.
- C. The licensee or its employees shall provide immediate notification to the department of knowledge of any theft of medical marijuana or product, or violation of the Act, or these rules.
- D. The licensee shall compile a written report to be promptly filed with the department on any incident in which the licensee has knowledge of, or reasonable suspicion of a violation of the Act, these rules, or its system of internal controls has occurred.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 19. Inventory

§ 1901. Medical Marijuana Inventory; Inventory Tracking System Required

- A. The licensee shall provide a reliable and ongoing supply of medical marijuana as required by Louisiana R.S. 40:1046(C)(2)(D).
- B. The licensee shall establish inventory controls and procedures for conducting inventory reviews and comprehensive inventories of plant material, medical marijuana, and product to prevent and detect any diversion, theft, or loss in a timely manner.
- C. The licensee shall maintain a record of its inventory of all medical marijuana waste, product waste, and plant material waste for disposal.
- D. The licensee shall be required to use the LMMTS as the primary inventory tracking system of record. The system and all use thereof shall conform to the requirements set forth in Section 1903 and Chapter 19.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1903. General Inventory Tracking System Use

- A. All inventory tracking activities by the licensee shall be tracked through use of the LMMTS. The licensee shall reconcile all on-premises and in-transit medical marijuana and product inventories each day in the LMMTS at the close of business.
- B. Common Weights and Measures.
- 1. the licensee shall utilize a standard of measurement that is supported by the LMMTS to track all medical marijuana and product;
- 2. a scale used to weigh such product prior to entry into the LMMTS shall be tested and approved in accordance with R.S 3:4601, et. seq.
- C. LMMTS Administrator and User Accounts Security and Record
- 1. the licensee is accountable for all actions permittees take while logged into the LMMTS or otherwise conducting medical marijuana or product inventory tracking activities; and
- 2. Each individual user is also accountable for all of his or her actions while logged into the LMMTS or otherwise conducting medical marijuana or product inventory tracking activities, and must maintain compliance with all relevant laws and rules.
- D. Secondary Software Systems Allowed
- 1. nothing in this rule prohibits the licensee from using separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems; and
- 2. a licensee shall ensure that all relevant LMMTS data is accurately transferred to and from the LMMTS for the purpose of reconciliations with any secondary systems.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1905. Inventory Tracking System Access

- A. The licensee shall have at least one individual permittee who is a LMMTS administrator. The licensee may also designate additional permittees to obtain LMMTS administrator accounts in accordance with internal controls.
- B. In order to obtain a LMMTS administrator account, a person must attend and successfully complete all required LMMTS training. The department may also require additional ongoing, continuing education for an individual to retain his or her LMMTS administrator account.
- C. The licensee may designate permittees who hold a valid employee permit as a LMMTS User. The licensee shall ensure that all permittees who are granted LMMTS user account access for the purposes of conducting inventory tracking functions in the system are trained by LMMTS administrators in the proper and lawful use of LMMTS.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1907. ID Tags Required

- A. The licensee shall be responsible to ensure its inventories are properly tagged where the LMMTS requires ID tag use. The licensee must ensure it has an adequate supply of ID tags to properly identify medical marijuana and product as required by the LMMTS.
- B. The licensee is responsible for the cost of all ID tags and any associated fees as approved by the

department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1909. Conduct While Using Inventory Tracking System

A. The licensee and its designated LMMTS administrators and LMMTS users shall enter data into the LMMTS that fully and transparently accounts for all inventory tracking activities. Both the licensee and the permittees using the LMMTS are responsible for the accuracy of all information entered into the LMMTS. Any misstatements or omissions may be considered a violation of these rules.

- B. Individuals entering data into the LMMTS shall only use that individual's LMMTS account.
- C. If at any time the licensee loses access to the LMMTS for any reason, the licensee shall keep and maintain comprehensive records detailing all medical marijuana and medical marijuana-infused product tracking inventory activities that were conducted during the loss of access. See Section 1301 Reporting & Record Keeping. Once access is restored, all medical marijuana and product inventory tracking activities that occurred during the loss of access shall be entered into the LMMTS. The licensee must document when access to the system was lost and when it was restored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 1911. System Notifications

A. The licensee shall monitor all compliance notifications from the LMMTS. The licensee shall resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the LMMTS until the licensee resolves the compliance issues detailed in the notification.

B. The licensee shall take appropriate action in response to informational notifications received through the LMMTS, including but not limited to notifications related to ID billing, enforcement alerts, and other pertinent information.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 21. Quality Control/ Assurance Program

§ 2101. Quality Control

A. The licensee shall develop and implement a written quality assurance program for determining necessary storage conditions and shelf life for both medical marijuana concentrates and products.

- 1. the quality assurance program shall include procedures to be followed if the mandated testing described in Chapter 23 indicates contamination or non-homogenous products.
- 2. any area within the production facility where medical marijuana will be produced into an edible form shall comply with the Louisiana State Food, Drug & Cosmetic Law (R.S. 40:601) et. seq.
- 3. no products requiring refrigeration or hot-holding shall be manufactured at a production facility for sale or distribution to a dispensary due to the potential for food-borne illness.
- B. the licensee shall develop and follow written procedures determining storage conditions and establishing shelf life for each product type such that:
 - 1. samples are collected in a manner that provides analytically sound and representative samples;
- 2. sample size and test intervals are based on statistical criteria for each attribute examined to ensure valid stability estimates;
 - 3. samples are labeled with the unique batch identifier;
- 4. samples are tested at a minimum for both potency and microbiological contamination against the limits set forth in Chapter 23;
 - 5. storage conditions do not involve refrigeration, heating, or specialized ventilation systems;
- 6. the same container-closure system in which the product is dispensed at point of sale is used during the shelf life testing; and
- 7. the documentation supporting required storage conditions and shelf life determinations are retained for at least five years.
- C. The licensee shall develop and follow written procedures for responding to mandated testing results indicating contamination of any kind including:
 - 1. documenting the destruction of the contaminated medical marijuana or product as described in

Chapter 14;

- 2. determining the source of the contamination;
- 3. documentation of the elimination of the source of contamination; and
- 4. retention of all documents involved in the incident for at least five years.
- D. The licensee shall bear any and all costs incurred in determining the shelf life, the storage conditions and the activities necessary to respond to findings of contamination or non-homogeneity.
- E. If shelf life studies have not been completed, the licensee may assign a tentative expiration date based on any available stability information. The licensee shall concurrently conduct shelf life studies to determine the actual product expiration date.
- F. After the licensee verifies the tentative expiration date, or determines the appropriate expiration date, the licensee shall include that expiration date on each batch of product.
- G. Shelf life testing shall be repeated if the production facility's process or the product's chemical composition is changed.
- H. The licensee shall retain a reserve sample that represents each batch of medical marijuana and store it under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the product is dispensed, or in one that has similar characteristics. The reserve sample must consist of at least twice the quantity necessary to perform all the required tests.
- I. The licensee shall retain the reserve for at least one year following the batch's expiration date. At the end of this time or later, the reserve shall be destroyed following the procedures set forth in Chapter 27.
- J. If the department deems that public health may be at risk, the department may require the licensee to release any reserve sample to be tested at any time for any analysis it deems necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 23. Laboratory Approval and Testing § 2301. Laboratory Approval

- A. No laboratory shall handle, test or analyze medical marijuana or product unless approved by the department in accordance with this Section. A list of approved laboratories will be made available by the department on its website.
- B. No laboratory shall be approved to handle, test or analyze medical marijuana or product unless the laboratory:
- 1. is accredited to International Organization for Standards (ISO) 17025 standards by a private laboratory accrediting organization for the analyses being conducted. Additionally, the laboratory must provide the department with a copy of the most recent inspection report granting accreditation and every inspection report thereafter. Failure to maintain accreditation to the ISO 17025 will result in the revocation of the department's approval for medical marijuana or product testing;
- 2. is independent from all other persons involved in the medical marijuana industry in Louisiana, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial, management or other interest in a licensed dispensary pharmacy, dispensary facility, licensee, production facility, certifying physician or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of medical marijuana or product;
- 3. employs, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification;
- 4. maintains a written and documented system to evaluate and document the laboratory's and each employee's competency in performing authorized required tests. Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls);
- 5. submits to an on-site facility review by the department or its designated agent prior to the granting of departmental approval. Facilities will continue to be subject to inspection at any time subsequent to approval; and
- 6. accepts the requirement that laboratories utilize the department's approved computerized inventory tracking system (LMMTS) to post results of sample analyses for review by the department and licensee. The laboratory is responsible for any costs associated with their access to the computerized inventory tracking system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2303. Laboratory Testing

- A. Each batch of medical marijuana concentrate and product shall be made available by the licensee for an employee of an approved laboratory or otherwise independent sample collector to select a random and representative sample of sufficient volume to conduct required analyses, which shall be tested by an approved laboratory.
- 1. medical marijuana concentrate shall not be used to produce any form of product until it has passed all analysis limits for:
 - a. active ingredient analysis for characterization of potency;
- b. pesticide active ingredients, including but not limited to, the most recent list of targeted pesticides published by the department;
 - c. residual solvents;
 - d. heavy metals; and
 - e. mycotoxins.
- 2. product shall not be released for delivery to a dispensary for sale or consumption until it has passed all analysis limits for:
 - a. microbiological contaminants;
 - b. active ingredient analysis for accuracy of potency; and
 - c. homogeneity.
- B. The department may select a random sample at any point in the process for the purpose of analysis for anything the department deems necessary.
- C. Samples shall be secured in a manner approved by the department at all times when not in immediate use for the analyses being conducted.
- D. Testing Specifications and Limits
- 1. every sample shall undergo a microbiological test. For purposes of the microbiological test, a sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products in colony forming units per gram (CFU/g) as follows:
 - a. Total yeast and mold: <10,000 CFU/g; and
 - b. E. coli (pathogenic strains) and Salmonella spp. <1 CFU/g
- 2. every sample shall undergo a mycotoxin test. For purposes of the mycotoxin test, a sample shall be deemed to have passed if it meets the following standards:
 - a. Aflatoxin B1 <20 ppb;
 - b. Aflatoxin B2 <20 ppb;
 - c. Aflatoxin G1 <20 ppb;
 - d. Aflatoxin G2 <20 ppb; and
 - e. Ochratoxin <20 ppb.
- 3. every sample shall undergo a pesticide chemical residue test. For purposes of the pesticide chemical residue test, a sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in subpart C of USEPA's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food [40 CFR 180 (2014)];
- 4. every sample shall undergo a residue solvent test. For purposes of the residue solvent test, a sample shall be deemed to have passed if the following solvents are below the limits listed below:
 - a. Butanes <800 ppm;
 - b. Heptanes <500 ppm;
 - c. Benzene < 1 ppm;
 - d. Toluene <1 ppm;
 - e. Hexanes < 10 ppm;
 - f. Total Xylenes <1 ppm; and
 - g. Ethanol <5,000 ppm.
- 5. every sample shall undergo a heavy metal test. For the purpose of the heavy metal test, a sample shall be deemed to have passed if it meets the following standards:
 - a. Arsenic <10ppm;
 - b. Cadmium <4.1ppm;
 - c. Lead <10ppm; and
 - d. Mercury <2.0ppm.
- 6. every sample shall undergo an active ingredient analysis or potency analysis. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. For product samples, the

potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing;

- a. requires analysis of the following actives:
 - i. THC (tetrahydrocannabinol);
 - ii. THCA tetrahydrocannabinol acid;
 - iii. CBD cannabidiol; and
 - iv. CBDA cannadidiolic acid.
- b. for product analysis, a variance of no more than plus or minus fifteen percent is allowed from the labeled amount of active ingredient. Thus a product labeled as containing 10 milligrams THC must contain no less than 8.50 milligrams THC and no more than 11.50 milligrams THC.
- 7. every sample shall undergo a homogeneity test. A product will be considered not homogenous if ten percent of the product contains more than twenty percent of the total active ingredient.
- E. If a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with Chapter 27.
- F. If a medical marijuana concentrate sample fails residual solvents testing, then, with prior approval of the department, the product may be subjected to an appropriate remedy (ex. vacuum drying), reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with Chapter 27. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.
- G. If a product fails the microbiological testing the entire batch from which the sample was taken shall be disposed of in accordance with Chapter 27.
- H. If a product fails the potency or homogeneity testing then, with prior approval of the department, the product can be re-sized and tested again. The re-formulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed of in accordance with Chapter 27.
- I. The laboratory shall file with the department and licensee an electronic copy of each laboratory test result for any sample that does not pass a test. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available at the department's request.
- J. The laboratory shall dispose of any remaining medical marijuana or product samples no sooner than 60 days following the completion of any testing. Disposal will be performed in accordance with Chapter 27.
- K. The licensee shall provide to the dispensary the laboratory test results for each batch of product purchased. AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 25. Transportation

§ 2501. Transportation

- A. The licensee or its authorized permittee shall only be allowed to transport medical marijuana or product to the following locations:
 - 1. from its production facility to dispensaries;
 - 2. from its production facility to a laboratory for testing or research; and
- 3. when a specific non-routine transport request from the licensee is approved in writing by the department.
- B. The licensee or its authorized permittee shall:
- 1. have a valid Louisiana driver's license and be insured above the legal requirements in Louisiana; and
 - 2. be capable of securing (locking) medical marijuana and product items during transportation.
- C. Prior to transporting medical marijuana or product, a licensee shall generate a transport manifest, utilizing LMMTS, that accompanies every transport of medical marijuana or product. Such manifests shall contain the following information:
- 1. the name, contact information of a licensee authorized representative, licensed premises address, and the authorized permittee transporting the medical marijuana or product;
- 2. the name, contact information, and premises address of the dispensary or laboratory receiving the delivery;
- 3. medical marijuana or product name and quantities (by weight or unit) of each item contained in each transport, along with the requisite unique identification number for every item;

- 4. the date of transport and time of departure;
- 5. arrival date and estimated time of arrival;
- 6. delivery vehicle make and model and license plate number; and
- 7. name and signature of the authorized permittee accompanying the transport.
- D. Only the licensee or its authorized permittee may transport medical marijuana or product from the production facility to multiple dispensaries in a single trip in the event that each transport manifest correctly reflects specific inventory in transit.
- E. Transport manifests shall be available for viewing through LMMTS, to the dispensary, laboratory for testing, and the department before the close of business the day prior to transport.
- F. The licensee or its authorized employee shall provide a copy of the transport manifest to law enforcement if requested to do so while in transit.
- G. An authorized employee of the dispensary or approved laboratory for testing shall verify that the medical marijuana or product are received as listed in the transport manifest by:
- 1. verifying and documenting the type and quantity of the transported medical marijuana or product against the transport manifest; and
 - 2. returning a copy of the signed transport manifest to the production facility.
- H. A receiving dispensary or approved laboratory for testing shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in LMMTS and in any relevant business records.
- I. The licensee shall ensure that all medical marijuana, plant material, or product transported on public roadways is:
- 1. only transported in a locked, safe and secure storage compartment that is part of the motor vehicle transporting the medical marijuana or product, or in a locked storage container that has a separate key or combination pad;
 - 2. transported so it is not visible or recognizable from outside the vehicle; and
- 3. transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical marijuana or bears the name or logo of the licensee.
- J. Authorized permittees who are transporting medical marijuana or product on public roadways shall:
 - 1. travel directly to the dispensary or laboratory testing facility; and
 - 2. document refueling and all other stops in transit, including:
 - a. the reason for the stop;
 - b. the duration of the stop;
 - c. the location of the stop; and
 - d. all activities of employees exiting the vehicle.
- K. Every authorized permittee shall have access to a secure form of communication with the licensee and the ability to contact law enforcement through the 911 emergency systems at all times that the motor vehicle contains medical marijuana or product. If an emergency requires stopping the vehicle, the employee shall report the emergency immediately to law enforcement through the 911 emergency systems and the licensee, which shall immediately notify the department. The employee shall also complete an incident report form provided by the department.
- L. The licensee shall ensure that all delivery times and routes are randomized.
- M. Under no circumstance shall any person other than a designated permittee have actual physical control of the motor vehicle that is transporting the medical marijuana or product.
- N. The licensee shall staff all transport motor vehicles with a minimum of two employees. At least one employee must remain with the motor vehicle at all times that the motor vehicle contains medical marijuana or product.
- O. A permittee shall carry his permittee identification card at all times when transporting or delivering medical marijuana or product and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.
- P. The licensee shall ensure that a vehicle containing medical marijuana or product in transit is not left unattended.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 27. Sanitation and Disposal § 2701. Production Facility Sanitation

- A. The production facility shall be designed, constructed and operated in such a manner that:
 - 1. all buildings, fixtures and other facilities are maintained in a sanitary condition;
 - 2. floors, walls and ceilings are adequately cleaned;
- 3. litter and waste are properly removed and all waste disposal operating systems are maintained in such a manner that they do not constitute a source of contamination;
- 4. rubbish is disposed of so as to minimize the development of odor and minimize the potential for waste becoming an attractant, harborage or breeding place for pests;
- 5. all activities and operations involved in the receiving, inspecting, transporting, segregating, preparing, production, packaging and storing of medical marijuana or products shall be conducted in accordance with adequate sanitation principles;
- 6. all contact surfaces, including utensils and equipment used for the preparation of medical marijuana or products, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be designed and shall be of such material and workmanship as to be adequately cleanable, and shall be properly maintained;
- 7. only sanitizing agents registered with the department pursuant to the Act shall be used in the production facility, and they shall be used in accordance with labeled instructions;
- 8. the licensee shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and in good repair; and
- 9. hand-washing facilities shall be adequate and conveniently located in the production facility, and furnished with running water at a suitable temperature. They must provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices.
- B. Permittees and authorized visitors to the production facility shall follow hygienic practices while present at the facility, including but not limited to the following:
 - 1. maintaining adequate personal cleanliness;
- 2. washing hands thoroughly in adequate hand-washing areas before starting work and at any other time when hands may have become soiled or contaminated; and
- 3. permittees and authorized visitors who, by medical examination or supervisory observation, are shown to have, or appear to have, an illness, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with medical marijuana or products, shall be excluded from any operations that may be expected to result in microbial contamination until the condition is corrected.
- C. Prior to commencing operation, the production facility in its entirety will be inspected by State Fire Marshall, Department of Health and Hospitals, and any other entity required by law.
- D. The authorized health inspectors may at any time enter any building, room, enclosure, or premises occupied or used, or suspected of being occupied or used, in production facility activities for the purpose of inspecting the premises and all utensils, fixtures, furniture, and machinery used in the production facility

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2703. Potable Water Supply

- A. Potable water supply lines shall not be connected to process water lines, chemical lines or equipment, unless proper backflow protection is installed.
- B. Water service lines that connect a production facility to a public water supply shall include either a reduced pressure principle backflow preventer or a fixed proper air gap, in accordance with the Part XIV (Plumbing) of the Sanitary Code, State of Louisiana.
- C. Water service lines that connect a production facility to a potable water supply other than a community public water supply shall include either a reduced pressure principle backflow preventer or a fixed proper air gap, in accordance with the Part XIV (Plumbing) of the Sanitary Code, State of Louisiana
- D. Installation, maintenance and inspection of backflow prevention devices shall be carried out in accordance with the requirements of Part XIV (Plumbing) of the Sanitary Code, State of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2705. Disposal of Waste

A. Disposal of waste rendered unusable shall follow the methods set forth in this section. For the purpose of this section "waste" shall include:

- 1. plant material waste;
- 2. medical marijuana waste; and
- 3. product waste.
- B. The licensee shall dispose of any waste as provided for in this section, and maintain a written record of disposal that includes:
 - 1. the date returned;
 - 2. the quantity returned; and
 - 3. the type and batch number returned.
- C. Waste must be stored, secured, locked and managed in accordance with these rules and as submitted and approved in the licensee's written system of internal controls.
- D. The licensee shall provide the department, through the LMMTS, a minimum of seven days notice prior to rendering the product unusable and disposing of the product.
- E. The allowable method to render waste unusable is by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50% non-medical marijuana waste by volume. Other methods to render waste unusable must be approved by the department before implementation. Material used to grind with the waste may include:
 - 1. food waste;
 - 2. yard waste;
 - 3. vegetable-based grease or oils;
 - 4. paper waste;
 - 5. cardboard waste;
 - 6. plastic waste;
 - 7. soil; or
- 8. other wastes approved by the department (e.g., non-recyclable plastic, broken glass, leather, agricultural material, biodegradable products, paper, clean wood, fruits, vegetables, and plant matter).
- F. Waste shall be rendered unusable prior to leaving a production facility. Waste rendered unusable following the methods described in this Section shall be disposed of by delivery to an approved solid waste facility for final disposition. Examples of acceptable permitted solid waste facilities include:
 - 1. compost, anaerobic digester;
 - 2. landfill, incinerator, or other facility with approval of the jurisdictional health department; or
 - 3. a waste-to-energy facility
- G. Inventory Tracking Requirements:
- 1. in addition to all other tracking requirements set forth in these rules, the licensee shall utilize the LMMTS to ensure its post-harvest waste materials are identified, weighed and tracked while on the licensed premises until disposed of.
- 2. all waste shall be weighed, recorded and entered into LMMTS prior to mixing and disposal. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance.
- 3. all waste shall be weighed before leaving the production facility. A scale used to weigh waste prior to entry into the LMMTS shall be tested and approved in accordance with R.S 3:4601, et. seq.
- 4. the licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of waste.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 29. Labeling

§ 2901. Labeling Requirements

- A. Each product shall be labeled by the licensee prior to sale to a dispensary. Each label shall be securely affixed to the package and shall include:
- 1. the batch number(s) assigned by the licensee to the marijuana plant(s) from which the medical marijuana used in the product was harvested;
- 2. a complete list of solvents, chemicals and pesticides used in the creation of any medical marijuana concentrate;
- 3. a complete list of all ingredients used to manufacture the product, which may include a list of any potential allergens contained within, or used in the manufacture of a product;
 - 4. the potency of the THC and CBD in the product, expressed in milligrams for each cannabinoid;
 - 5. the net weight, using a standard of measure compatible with the LMMTS, of the product prior to

its placement in the shipping container;

- 6. a product expiration date, upon which the product will no longer be fit for consumption, or a use-by date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a product, the licensee shall not alter that date or affix a new label with a later use-by or expiration date; and
- 7. a statement that the product has been tested for contaminants, that there were no adverse findings, and the date of testing.
- B. Labeling text on any product may not make any false or misleading statements regarding health or physical benefits to the consumer. Each label must include the following statements:
- 1. "Contains Medical Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF CHILDREN."
- 2. "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."
- 3. a statement that it is illegal for any person to possess or consume the contents of the package other than the qualifying patient.
- C. Labeling text required by this section to be placed on any product may be no smaller than 1/16 of an inch, must be printed in English and must be unobstructed and conspicuous.
- D. The following information is permissible on a label:
 - 1. the product's compatibility with dietary restrictions; and
 - 2. a nutritional fact panel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2903. Packaging Requirements

- A. The licensee shall ensure that every product being sent to a dispensary for sale to a qualified patient is placed within a child resistant, light resistant, tamper proof container prior to sale or transport to the dispensary.
- B. If it is not intended for the entire product to be used at a single time, the packaging must be resealable in a manner that maintains its child resistant effectiveness for multiple openings.
- C. A product may not be placed in packaging that specifically targets individuals under the age of 21. Any packaging must not:
- 1. bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;
 - 2. use the word "candy" or "candies";
- 3. use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; or
- 4. use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe that the product has been endorsed, manufactured, or used by any state, parish, municipality or any agent thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2905. Product Dosage Identification

A. Each product shall be marked, stamped or emprinted with the dosage, as approved by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

§ 2907. Advertising

- A. The licensee shall not advertise through any public medium, including but not limited to newspapers, television, radio, internet, or any other means designated to market its products to the general public. The licensee may market its products directly to the licensed dispensaries and to physicians through direct mail, brochures or other means directed solely to the licensed dispensaries and/or physicians and not available to the general public.
- B. Any advertisement permitted by Paragraph (A) shall not:
 - 1. make any deceptive, false, or misleading assertions or statements regarding any product; or
- 2. assert that its products are safe because they are regulated by the department. The licensee may state in advertisements that its products have been tested by an approved laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, LR 42:

Chapter 31. Enforcement

§3101. Enforcement

violated;

A. Whenever the department has any reason to believe that a violation of the Act or this Chapter or of any rule or regulation adopted pursuant to this Chapter has occurred, the department may present the alleged violations to a hearing officer for a determination.

- B. The department may impose civil penalties and/or suspend, revoke or place on probation any permitee or licensee for the commission of a violation of the Act of these rules. Civil penalties may be assessed, probation may be imposed, and permits and licenses may be suspended or revoked only upon a ruling of the hearing officer based on an adjudicatory hearing held in accordance with the Administrative Procedure Act.
 - 1. the department shall appoint a hearing officer to preside over all hearings.
- 2. the department shall notify the alleged violator of the hearing, by personal service or certified mail, at least thirty days prior to the date the hearing is held;
 - 3. the notice shall contain the following information:
 - a. a statement of the alleged violation;
 - b. the specific Section of the Act or these rules and regulations alleged to have been
 - c. the date, time, and place where the hearing will be held;
- d. a statement of the rights which will be accorded to the licensee or registered employee at the hearing; and
- e. a statement as to the possible penalties which may be imposed upon a finding by the hearing officer at the hearing that the alleged violator committed the alleged violation.
- 4. the alleged violator shall have the right to representation by legal counsel and the right to examine and cross-examine witnesses as in civil cases. The alleged violator shall have the right to compel the attendance of witnesses and the production of evidence upon depositing with the department the fees required for issuing subpoenas and subpoenas duces tecum in civil cases.
- C. Any person who violates any provision of the Act or this Chapter or any rule or regulation adopted pursuant thereto or any provision of a stop order, shall be subject to a civil penalty of not more than fifty thousand dollars for each act of violation and for each day of violation. Each day on which a violation occurs shall be a separate offense.
- D. The department may summarily suspend the licensee or a permit without a hearing, simultaneously with the institution of proceedings for a hearing, if the department finds that the public safety or welfare immediately requires this action. In the event that the department summarily suspends a licensee or a permit, a hearing shall be held within 30 days after the suspension has occurred. The suspended party may seek a continuance of the hearing, during which the suspension shall remain in effect. The proceeding shall be concluded without reasonable delay. If the department does not hold a hearing within 30 days after the date of the suspension, and the licensee or permitee has not requested a continuance, the license or permit shall be automatically reinstated.
- E. The department may require an individual permitee or the licensee against whom disciplinary action has been taken by the department to pay the reasonable costs incurred by the department for the hearing or proceedings, including its legal fees, court reporter, investigators, witness fees, and any such costs and fees incurred by the department. These costs and fees shall be paid no later than thirty days after the decision of the board becomes final. No license or permit shall be renewed or reinstated until such costs have been paid.
- F. The department may institute civil proceedings in the nineteenth district court to enforce the rulings of the hearing officer. The department may institute civil proceedings seeking injunctive relief to restrain and prevent violations of the provisions of this Part or of the rules and regulations adopted under the provisions of this Part in the nineteenth district court.
- G. As to every matter on which a hearing is held, the presiding hearing officer shall prepare a written findings of fact and conclusions of law, which shall contain, at a minimum, the record of the hearing, including all submissions, his finding of the facts that are pertinent to the decision, his conclusions of applicable law related to the decision, and his decision. The submission shall be in writing, shall be provided to all involved applicants, and shall be a public record, except for any submitted materials which are confidential pursuant to law.
- H. The hearing officer shall render his decision within thirty days after the hearing is conducted.
- I. All appeals from any decision of the hearing officer shall be filed in accordance with R.S. 49:955.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046

Family Impact Statement

The proposed Rule does not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

- (1) the stability of the family;
- (2) the authority and rights of persons regarding the education and supervision of their children;
- (3) the functioning of the family;
- (4) family earnings and family budget;
- (5) the behavior and personal responsibility of children;
- (6) the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule does not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

- (1) the effect on household income, assets, and financial security;
- (2) the effect on early childhood development and preschool through postsecondary education development;
- (3) the effect on employment and workforce development;
- (4) the effect on taxes and tax credits;
- (5) the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Statement

The proposed Rule will have no adverse impact on small businesses as defined in the Regulatory Flexibility Act.

Provider Impact Statement

The proposed Rule does not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

- (1) the effect on the staffing level requirements or qualifications required to provide the same level of service;
- (2) the total direct and indirect effect on the cost to the providers to provide the same level of service; or
- (3) the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, data, opinions and arguments regarding the proposed Rule. Written submissions must be directed to Tabitha Gray, Executive Counsel, Department of Agriculture & Forestry, 5825 Florida Blvd., Suite 2000, Baton Rouge, LA 70806 and must be received no later than 12:00 p.m. on January 4, 2017. No preamble is available.

Mike Strain, DVM Commissioner of Agriculture and Forestry