

**This is an emergency amendment to 16.8.1 NMAC amending Section 7, effective 12/02/2021.**

**16.8.1.7 DEFINITIONS:** Unless otherwise defined below, terms used in Title 16, Chapter 8, have the same meanings as set forth in the Cannabis Regulation Act and the Lynn and Erin Compassionate Use Act.

**A. Definitions beginning with “A”:**

(1) “Act” means the Cannabis Regulation Act, Sections 26-2C-1 to -42, NMSA 1978.

~~(1)~~ (2) “Advisory committee” means the cannabis regulatory advisory committee.

(3) “Adulterated” has the meaning stated in the New Mexico Food Act, Section 25-2-10, NMSA 1978.

(4) “Allergen” (“Major Food Allergen”) means:

(a) milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(b) a food ingredient that contains protein derived from a food, as specified in paragraph 1 of this Subsection.

(c) “Major food allergen” does not include:

(i) any highly refined oil derived from a food specified in paragraph 1 of this Subsection and any ingredient derived from such highly refined oil; or

(ii) any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).

~~(2)~~ (6) “Applicant” means any person who is seeking to become licensed pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, or division rules.

(7) “Approved” means acceptable to the division based on the division’s determination of conformity with principles, practices, industry standards, and generally recognized standards that protect public health and compliance with the requirements of this part and the act.

**B. Definitions beginning with “B”:** “Batch” means, with regard to cannabis, an identified quantity of cannabis no greater than 15 pounds that is of the same strain of cannabis, that is harvested during the same specified time period from the same specified cultivation area, and with respect to which the same agricultural practices were utilized, including the use of any pesticides; and with regard to concentrated and cannabis product, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.

**C. Definitions beginning with “C”:**

(1) “Cannabis finished product” means a cannabis product that is packaged and labeled for retail sale.

~~(1)~~ (2) “Cannabis Regulation Act” means the Cannabis Regulation Act, as enacted in Chapter 4, Sections 1 through 42 of New Mexico Laws of 2021, and as may be amended thereafter.

~~(2)~~ (3) “Cannabis Waste” means all parts of the plant genus Cannabis which may or may not contain a delta-9-tetrahydrocannabinol concentration of more than three-tenths percent on a dry weight basis, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin; and the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake; or the sterilized seed of the plant that is incapable of germination which has been designated as no longer usable cannabis.

(4) “Certificate of analysis” means an official certificate issued by a cannabis testing laboratory signed by an authorized official of the cannabis testing laboratory that guarantees the results of the laboratory’s testing of a sample.

~~(3)~~ (5) “Concentrated cannabis product (“concentrate”)” means a cannabis product that is manufactured by a division approved mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains or that is intended to contain at the time of sale or distribution, no less than thirty-percent THC by weight.

(6) “Conditional employee” means a potential edible/topical cannabis manufacturing facility employee to whom a job offer is made, conditional on responses to subsequent medical questions or

examinations designed to identify potential employees who may be suffering from a disease that may be transmitted through edible or topical cannabis products or edible or topical cannabis finished products and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

**D. Definitions beginning with “D”:**

(1) **“Division”** means the cannabis control division.

(2) **“Diversion”** means the unlawful transfer of a cannabis plant, plant material, or cannabis product.

(3) **“Dried cannabis”** means the dried leaves, flowers, and trim of the female cannabis plant, but does not include the seeds, stalks, or roots of the cannabis plant.

(4) **“Drinking water”** means water that meets criteria as specified in 20.7.10 NMAC.

Drinking water is traditionally known as “potable water” and includes the term “water” except where the term used connotes that the water is not potable, such as “boiler water,” “mop water,” “rainwater,” “wastewater,” and “non-drinking” water.

**E. Definitions beginning with “E”:** ~~[RESERVED]~~

(1) **“Edible cannabis finished product”** means a cannabis product that is packaged and labeled for retail sale and is intended for human ingestion.

(2) **“Employee”** means the licensee, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in an edible/topical cannabis manufacturing facility.

**F. Definitions beginning with “F”:** ~~[RESERVED]~~

(1) **“Food” (“ingredient”)** means an edible substance used or intended for use in whole or in part in the formulation of an edible cannabis finished product, and is not cannabis or cannabis product.

(2) **“Food-contact surface”** means:

(a) A surface of equipment or a utensil with which food or edible cannabis products normally comes into contact; or

(b) A surface of equipment or a utensil from which food or edible cannabis products may drain, drip, or splash:

(i) Into a food or edible cannabis products, or

(ii) Onto a surface normally in contact with food or edible cannabis products.

(3) **“Food employee”** means an individual working with:

(a) unpackaged edible or topical cannabis products;

(b) unpackaged ingredients; or

(c) equipment, utensils, or surfaces that contact unpackaged cannabis products and ingredients used to manufacture edible or topical cannabis products, or edible or topical cannabis finished products.

**G. Definitions beginning with “G”:** ~~[RESERVED]~~ **“Good manufacturing practices” (GMPs)** means the minimum sanitary and processing requirements related to the production methods, equipment, facilities, and other controls that a cannabis processing facility must meet to assure that cannabis products and cannabis finished products are safe and wholesome.

**H. Definitions beginning with “H”:** ~~[RESERVED]~~

**I. Definitions beginning with “I”:** ~~[RESERVED]~~

(1) **“Imminent health hazard”** means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(a) the number of potential injuries; and

(b) the nature, severity, and duration of the anticipated injury.

(2) **“Ingredient”** means:

(a) food;

(b) additives;

(c) non-food ingredients used in topical cannabis products; and

(d) “ingredient” does not include cannabis or cannabis product.

**J. Definitions beginning with “J”:** ~~[RESERVED]~~

**K. Definitions beginning with “K”: [RESERVED]**

**L. Definitions beginning with “L”:**

(1) “Label” (“Labeling”) means any display of written, printed, or graphic matter printed on or affixed to any container and includes product inserts and other promotional materials including digital communications.

(2) “Law” means applicable local, state, and federal statutes, regulations, and ordinances.

~~(4)~~ (3) “Licensee” means any person who holds a license issued by the Division pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, or division rules.

~~(2)~~ (4) “Limited-access area” means an indoor or outdoor area on the premises of a licensed cannabis establishment where cannabis or cannabis products are cultivated, stored or held, weighed, packaged, manufactured, disposed or wasted, all point-of-sale (POS) areas, and any room or area storing a digital video surveillance system storage device.

~~(3)~~ (5) “Lot” means an identified portion of a batch, that is uniform and that is intended to meet specifications for identity, strength, and composition; or, in the case of a cannabis product or concentrate, an identified quantity produced in a specified period of time in a manner that is uniform and that is intended to meet specifications for identity, strength, and composition.

(4) (6) “Lynn and Erin Compassionate Use Act” means the Lynn and Erin Compassionate Use Act, Section 26-2B-1 et seq., NMSA 1978.

**M. Definitions beginning with “M”:**

(1) “Minor” means an individual who is less than 18 years of age.

(2) “Misbranded” has the meaning stated in the New Mexico Food Act, Section 25-2-11 NMSA 1978.

**N. Definitions beginning with “N”: ~~[RESERVED]~~ “NMED” means the New Mexico environment department.**

**O. Definitions beginning with “O”: ~~[RESERVED]~~ “Operational plan” means a written plan outlining the product formulation, production steps, safety requirements, distribution, labeling, and recall procedures that will be implemented by a cannabis manufacturer when processing edible or topical cannabis products or edible of topical cannabis finished products.**

**P. Definitions beginning with “P”:**

~~(1) “Pesticide” means a pesticide as defined by the New Mexico Pesticide Control Act, Section 76-4-1 et seq., NMSA 1978.~~

~~(2) “Plant” means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.~~

~~(3) “Policy” means a written statement of principles that guides and determines present and future decisions and actions of the licensed person.~~

~~(4) “POS” means point of sale system.~~

~~(5) “Person” means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, or any other legal or commercial entity.~~

~~(6) “Produce” means to engage in any activity related to the planting or cultivation of cannabis.]~~

(1) “Packaged” (“Packaging”) means the act of placing edible or topical product or edible or topical finished product into a container.

(2) “Person” means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, or any other legal or commercial entity.

(3) “Person in charge” means the individual present at a cannabis manufacturing facility who is responsible for the operation at the time of inspection.

(4) “Personal care items” means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person’s health, hygiene, or appearance, and includes items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(5) “Pesticide” means a pesticide as defined by the New Mexico Pesticide Control Act, Section 76-4-1 et seq., NMSA 1978.

(6) "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

(7) "Plant" means any cannabis plant, cutting, or clone that has roots or that is cultivated with the intention of growing roots.

(8) "Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

(a) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

(c) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(d) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(9) "Policy" means a written statement of principles that guides and determines present and future decisions and actions of the licensed person.

(10) "POS" means point of sale system.

(11) "Process authority" means an approved expert in the processes for controlling pathogenic microorganisms in food and/or cannabis products, and as such, is qualified by education, training and experience to evaluate all of the aspects of pathogen control measures and determine if such control measures, when properly implemented, will control pathogens effectively.

(12) "Produce" means to engage in any activity related to the planting or cultivation of cannabis.

(13) "Public water system" has the meaning stated in 20.7.10 NMAC.

**Q. Definitions beginning with "Q": [RESERVED]**

**R. Definitions beginning with "R"**

(1) "Recall" means [to request the return of a product after the discovery of a safety issue or product defect] a return of cannabis products, including edible or topical cannabis products and edible or topical cannabis finished products that are either known or suspected to be adulterated, misbranded, defective, or otherwise unsafe for human consumption, to the cannabis manufacturer, or that are destroyed, wasted, and disposed of in accordance with division rules related to wastage.

(2) "Rework" means clean, unadulterated food or edible or topical cannabis product or edible or topical finished product that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food or edible or topical cannabis finished product.

~~(2)~~ (3) "RLD" means the regulation and licensing department.

**S. Definitions beginning with "S":**

(1) "Security alarm system" means any device or series of devices capable of alerting law enforcement, including, but not limited to, a signal system interconnected with a radio frequency method such as cellular, private radio signals, or other mechanical or electronic device used to detect or report an emergency or unauthorized intrusion.

(2) "Segregate" means to separate and withhold from use or sale batches, lots, cannabis, usable cannabis, or cannabis products in order to first determine its suitability for use through testing by an approved laboratory.

(3) "Sewage" means liquid waste containing organic matter in suspension or solution and may include liquids containing chemicals in solution.

(4) "Smooth" means:

(a) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(b) a nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(c) a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

**T. Definitions beginning with “T”:**

(1) **“THC”** means tetrahydrocannabinol, a cannabinoid that is the primary psychoactive ingredient in cannabis.

(2) **“Testing”** means testing of cannabis and cannabis products using analytical analysis consistent with division rules.

(3) **“Time/temperature control for safety food”** means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(4) **“Topical cannabis finished product”** means a cannabis product that is packaged and labeled for retail sale and is intended to be applied externally to the skin and not intended to be ingested or inhaled.

(5) **“Total THC”** means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + % THC.

~~(3)~~ (6) **“Track and trace system”** means the electronic system designated by the division to track and trace the production, transportation, sale, and wastage of cannabis and cannabis products.

**U. Definitions beginning with “U”: [RESERVED]**

**V. Definitions beginning with “V”:** **“Vault”** means a limited access storage room that is within a licensed cannabis establishment and is outfitted with adequate security features for the purposes of storing cannabis, cannabis products, or cash.

**W. Definitions beginning with “W”:**

(1) **“Waste” or “wastage”** means the process of rendering cannabis or cannabis products unusable and unrecognizable, including the destruction of cannabis or cannabis products.

(2) **“Water activity”** ( $A_w$ ) means the measure of the free moisture in an edible cannabis finished product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

**X. Definitions beginning with “X”: [RESERVED]**

**Y. Definitions beginning with “Y”: [RESERVED]**

**Z. Definitions beginning with “Z”: [RESERVED]**

[16.8.1.7 NMAC - N 08/22/2021, A/E 12/02/2021]

**This is an emergency amendment to 16.8.2 NMAC, amending Sections 27 and 30, effective 12/2/2021.**

**16.8.2.27 MINIMUM REQUIREMENTS FOR THE PRODUCTION OF CANNABIS:**

- A. General requirements:** Licensees shall ensure the following:
- (1) all production activities are done on premises that are in compliance with state and local laws that do not conflict with the Cannabis Regulation Act or the Lynn and Erin Compassionate Use Acts;
  - (2) the licensee's right to use the quantity of water sufficient to meet the production facility's needs remains in good standing;
  - (3) plumbing shall be of adequate size and design, adequately installed, and maintained to carry sufficient quantities of water to required locations throughout the facility, including sufficient quantities of water to properly convey sewage and liquid disposable waste from the facility; and
  - (4) all weighting or measuring devices that are used in the wholesale of cannabis be appropriately documented as having undergone certified registration and calibration that is in accordance with applicable requirements of the New Mexico department of agriculture.
- B. Cultivation plan:** Licensees shall create and maintain a cultivation plan, which shall include all of the following:
- (1) a detailed premises diagram showing all cultivation activity areas, boundaries, and dimensions in feet.
  - (2) square foot measurement of mature cannabis plant cultivation area(s), including aggregate square footage if the mature cannabis plant cultivation areas are noncontiguous;
  - (3) area(s) outside of the mature cannabis plant cultivation areas where only immature plants shall be maintained, if applicable;
  - (4) designated pesticide and other agricultural chemical storage area(s);
  - (5) designated processing area(s) if the licensee will process on site;
  - (6) designated packaging area(s) if the licensee will package products on site;
  - (7) designated composting area(s) if the licensee will compost plant or cannabis waste on site;
  - (8) designated secured area(s) for cannabis waste if different than composting area(s);
  - (9) designated area(s) for harvested cannabis storage;
  - (10) designated seed production area(s) which may contain mature plants for nursery purposes only.
- C. Lighting:** For indoor and mixed-light cultivation, a licensee shall create and maintain a lighting diagram, which shall include the following:
- (1) location of all lights in the cannabis plant cultivation area(s); and
  - (2) maximum wattage, or wattage equivalent, of each light.
- D. Pest management:** Licensees shall create and maintain a pest management plan, which shall include product name and active ingredient(s) of all pesticides to be applied to cannabis during any stage of plant growth. Licensees are encouraged to create and implement integrated pest management protocols, including chemical, biological, and cultural methods to control or prevent the introduction of pests on the cultivation site.
- E. Cannabis waste:** Licensees shall create and maintain cannabis waste procedures meeting the requirements set forth in 16.8.2.22 NMAC.
- F. Safety and health requirements:** Licensees shall ensure the following:
- (1) all equipment, implements, and fixtures that are used for the production of cannabis shall be used exclusively for the production of cannabis and meet sanitation and safety standards required by the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, division rules, and any other state or federal laws;
  - (2) production is conducted in a manner that does not allow cross-contamination from chemical or biological hazards;
  - (3) any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including a boil, sore, or infected wound, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for cannabis, shall be excluded from any operations which may be anticipated to result in such contamination until the condition is corrected;

- (4) hand-washing facilities are provided that are adequate, accessible, furnished with running water at a suitable temperature, conveniently located in indoor production facilities, in restrooms, and wherever good sanitary practices require employees to wash or sanitize their hands, and stocked with effective hand-cleaning and sanitizing preparations, and sanitary towel service or suitable drying devices;
- (5) all persons involved in preparing or handling cannabis conform to hygienic practices while on duty, including:
  - (a) maintaining adequate personal cleanliness;
  - (b) wearing gloves while handling processed cannabis or unpackaged but processed cannabis products;
  - (c) possessing a valid food handler card issued by an ANSI/ASTM e2659-09 accredited Food Handler Training Certificate Program approved by the New Mexico environment department if handling processed cannabis or unpackaged but processed cannabis products; and
  - (d) washing hands thoroughly in an adequate hand-washing facility before starting work, at any other time when the hands may have become soiled or contaminated, and both before putting gloves on and after removal of gloves, if the person is handling processed cannabis or unpackaged but processed cannabis products;
- (6) operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where cannabis is exposed;
- (7) water damage is properly and timely treated to protect health and safety of employees and the public, and that fiberglass and other insulation material is not exposed;
- (8) adequate safety-type lighting in all areas where cannabis is produced or stored, if applicable, and where equipment is cleaned;
- (9) rubbish is disposed of so as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage, or breeding place for pests;
- (10) premises, fixtures, and physical facilities where cannabis or cannabis products are produced are maintained to ensure the health and safety of employee and the public;
- (11) contact surfaces, including utensils and equipment used for preparation of cannabis or cannabis products, are cleaned and sanitized as frequently as necessary to protect against contamination;
- (12) only environmental protection agency (EPA) registered sanitizing agents are used in production operations and that they are used in accordance with labeled instructions;
- (13) toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of cannabis or cannabis products and that otherwise satisfies the requirements of this rule;
- (14) storage and transportation of cannabis and cannabis products is accomplished under conditions that will maintain security and protect the cannabis or cannabis products against physical, chemical, and microbial contamination, as well as against deterioration of the cannabis or cannabis products and the container; and
- (15) that there is sufficient space for placement of equipment and storage of material as is necessary for the maintenance of sanitary operations for production of cannabis.

[16.8.2.27 NMAC - N, 08/24/2021; A/E, 12/2/2021]

**16.8.2.30 APPLICATION REQUIREMENTS FOR CANNABIS MANUFACTURER LICENSE:**

**A.** An initial application or renewal for cannabis manufacturer licensure shall include the following:

- (1) Contact information for the applicant and the cannabis establishment, to include:
  - (a) applicant's full legal name;
  - (b) applicant's mailing address;
  - (c) applicant's contact telephone number;
  - (d) applicant's contact email address;
  - (e) applicant's business physical address and mailing address, if different;
  - (f) applicant's business legal name, including a DBA name if applicable;
  - (g) applicant's business web address, if applicable;

- (h) applicant's 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 (Class I, Class II, Class III, or Class IV);
- (2) proof the applicant or 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 the applicant or controlling person;
- (3) legible and accurate diagram containing information required by Subsection 16.8.2.32 NMAC and description of the location of the land or facility to be used for the cannabis establishment and the method(s) to be used to manufacture cannabis (extraction, infusion, packaging, labeling), including a description of extraction and infusion methods, in a portable document format (.pdf), and if requested by the division, digital photographic photos;
- (4) fully executed and dated documentation of the applicant's ownership or legal authority to use the property, buildings, or other facilities, establishing the applicant is, or will be, entitled to possession of the premises for which the application is made;
- (5) demonstration of a legal right to use the quantity of water that the division determines is needed for cannabis manufacturing, as evidenced by either:
- (a) documentation from a water provider that the applicant has the right to use water from the provider and that the use of water for cannabis manufacturing is compliant with provider's rules, or
  - (b) documentation from the office of the state engineer showing that the applicant has a valid and existing water right, or a permit to develop a water right, at the proposed place of use of the cannabis establishment. The documentation may include any of the following:
    - (i) a state engineer permit or license in good standing, but not including a permit issued pursuant to Sections 72-12-1, -1.1, -1.2, or -1.3, NMSA 1978;
    - (ii) a subfile order or decree issued by a water rights adjudication court;
    - (iii) the findings of an office of the state engineer hydrographic survey; or
    - (iv) other documentation the office of the state engineer has deemed in writing as acceptable to the office of the state engineer under this rule.
- (6) a copy of a current business license, fire inspection report, and zoning approval;
- (7) if applicable, certification the applicant is in good standing with the New Mexico secretary of state, including all documents filed with the New Mexico secretary of state;
- (8) a list of all controlling persons, a list of other current or prior licensed cannabis businesses, documentation of the applicant's or a controlling person legal name change, and criminal history screening documents as set forth in 16.8.2.9 NMAC and the Cannabis Regulation Act;
- (9) 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;
- (10) a list of the types of products that will be manufactured, packaged, or labeled;
- (11) a complete written description of good manufacturing practices (GMPs).
- (12) a complete written description of the means that the manufacturer shall employ to safely manufacture cannabis products, including hygiene standards consistent with the requirements of the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, division rules, and other state or federal rules applicable to manufacturing;
- (13) A detailed description of the licensee's proposed plan for obtaining cannabis from a licensed cannabis producer or cannabis microproducer.
- (14) legible electronic images of the labeling and packaging of the cannabis or cannabis products that the manufacturer shall utilize, which satisfies the labeling and packaging requirements of the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act, division rules, and other state or federal rules applicable to labeling and packaging;
- (15) 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;
- (16) if applicable, a sample of the record form(s), which shall identify (among other items)

the name of the wholesale purchaser, the date of the sale, the quantity, and price of cannabis sold;

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

(18) 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;

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

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

(21) 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;

(22) 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;

(23) certification the applicant is not licensed under the Liquor Control Act.

(24) 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 grant-merced, federally designated opportunity zone, or other rural historic communities;

(25) an attestation that the manufacturer will not use dimethylsulfoxide (DMSO) in the production of cannabis products, and will not possess DMSO on the premises of the manufacturer;

(26) an attestation 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

(27) for a class IV license, a signed attestation from a licensed engineer stating the chemical extraction equipment is a closed loop system, is being utilized for its intended use and meets requirements of subsection I of 16.8.2.34 NMAC;

(28) for class II, III, and IV licenses, evidence that the applicant has completed the self-certification required for the production of edibles and topicals from the New Mexico environment department and ~~[that such permits are valid]~~ provide confirmation from the New Mexico environment department at the time the license application is submitted; and

(29) 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 five 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.

[16.8.2.30 NMAC – N/E, 09/08/2021; A/E, 12/2/2022]

**This is an emergency rule creation of 16.8.6 NMAC adding Sections 1 through 15, effective 12/02/2021.**

**TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING  
CHAPTER 8 COMMERCIAL AND MEDICAL CANNABIS  
PART 6 HEALTH AND SAFETY, FOOD AND PRODUCT SAFETY, ENVIRONMENTAL  
IMPACTS, AND NATURAL RESOURCES**

**16.8.6.1 ISSUING AGENCY:** New Mexico Regulation and Licensing Department, Cannabis Control Division.

[16.8.6.1 NMAC – N/E, 12/02/2021]

**16.8.6.2 SCOPE:** This rule applies to all applicants for licensure pursuant to the Cannabis Regulation Act, the Lynn and Erin Compassionate Use Act or division rules, and where applicable, the general public.

[16.8.6.2 NMAC - N/E, 12/02/2021]

**16.8.6.3 STATUTORY AUTHORITY:** The requirements set forth herein are promulgated by the cannabis control division pursuant to the authority granted under the Cannabis Regulation Act and the licensing provisions of the Lynn and Erin Compassionate Use Act.

[16.8.6.3 NMAC - N/E, 12/02/2021]

**16.8.6.4 DURATION:** Permanent.

[16.8.6.4 NMAC - N/E, 12/02/2021]

**16.8.6.5 EFFECTIVE DATE:** 12/02/2021, unless a later date is cited at the end of a section.

[16.8.6.5 NMAC - N/E, 12/02/2021]

**16.8.6.6 OBJECTIVE:** The objective of Part 6 is to set forth standards related to health and safety, food and product safety, environmental impacts, and natural resources to ensure public health, safety, and well-being. Part 6 is not applicable to personal use of cannabis pursuant to the Cannabis Regulation Act or the Lynn and Erin Compassionate Use Act.

[16.8.6.6 NMAC - N/E, 12/02/2021]

**16.8.6.7 PREREQUISITE AND RESPONSIBILITY FOR OPERATION:**

**(A)** Prior to the submission of a license application for a class II, III, or IV cannabis manufacture licensure, each applicant or licensee engaged in the manufacturing of edible or topical cannabis products and/or edible or topical cannabis finished products shall provide to NMED a certification that:

**(1)** the facility where the cannabis manufacturer operates, and the manufacturing equipment used will be constructed and maintained in accordance with the requirements of this part; and

**(2)** edible and topical cannabis products and edible and topical finished products will be stored, manufactured, packaged, repackaged, labeled, relabeled, tested, reworked, and/or wasted in accordance with the requirements of this part.

**(B)** A certification shall include information specified in Subparagraphs (a) through (i) of Paragraph (1) of Subsection A of 16.8.2.30 NMAC.

**(C)** Any person signing a certification pursuant to this section shall include the following signed statement: "I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information."

(D) NMED shall provide confirmation of receipt to each applicant or licensee that provides a certification.

(E) Each applicant or licensee shall provide the NMED confirmation to RLD as specified in Paragraph (1) of Subsection A of 16.8.2.30 NMAC. [16.8.6.7 NMAC - N/E, 12/02/2021]

### **16.8.6.8 OPERATIONAL PLANS:**

(1) A licensee shall prepare a written operational plan containing the following information, as applicable, for each edible or topical cannabis product or edible or topical cannabis finished product to be manufactured, labeled, relabeled, packaged, or repackaged:

(a) planned source of cannabis products and ingredients;

(b) names of the ingredient(s);

(c) the final product pH;

(d) the final product water activity ( $A_w$ );

(e) names of preservative(s);

(f) the type of packaging to be used that complies with all requirements of section 16.8.3.13 of this part and whether the packaging is integral to product stability;

(g) the intended distribution of the product;

(h) if the product is to be distributed at ambient, refrigerated or frozen temperature;

(i) the expected shelf life during distribution, retail storage, and in the hands of the end user;

(j) how the product should be prepared for consumption;

(k) what mishandling of the product might occur in the merchandising channels or in the hands of the end user;

(l) the proposed recall plan, meeting the requirements of 16.8.2.11 NMAC;

(m) the complete operational procedure for product formulation, including:

(i) a written, detailed description of the intended manufacturing process, including method of infusion;

(ii) a flow chart illustrating the manufacturing process; and

(iii) identification of critical control points.

(n) written good manufacturing practices (GMPs);

(o) other policies and procedures related to the safe and sanitary operation of the cannabis manufacturer;

(p) proposed product labels that comply with all requirements of section 16.8.3.14 of this part;

(q) proposed record keeping and chain of custody systems;

(r) a description of the batch/lot ID coding system;

(s) proposed pest control plan; and

(t) procedures for remedial measures to bring cannabis products into compliance with division standards; destruction, storage, or disposal of a tested batch of cannabis products if the testing samples from the tested batch indicate noncompliance with applicable health and safety standards; and destruction, storage, and disposal of recalled cannabis products.

(2) Prior to adding new edible or topical cannabis products or edible or topical cannabis finished products, or changing the stated process for any existing product in the product line, a licensee shall:

(a) for a new product, prepare a written operational plan as specified in Section 9 of this part; and

(b) for an existing product for which a change will be made in the manufacturing process, update the existing operational plan.

(3) A licensee shall have an edible cannabis finished product operational procedure approved by a process authority to verify all critical factors of public health significance are addressed when the product is determined to require a product assessment as determined by table A or table B as follows:

Table A. Interaction of pH and  $A_w$  for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently packaged

<u>A<sub>w</sub> values</u>	<u>pH: 4.6 or less</u>	<u>pH: &gt; 4.6 - 5.6</u>	<u>pH: &gt; 5.6</u>
<u>&lt;0.92</u>	<u>non-TCS food*</u>	<u>non-TCS food</u>	<u>non-TCS food</u>
<u>≥ 0.92 - 0.95</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA**</u>
<u>≥ 0.95</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

\*\* PA means Product Assessment required

Table B. Interaction of PH and A<sub>w</sub> for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

<u>A<sub>w</sub> values</u>	<u>pH: &lt; 4.2</u>	<u>pH: 4.2 - 4.6</u>	<u>pH: &gt; 4.6 - 5.0</u>	<u>pH: &gt; 5.0</u>
<u>&lt; 0.88</u>	<u>non-TCS food*</u>	<u>Non-TCS food</u>	<u>non-TCS food</u>	<u>non-TCS food</u>
<u>0.88 – 0.90</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA**</u>
<u>&gt; 0.90 – 0.92</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>
<u>&gt; 0.92</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>	<u>PA</u>

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

\*\* PA means Product Assessment required

**(4)** The licensee shall maintain current operational plans on the licensed premises during all hours of operation and shall, upon request, make them available for review by the division. [16.8.6.8 NMAC - N/E, 12/02/2021]

#### **16.8.6.9 MANAGEMENT AND PERSONNEL:**

**A.** Adoption of food code parts 2-1, 2-3 and 2-4 and section 2-103.11. Except as otherwise provided, parts 2-1, 2-3 and 2-4 and section 2-103.11 of the 2017 United States food and drug administration model food code is hereby adopted and incorporated in its entirety.

**B.** A licensee shall have written procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the edible cannabis manufacturing facility. The procedures shall be maintained onsite and address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.

**C.** Except as otherwise provided, the licensee shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the cannabis manufacturer facility during all hours of operation.

**D.** If edible or topical cannabis products or edible or topical cannabis finished products are manufactured as part of a vertically integrated cannabis establishment or integrated cannabis microbusiness that is the legal responsibility of the same licensee and that are located on the same licensed premises, the licensee may designate a single person in charge who is present on the licensed premises during all hours of operation.

**E.** The person in charge shall have the education, training, or experience necessary to supervise the production of clean and safe edible or topical cannabis products or edible or topical cannabis finished products and ensure the cannabis manufacturer remains in compliance with this part, division rules, and the act at all times.

**F.** Personal care items on the premises shall be stored in a manner to protect edible and topical cannabis products, edible and topical cannabis finished products, other ingredients, equipment, and utensils from contamination at all times.

**G.** A licensee shall:

**(a)** immediately contact the division to report an illness of an employee or conditional

employee as specified under Subsection A of this section;

(b) immediately discontinue operations and notify the division if an imminent health hazard may exist as specified in 16.8.3.17 NMAC;  
[16.8.6.9 NMAC - N/E, 12/02/2021]

**16.8.6.10 EDIBLE AND TOPICAL CANNABIS MANUFACTURER REQUIREMENTS:**

A. Adoption of 21 CFR 117. Except as otherwise provided, Subpart F and the sections, specified in paragraphs 1-7 of this subsection, of Subparts A and B of the United States code of federal regulations, title 21, part 117 are hereby adopted and incorporated in their entirety:

- (1) 117.3 Definitions;
- (2) 117.20 Plant and grounds;
- (3) 117.35 Sanitary operations;
- (4) 117.37 Sanitary facilities and controls;
- (5) 117.40 Equipment and utensils;
- (6) 117.80 Processes and controls; and
- (7) 117.110 Defect action levels and Subpart F.

B. Modifications. Except as otherwise provided, the following modifications are made to the incorporated subparts of 21 CFR 117:

- (1) 117.301: All records required by this part are subject to all requirements of this subpart;
- (2) 117.315(c): Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location; and
- (3) 117.320: All records required by this part must be made promptly available to the division for official review and copying upon oral or written request.

C. Omissions. Except as otherwise provided, the following omissions are made to the incorporated subparts of 21 CFR 117:

- (1) 117.310;
- (2) 117.315(d);
- (3) 117.325;
- (4) 117.335; and
- (5) The following terms are omitted from section 117.3 Definitions:
  - (a) Allergen;
  - (b) Food;
  - (c) Food-contact surfaces;
  - (d) Lot;
  - (e) Manufacturing/processing; and
  - (f) Packing.

D. Adoption of food code parts 4-5, 4-6 and 4-7. Except as otherwise provided, parts 4-5, 4-6, and 4-7 of the 2017 United States food and drug administration model food code is hereby adopted and incorporated in its entirety.

E. Modifications. Except as otherwise provided, the following modifications are made to the incorporated subparts of the 2017 United States food and drug administration model food code:

- (1) 4-603.12 Precleaning.
  - (a) Food or cannabis product debris on equipment and utensils shall be scraped over a waste disposal unit or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.
  - (b) If necessary, for effective cleaning, utensils and equipment shall be pre-flushed, presoaked, or scrubbed with abrasives. Ethyl alcohol (ethanol) or isopropyl alcohol (isopropanol) are acceptable for pre-flushing or presoaking.

F. Omissions. Except as otherwise provided, the following omissions are made to the incorporated subparts of the 2017 United States food and drug administration model food code:

- (1) 4-502.12;
- (2) 4-502.13(B);
- (3) 4-502.14;
- (4) 4-602.11(A)(1);
- (5) 4-602.11(B);
- (6) 4-602.11(D)(3); and

(7) 4-602.11(E)(2)-(3).

**G. Cannabis Product Ingredient Source.**

(1) Ingredients shall be received from sources as specified in 7.6.2 NMAC.

(2) Cannabis products, ingredients, and edible or topical cannabis finished products intended for human consumption shall be transported under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of the cannabis products, ingredients, and cannabis finished products, as well as against deterioration of the cannabis products, ingredients, and cannabis finished products and the container in accordance with the New Mexico Food Service Sanitation Act and the New Mexico Food Act.

H. The current 21 CFR 111 and United States federal food, drug, and cosmetic act, title 21, chapter 9 and 7.6.2 NMAC are hereby adopted as a technical reference and interpretation guide.  
[16.8.6.10 NMAC – N/E, 12/02/2021]

**16.8.6.11 WATER SUPPLY:**

A. Drinking water shall be obtained from an approved source that is:

(1) a public water system; or

(2) a non-public water system that is constructed, maintained, and operated according to law.

B. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

C. Except as specified under Subsection D of this section:

(1) Water from a public water system shall meet the construction and drinking water quality standards specified in 20.7.10 NMAC; and

(2) Water from a non-public water system shall meet:

(a) the construction requirements and drinking water quality standards of a non-community water system as specified in 20.7.10 NMAC; and

(b) the drinking water source setback requirements as specified in 20.7.3 NMAC.

D. A non-drinking water supply shall be used only if its use is approved and shall be used only for nonculinary purposes such as air conditioning, non-cannabis equipment cooling, and fire protection.

E. Except when used as specified in Subsection D of this section, water from a non-public water system shall meet the sampling requirements of a non-community water system as specified in 20.7.10 NMAC.

F. The most recent sample report for the non-public water system shall be retained on file in the cannabis manufacturer facility or the report shall be maintained as specified by state water quality regulations.

G. Water shall be received from the source through the use of:

(1) an approved public water main; or

(2) one or more of the following that shall be constructed, maintained, and operated according to law:

(a) Non-public water main, water pumps, pipes, hoses, connections, and other appurtenances;

(b) Water transport vehicles; or

(c) Water containers.

[16.8.6.11 NMAC - N/E, 12/02/2021]

**16.8.6.12 EDIBLE AND TOPICAL CANNABIS FINISHED PRODUCT TESTING:**

A. Edible and topical cannabis finished products shall meet the requirements specified in division rules related to testing prior to being transported or transferred from the licensed premises, distributed, sold or otherwise made available to consumers.

B. Edible and topical cannabis finished products that do not meet the requirements of Subsection A of this section shall:

(1) be segregated

(2) reworked, remediated or reconditioned as specified in division rules related to testing; or

(3) destroyed, wasted, and disposed of in accordance with the wastage requirements of the division.

[16.8.6.12 NMAC – N/E, 12/02/2021]

**16.8.6.13 EDIBLE AND TOPICAL CANNABIS FINISHED PRODUCT TESTING**

**LABORATORIES:** Testing required by the division shall be conducted by a division-approved cannabis testing laboratory that has no direct ownership or financial interest in the facility for which the testing is being conducted. [16.8.6.13 NMAC - N/E, 12/02/2021]

**16.8.6.14 CEASING OPERATIONS AND REPORTING:**

**A.** Except as specified in Subsections B and C of this section, a licensee shall immediately discontinue operations if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne or cannabis-borne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health, employees, or the environment.

**B.** A licensee need not discontinue operations in an area of a cannabis manufacturer facility that is unaffected by the imminent health hazard.

**C.** Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the division may allow the licensee to continue operations in the event of an extended interruption of electrical or water service if:

- (1)** a written emergency operating plan has been approved by the division;
- (2)** immediate corrective action is taken by the licensee to eliminate, prevent, or control any food safety risk and imminent health hazard associated with the electrical or water service interruption; and
- (3)** the division is informed upon implementation of the written emergency operating plan.

**D.** If operations are discontinued as specified in Subsection A of this section or otherwise according to law, the licensee shall obtain approval from the division before resuming operations.

[16.8.6.14 NMAC - N/E, 12/02/2021]

**16.8.6.15 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.

[16.8.6.16 NMAC - N/E, 12/02/2021]