This is an amendment to 16.8.2 NMAC replacing and Section 56 and adding Sections 57, 58, 59, 60, 61, 62 and 63 effective 07/12/2022.

16.8.2.56 CANNABIS RESEARCH LABORATORY LICENSURE; GENERAL PROVISIONS:

A. License Types: The division may license three classes of research:

(1) Tier I: A cannabis research laboratory Tier I may produce cannabis to be ingested by human or animal subjects, or produce cannabis not meant for ingestion, for division approved clinical, agricultural, or market research studies; produce federally legal cannabis products; and may conduct division approved clinical, agricultural, or market research studies;

(2) Tier II: A cannabis research laboratory Tier II may produce cannabis not meant for ingestion, or purchase cannabis to be ingested by human or animal subjects, for division approved clinical, agricultural, or market research studies; and may conduct division approved clinical, agricultural, or market research studies

(3) Tier III: A cannabis research laboratory Tier III may not produce cannabis and may only purchase cannabis or cannabis products from licensed cannabis research laboratories Tier I and Tier II, as appropriate for approved clinical, agricultural, or market research studies; and may conduct clinical, agricultural, or market research studies.

B. A Tier II or Tier III cannabis research laboratory may purchase cannabis from another licensed cannabis establishment with approval from the cannabis control division only if such research relates to brand specific inquiries (e.g., including studies comparing similar products from different brands or conducting cultivar specific efficacy studies for certain conditions) where use of cannabis or cannabis products produced by a cannabis research laboratory is impossible.

C. Except as noted in subsection (B), a cannabis research laboratory license permits a licensee to produce, process, transport, transfer, sell and possess cannabis consistent with its license type for research and related purposes.

D. A cannabis research laboratory may also produce and distribute federally legal cannabis products as authorized by state and federal law pertaining to drug products.

E. A cannabis research laboratory will provide notice to the cannabis control division prior to commencing the production and distribution of any federally legal cannabis product, including evidence of federal authorizations.

F. All applications for licensure authorized pursuant to the Cannabis Regulation Act shall be made upon current forms prescribed by the division.

[16.8.2.56 NMAC – Rp 16.8.2.56 NMAC, 07/12/2022]

16.8.2.57 APPLICATION REQUIREMENTSFOR CANNABIS RESEARCH LABORATORY LICENSE:

A. An initial application or renewal for cannabis research laboratory licensure shall include the following:

(1) Business and controlling person(s) contact information, to include:

(a) legal business name, including DBA if applicable

(b) type of business entity;

(c) business mailing address;

(d) business telephone number;

(e) business email address;

(f) business physical address, if different;

(g) business web address, if applicable;

(h) business hours of operation;

(i) name and contact information for each controlling person;

(j) demographic data pursuant to the Cannabis Regulation Act; and

(k) license type sought (Tier I, Tier II, or Tier III);

(2) proof each controlling person is at least 21 years of age, which shall include identification issued by a federal or state government that includes the name, date of birth, and picture of

controlling person;

(3) if applicable, certification the applicant is in good standing with the New Mexico secretary of state;

(4) a list of other current or prior licensed cannabis businesses;

(5) a list of other names used by controlling person(s);

(6) name and contact information for the primary controlling person for the business or an authorized representative of the business if not a controlling person;

(7) criminal history screening documents as set forth in 16.8.2.9 NMAC and the Cannabis Regulation Act;

(8) a detailed description of any criminal convictions of the applicant and any controlling person, including the date of each conviction, dates of incarceration, probation or parole, if applicable, description of the offense, and statement of rehabilitation of each conviction;

(9) if applicable, a detailed research plan, including but not limited to the applicant's plan for recruiting research subjects, producing or acquiring cannabis, dispensing cannabis, plans for continuing research, and the forms of usable cannabis and cannabis-derived products to be examined;
if applicable, a detailed description of any private or public partnerships with higher education institutions, other cannabis research laboratories, or private business;

(10) if applicable, drug enforcement administration license to conduct research;

(11) if applicable, proof of prior approval by the New Mexico regulation and licensing department for the use of any compressed gas extraction equipment to be utilized by the manufacturer;

(12) if applicable, the applicant's DEA license or any conditional approval from the DEA to bulk manufacture cannabis for research, or the applicant's plan for seeking such licensure in the future;

(13) certification the applicant will not use dimethylsulfoxide (DMSO) in the production of cannabis derived products, and will not possess DMSO on the premises of the licensee;

(14) evidence that the applicant has obtained all necessary permits required for the production of edible and topical cannabis products from the New Mexico environment department and that such permits are valid at the time the license application is submitted

(15) certification the applicant will adhere to cannabis transport requirements pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, or division rules;

(16) certification the applicant will adhere to security requirements pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, or division rules;

(17) certification the applicant will adhere to applicable federal, state and local laws governing the protection of public health and the environment, including occupational health and safety, food safety, fire safety, environmental impacts, natural resource protections, air quality, solid and hazardous waste management, and wastewater discharge;

(18) certification the applicant has never been denied a license or had a license suspended or revoked by the division or any other state cannabis licensing authority or a detailed description of any administrative orders, civil judgements, denial or suspension of a cannabis license, revocation of a cannabis license, or sanctions for unlicensed cannabis activity by any state licensing authority, against the applicant, controlling person, or a business entity in which the applicant or controlling person was a controlling person within the three years immediately preceding the date of the application;

(19) certification the applicant will adhere to production and manufacturing requirements pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, or division rules, including creating and maintaining a cultivation plan, and cannabis waste procedures for cannabis products;

(20) certification the applicant will adhere to New Mexico department of agriculture (NMDA) pesticide registration, licensing, and use requirements to ensure a safe product and environment;

(21) applicant's social and economic equity plan to encourage economic and social diversity in employment, including race, ethnicity, gender, age, and residential status of licensee, controlling persons and employees of applicant and whether the applicant, controlling persons, employees or the locations where the cannabis products are produced are located in an underserved rural community, including tribal, acequia, land grantmerced, federally designated opportunity zone, or other rural historic communities;

(22) an attestation by a person authorized to act on behalf of the business of the following statement: Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true and accurate. I understand that a misrepresentation of fact or violation of these rules may result in denial of the license application or revocation of a license issued; and

(23) payment of any required fees as set forth in 16.8.11 NMAC.

B. Verification of information: The division may verify information contained in each application and accompanying documentation by:

(1) contacting the applicant or controlling person by telephone, mail, or electronic mail;

(2) conducting an on-site visit;

(3) requiring a face-to-face or virtual meeting and the production of additional documentation; or

(4) consulting with state or local governments.

C. Trade secrets: Any applicant submitting operating procedures and protocols to the division pursuant to the Lynn and Erin Compassionate Use Act, the Cannabis Regulation Act, or division rules, may claim such information as a trade secret or confidential by clearly identifying such information as "confidential" on the document at the time of submission. Any claim of confidentiality by an applicant must be based on the applicant's good faith belief that the information marked as confidential constitutes a trade secret as defined in the Uniform Trade Secrets Act, Sections 57-3A-1 to -7, NMSA 1978. In the event the division receives a request to inspect such documents, the division will notify the applicant or licensee, via the current email of record. If the division does not receive an injunction pursuant to the Uniform Trade Secrets Act within 10 days of the request to inspect, the division will make the documents marked confidential available for inspection as required pursuant to the Inspection of Public Records Act.

[16.8.2.57 NMAC – N, 07/12/2022]

16.8.2.58 SUBMITTAL OF APPLICATION FOR AMENDED CANNABIS RESEARCH LABORATORY LICENSE:

A. Application: A licensed research laboratory shall submit to the division an application form for an amended license, if applicable and obtain approval from the division, prior to implementing any of the following:

(1) material or substantial change of the size or location of the premises;

(2) change of licensee's legal or business name;

(3) change or modification in extraction type(s) or equipment;

(4) material or substantial change in water source;

(5) addition or elimination of a controlling person;

(6) material or substantial change to a license's security system; or

(7) material or substantial modification of the premise.

B. Amended license not required: Changes to standard operating policies and procedures may be made without providing notification to the division, provided that licensees shall maintain at each licensed premises a copy of all current and prior operating policies and procedures.

C. Requirements and processing of application for amended license: The application for amended license must comply with all requirements applicable to initial applications, except that the application shall be clearly designated as one for an amended license. The division shall approve or deny an application for amended license within 90 days of receiving a completed application. Denial of an application for amendment shall be pursuant to the Uniform Licensing Act.

D. Material or substantial change: Material or substantial changes requiring approval include:

(1) increase or decrease in the size of the premises, including the sale of property used for the cannabis establishment, the purchase of additional property for the use of the cannabis establishment, or a change in the location of the cannabis establishment;

(2) a modification in the licensee's access to the water source submitted with an application for initial or renewal licensure or a ten percent, or more, increase in the licensee's water usage;

(3) change to a license's security system, including relocation or security points or installation of a new security system; or

(4) modification of the premises to relocate cannabis activities.

[16.8.2.58 NMAC – N, 07/12/2022]

16.8.2.59 EXPEDITED APPROVAL PROCESS: The division shall create an early approval process for entities that are either registered or conditionally approved by the FDA to manufacture bulk cannabis for research or to research cannabis.

A. Any entity conditionally approved for or holding a valid DEA registration as enumerated below

may, within 60 days of the effective date, apply to the cannabis control division for expedited approval as follows:

(1) An entity that is registered with or conditionally approved by the DEA to manufacture bulk cannabis for research may seek early approval for a Tier I License; or

(2) An entity that is registered with or conditionally approved by the DEA to research cannabis may seek early approval for a Tier III license.

B. If an applicant meets all the relevant requirements of this section, the division shall issue the research laboratory license within 30 days of receiving a completed application.

[16.8.2.59 NMAC – N, 07/12/2022]

16.8.2.60 PREMISES DIAGRAM:

All licensees shall have a detailed diagram of the premises on hand at all times and made available for in person inspection by the Division or its agents upon request. This premises diagram shall conform to the requirements set forth in 16.8.2 NMAC.

[16.8.2.60 NMAC – N, 07/12/2022]

16.8.2.61 CANNABIS RESEARCH LABORATORY POLICIES AND PROCEDURES:

A. Minimum policy and procedure requirements: Licensees shall develop, implement, and maintain on the licensed premises, standard policies and procedures, which shall include the following:

(1) cannabis research criteria and procedures, which shall be consistent with the requirements of applicable state laws, including the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, division rules, and shall include at a minimum, the following topics:

(2) protocols for research;

(3) recordkeeping and chain of custody protocols for transportation of cannabis or cannabis product; and procedures for testing and destruction of cannabis or cannabis products;

(4) employee policies and procedures to address the following minimum requirements:

(5) adherence to state and federal laws;

(6) responding to an emergency, including robbery or a serious accident or incident;

(7) alcohol and drug-free workplace policies and procedures;

(8) safety and security procedures;

(9) occupational health and safety;

(10) crime prevention techniques; and

(11) if applicable, confidentiality laws, including the Health Insurance Portability and Accountability Act of 1996; and

(12) statements signed by employees indicating receipt and understanding of policies and procedures.

B. Training program: Licensee shall implement a training program, approved by the division, to ensure that all personnel present at the premises are provided information and training that, at minimum, covers the following topics within 30 days of the start of employment:

(1) employee health and safety;

(2) health and safety hazards;

(3) hazard communication for all solvents or chemicals used at the licensed premises and as described in the safety data sheet for each solvent or chemical;

(4) requirements for the proper use of health and safety measures and controls;

(5) emergency procedures;

(6) security procedures; and

(7) record keeping requirements.

C. A licensee, or employee, involved in the handling, transportation, manufacture, extraction, testing, or packaging of cannabis products must successfully complete a food handler course accredited by the American national standards institute (ANSI) prior to conducting any related activities. Such training shall be maintained while employed under a cannabis research licensee. The licensee shall obtain documentation evidencing the fulfillment of this requirement.

D. Training documentation:

(1) Licensee shall ensure that all personnel receive annual refresher training to cover, at minimum, the topics listed in this section.

(2) The licensee shall maintain a record, which contains at minimum:

(a) duties of each personnel;

(b) a list of all personnel at the premises, including at minimum, name and job title;

(3) documentation of training topics and dates of training completion;

(4) the signature of each employee verifying receipt and understanding of each training or refresher training completed.

E. Retention of training documentation: Licensees shall maintain documentation of an employee's training for a period of two years for current employees and at least six months after the termination of an employee's employment.

[16.8.2.61 NMAC – N, 07/12/2022]

16.8.2.62 HUMAN SUBJECT PROTECTIONS:

A. Before conducting research involving human subjects, the licensee shall:

(1) provide the division with documentation that the study has received institutional review board (IRB) approval, as defined and described in 45 CFR Part 46, federal policy for the protection of human subjects; and

(2) obtain "informed consent," as defined and described in 45 CFR Part 46, federal policy for the protection of human subjects, from the human research subject.

B. Nothing in this part relieves the licensee from complying with applicable FDA and state requirements governing cannabis research.

[16.8.2.62 NMAC – N, 07/12/2022]

[~~16.8.2.56~~] 16.8.2.63 SEVERABILITY: If any part or application of this rule is held to be invalid, the remainder or its application to other situations or persons shall not be affected. Any section of this rule legally severed shall not interfere with the remaining protections and duties provided by this rule.

[16.8.2.63 NMAC – Rn, 16.8.2.43 NMAC, 01/11/2022; Rn, 16.8.2.56 NMAC, 07/12/2022]

History of 16.8.2 NMAC: [RESERVED]