

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 10 HEMP POST-HARVEST PROCESSING
PART 2 HEMP EXTRACTION, PRODUCTION, TRANSPORTATION, WAREHOUSING, AND TESTING

20.10.2.1 ISSUING AGENCY: New Mexico Environment Department, P.O. Box 5469, Santa Fe, New Mexico 87502, Telephone No. (505) 827-2855.
[20.10.2.1 NMAC - N, 1/28/2020]

20.10.2.2 SCOPE: All individuals, businesses, agencies, institutions, or other entities engaged in the transportation, extraction, storage, or processing of hemp products in New Mexico.
[20.10.2.2 NMAC - N, 1/28/2020]

20.10.2.3 STATUTORY AUTHORITY: The Hemp Manufacturing Act, NMSA 1978, Sections 76-24-1 to 76-24-10 (2017 as amended through 2019); Department of Environment Act, NMSA 1978, Sections 9-7A-1 through 9-7A-15 (1991 as amended through 2003).
[20.10.2.3 NMAC - N, 1/28/2020]

20.10.2.4 DURATION: Permanent.
[20.10.2.5 NMAC - N, 1/28/2020]

20.10.2.5 EFFECTIVE DATE: January 28, 2020, unless a later date is cited at the end of a section.
[20.10.2.4 NMAC - N, 1/28/2020]

20.10.2.6 OBJECTIVE: To establish uniform standards for the transportation, extraction, processing, and testing of hemp products for the purpose of ensuring the safe manufacture and accurate presentation of hemp products for human consumption, absorption, and inhalation.
[20.10.2.6 NMAC - N, 1/28/2020]

20.10.2.7 DEFINITIONS:

- A.** “Act” means the Hemp Manufacturing Act, Section 76-24-1, et seq., NMSA 1978.
- B.** “Adulterated” has the meaning stated in the New Mexico Food Act, Section 25-2-10 NMSA 1978.
- C.** “Applicant” means a person who has submitted a hemp facility application to the regulatory authority.
- D.** “Application” means documents provided by, and submitted to, the regulatory authority by an applicant as part of the process for obtaining a permit to extract, process, or engage in other manufacturing activities of hemp or hemp products.
- E.** “Approved” means acceptable to the regulatory authority based on the regulatory authority’s determination of conformity with principles, practices, and generally recognized standards that protect public health and compliance with the requirements of this part and the act.
- F.** “Blend” means to combine into an integrated whole.
- G.** “Board” means the environmental improvement board.
- H.** “Cannabis sativa L.” means the plant cannabis sativa L. and any part of the plant, whether growing or not.
- I.** “CBD” means cannabidiol and is a cannabinoid and the primary non-psychoactive ingredient found in hemp.
- J.** “Certificate of analysis” means an official certificate issued by a hemp laboratory signed by an authorized official of the hemp laboratory that guarantees the results of the laboratory’s testing of a sample.
- K.** “Conditional employee” means a potential hemp employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential hemp employees who may be suffering from a disease that may be transmitted through hemp, hemp extract, hemp-derived material, or hemp finished product and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.
- L.** “Disposition” means storing, transferring to another person, or disposal.

M. “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.

N. “Employee” means the permit holder, person in charge, hemp 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 a hemp facility.

O. “Hemp” means the plant cannabis sativa L. and any part of that plant, including seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not, with a THC concentration of not more than three-tenths percent on a dry weight basis.

P. “Hemp-derived material” means any material containing THC in any concentration derived from cannabis sativa L. through any activity authorized pursuant to the act.

Q. “Hemp employee” means an individual working with unpackaged hemp products or equipment utensils, or surfaces that contact unpackaged hemp products.

R. “Hemp extract” means oil and extracts, including cannabidiol, cannabidiolic acid, and other identified and non-identified compounds derived from hemp.

S. “Hemp extraction facility” means an operation that produces hemp extract.

T. “Hemp facility” means a hemp extraction facility, hemp manufacturing facility, hemp processing facility or hemp warehouse.

U. “Hemp finished product” means a hemp product that is intended for retail sale and containing hemp or hemp extracts for human consumption, absorption, or inhalation that has a THC concentration of not more than three-tenths of one percent (0.30%).

V. “Hemp harvest certificate” means a document issued by the New Mexico department of agriculture to a person licensed to harvest hemp for distribution or sale certifying that a quantity of hemp meets the THC concentration required pursuant to 21.20.3 NMAC.

W. “Hemp laboratory” means an analytical laboratory approved by the regulatory authority to conduct laboratory analysis of hemp products.

X. “Hemp manufacturing facility” means an operation, other than a hemp extraction facility, that produces hemp products, other than hemp extract, and provides hemp products for sale or distribution to other business entities.

Y. “Hemp processing facility” means an operation, other than a hemp manufacturing facility, where hemp is processed or dried into a hemp finished product or into a hemp product that does not require further processing before being offered as a hemp finished product.

Z. “Hemp products” means hemp, hemp-derived material, hemp extract, and hemp finished product.

AA. “Hemp transportation manifest” means a form used for identifying the quantity, composition, origin, and destination of hemp products during transportation.

BB. “Hemp transportation unit” means a motor vehicle department-licensed, driven or towed wheeled vehicle utilized to transport hemp products.

CC. “Hemp warehouse” means a location, other than a hemp extraction facility or hemp manufacturing facility, where hemp extract is stored.

DD. “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:

- (1) the number of potential injuries; and
- (2) the nature, severity, and duration of the anticipated injury.

EE. “Law” means applicable local, state, and federal statutes, regulations, and ordinances.

FF. “Licensee” means a person that possesses a valid license for hemp production issued by NMDA.

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

1978.

HH. “NMDA” means the New Mexico department of agriculture.

II. “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 hemp facility when processing hemp products.

JJ. “Permit” means the document issued by the regulatory authority that authorizes a person to operate a hemp facility.

KK. “Permit holder” means the entity that:
(1) is legally responsible for the operation of the hemp facility such as the owner, the owner’s agent, or other person; and

(2) possesses a valid permit to operate a hemp facility.

LL. “Person” means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

MM. “Person in charge” means the individual present at a hemp facility who is responsible for the operation at the time of inspection.

NN. “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.

OO. “Poisonous or toxic materials” means substances that are not intended for ingestion and are included in four categories:

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

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

(3) 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

(4) 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.

PP. “Premises” means:

(1) The physical facility, its contents, and the contiguous land or property under the control of the permit hold; or

(2) The physical facility, its contents, and the land or property not described in paragraph (1) of this definition if its facilities and contents are under the control of the permit holder and may impact hemp facility personnel, facilities, or operations, and a hemp facility is only one component of a larger operation.

QQ. “Process authority” means an approved expert in the processes for controlling pathogenic microorganisms in food and/or hemp 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.

RR. “Public water system” has the meaning stated in 20.7.10 NMAC.

SS. “Recall” means a return of hemp products that are either known or suspected to be adulterated, misbranded, or otherwise unsafe for human consumption, to the manufacturer or distributor, or that are disposed of by approved methods.

TT. “Regulatory authority” means the New Mexico environment department.

UU. “RLD / LP Gas Bureau” means the New Mexico regulation and licensing department, LP gas bureau.

VV. “Secretary” means the secretary of New Mexico environment department or a designee.

WW. “Sewage” means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

XX. “THC” means delta-9 tetrahydrocannabinol (CAS number 1972-08-3) as measured using a post-decarboxylation method and based on percentage dry weight.

YY. “THCA” means tetrahydrocannabinolic acid (CAS number 23978-85-0).

ZZ. “Variance” means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this part if the regulatory authority determines that no hazard to human health or the environment will result from the modification or waiver.

[20.10.2.7 NMAC - N, 1/28/2020]

20.10.2.8 GENERAL PROVISIONS:

A. Prerequisite and Responsibility for Operation:

(1) A person may not operate a hemp facility without a valid permit to operate as issued by the regulatory authority.

(2) When more than a single hemp facility is operated on the premises, each one shall be separately permitted.

(3) When a food processing plant permitted by the regulatory authority also operates as a hemp facility, both operations shall be permitted separately.

(4) Except as otherwise provided, the permit holder shall be responsible for all hemp facility operations conducted on the premises for which a permit is issued.

(5) When multiple hemp facilities are permitted by multiple permit holders on the same premises, each permit holder shall only be responsible for the hemp facility operations within the scope of their permit.

(6) Each permit holder shall be responsible for shared facilities or equipment on the premises.

(7) The permit holder shall ensure that the hemp facility remains in compliance with this part and the act. A violation of any provision of this part or the act may result in civil or criminal proceedings authorized in law, including but not limited to the assessment of civil penalties, the suspension or revocation of permit(s), destruction of hemp products, or other such actions.

(8) The issuance of a permit does not relieve any person operating a hemp facility from the responsibility of complying with other applicable laws, ordinances and regulations.

B. Application, Plans, and Specifications Requirements:

(1) An applicant shall submit a written application for a permit, on a form provided by the regulatory authority, at least 30 calendar days prior to operating a hemp facility.

(2) An applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval at least 30 calendar days before:

(a) the construction of a hemp facility;

(b) the conversion of an existing structure for use as a hemp facility;

(c) the remodeling of a hemp facility or a change of type of hemp facility if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this part; or

(d) opening or changing ownership of an existing hemp facility, if current plans and specifications are not on file with the regulatory authority.

(3) It is the sole responsibility of the applicant to provide the regulatory authority with a complete permit application. The regulatory authority will not act on incomplete permit applications.

C. Operational Plans.

(1) Except as otherwise provided in paragraph (5) of this subsection, a hemp facility shall submit a written operational plan containing the following information, as applicable, for each product(s) to be extracted, manufactured and transported with the application for a permit:

(a) Planned source of hemp products.

(b) Names of the ingredient(s);

(c) The final product pH;

(d) The final product water activity (Aw);

(e) Names of preservative(s);

(f) The type of packaging to be used and whether the packaging is integral to product stability;

(g) The intended distribution and use condition 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 consumer;

(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 consumer;

(l) A description of the batch/lot ID coding system, as required in this section;

(m) The proposed recall plan;

(n) The complete operational procedure for the intended process, using a flow chart, and the following, if applicable:

(i) The proposed extraction method, and approval from RLD/LP Gas Bureau if utilizing propane or butane for extraction;

(ii) The proposed process for the removal of all harmful solvents used during the extraction process;

solvents;

(iii) The intended disposition for all unused hemp product and residual

dangers associated with extraction methods;

(iv) The safety measures proposed to protect the public and employees from

NMAC;

(o) Proposed product labels that comply with all requirements of 20.10.2. 13

(p) Proposed record keeping system to assure traceability of hemp products from harvest to hemp finished products; and

(q) Proposed pest control plan.

(2) Prior to adding new hemp products, or changing the stated process for any existing product in the product line, the hemp facility shall provide to the regulatory authority:

(a) For each new hemp product, the same information as specified for the initial application in this section; and

(b) For each existing product for which a change will be made in the manufacturing process, the applicable changes to the information previously submitted pursuant to this section.

(3) The regulatory authority may require that the hemp facility's processes be reviewed by an approved process authority to verify all critical factors of public health significance are addressed.

(4) Recall procedures shall be prepared for hemp products that may be adulterated, misbranded, or otherwise unsafe for human consumption and shall include:

(a) Plans for identifying products which may be adulterated or misbranded;

(b) Procedures for collecting, warehousing, controlling, reworking, and/or disposal of recalled products;

(c) System for determining the effectiveness of recalls; and

(d) Persons to contact when implementing a recall, including the regulatory authority.

(5) A hemp warehouse is exempt from the requirements of Paragraph (1) of Subsection C of this section, except hemp warehouses shall provide:

(a) Proposed pest control plan;

(b) If the product is to be stored at ambient, refrigerated or frozen temperature;

(c) Proposed record keeping system to assure traceability of hemp products from receipt to release;

(d) Proposed recall plan meeting the requirements specified in Paragraph (4) of this subsection; and

(e) If storing non-hemp products in the same warehouse as hemp products, a complete operational procedure outlining how hemp products will remain clearly identified, segregated from non-hemp products, and unadulterated during storage.

D. Fees, Penalty Fees, and Expiration Dates:

(1) Initial and renewal application fees are non-refundable and shall be:

(a) \$1000.00 for a hemp extraction facility;

(b) \$1000.00 for a hemp manufacturing facility;

(c) \$1000.00 for a hemp warehouse; and

(d) \$500.00 for a hemp processing facility.

(2) Application fees specified in Paragraph (1) of Subsection D of this section shall be paid upon submission of an initial or renewal application. Except as specified in Paragraph (5) of Subsection D of this section, application fees shall include all applicable costs associated with administration of a hemp facility permit.

(3) Permits issued pursuant to Subsection E of this section shall expire on the last day of the anniversary month of the date of original issue.

(4) The expiration of permits issued prior to January 28, 2020 shall be extended to the last day of the anniversary month of the date of original issue.

(5) When a re-inspection is scheduled by the regulatory authority a penalty fee of \$250.00 shall be assessed and paid by the permit holder prior to the re-inspection being conducted as specified in Subsection B of 20.10.2.16 NMAC or prior to the approval of a renewal application.

E. Permit Issuance, Permit Denial, Permit Renewal, and Change of Ownership:

(1) To qualify for a permit, an applicant shall:

hemp facility;
 requested information; and
 submitted;
 by the regulatory authority;
 demonstrates that the hemp facility is built or remodeled in accordance with the approved plans and specifications;
 and,
 order to retain the permit, shall:
 plans;
 employee or conditional employee as specified under Subsection A of 20.10.2.9 NMAC;
 imminent health hazard may exist as specified in 20.10.2.17 NMAC;
 specified in 20.10.2.11 and 20.10.2.16 NMAC;
 and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted;
 operation.
 request.
 appeal that are provided in law.

(a) be an owner of the hemp facility or an official authorized by the owner of a
 (b) comply with the requirements of this part and the act;
 (c) allow access to the hemp facility by the regulatory authority and to provide
 (d) pay the required fees as specified in Subsection D of this section.

(2) The regulatory authority shall issue a permit to the applicant after:
 (a) a properly completed application is submitted;
 (b) the required fee, as specified in Paragraph (1) of Subsection D of this section, is
 (c) the requirements specified in Subsections B and C of this section are approved
 (d) a preoperational inspection by the regulatory authority is conducted and
 (e) the hemp facility is in compliance with this part and the act.

(3) Upon acceptance of the permit issued by the regulatory authority, the permit holder, in
 (a) post the permit in a conspicuous location in the hemp facility;
 (b) comply with the provisions of this part, including the approved operational
 (c) immediately contact the regulatory authority to report an illness of a hemp
 (d) immediately discontinue operations and notify the regulatory authority if an
 (e) allow representatives of the regulatory authority access to the hemp facility as
 (f) replace existing facilities and equipment that comply with this part if:
 (i) the regulatory authority directs the replacement because the facilities
 (ii) the regulatory authority directs the replacement of the facilities and
 (iii) the facilities and equipment are replaced in the normal course of
 (g) comply with directives of the regulatory authority including time frames for
 (h) accept notices issued and served by the regulatory authority according to law.
 (i) be subject to the administrative, civil, injunctive, and criminal remedies
 (j) provide the most recent hemp facility inspection report to consumers upon

(4) If an application for a permit to operate is denied, the regulatory authority shall provide
 (a) the specific reasons or regulation citations for the permit denial; and
 (b) advisement of the applicant's right of appeal and the process and time frames for

(5) A permit may not be transferred. This includes a prohibition on transferring a permit
 from one person to another person, from one location to another location, or from one type of operation to another
 type of operation.

(6) The regulatory authority may issue a permit to a new owner of an existing hemp facility
 upon completion of requirements as specified in this subsection.

(7) The regulatory authority may renew a permit for a hemp facility upon submission of a
 renewal application provided by the regulatory authority and the required fee(s) as specified in Paragraph 1 of

Subsection D of this section.
[20.10.2.8 NMAC - N, 1/28/2020]

20.10.2.9 MANAGEMENT AND PERSONNEL:

A. Adoption of food code subparts 2-201, 2-301, and 2-401, and section 2-103.11. Except as otherwise provided, subpart 2-201, 2-301, and 2-401, 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 hemp facility 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 hemp facility. The procedures shall 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 permit holder 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 hemp facility during all hours of operation.

D. In a hemp facility with two or more separately permitted departments that are the legal responsibility of the same permit holder and that are located on the same premises, the permit holder may designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately permitted hemp facility on the premises.

E. The person in charge shall have the education, training, or experience necessary to supervise the production of clean and safe hemp product and ensure the hemp facility remains in compliance with this part and the act at all times.

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

[20.10.2.9 NMAC - N, 1/28/2020]

20.10.2.10 HEMP PRODUCT TRANSPORTATION REQUIREMENTS:

A. Hemp facilities shall only transport hemp product to NMED permitted hemp facilities or persons approved by the regulatory authority.

B. Except as provided in Subsections E and F of this section, hemp facilities shall create and utilize a hemp transportation manifest meeting the requirements of subsection C of this section when transporting hemp product.

C. A hemp transportation manifest created by a hemp facility shall contain the following information:

- (1) Name, address, phone number, and permit number of the hemp facility;
- (2) Name, address, and phone number of the person transporting the hemp product;
- (3) The hemp transportation unit's:
 - (a) year, make, model, and color (if applicable); and
 - (b) license plate number;
- (4) Batch/lot ID created by the hemp facility;
- (5) Item(s) description/composition of hemp product;
- (6) Quantity of hemp product;
- (7) Shipping date; and,
- (8) Destination of the hemp product, including the name, address, and phone number of the

person receiving the hemp product.

D. Hemp facilities transporting hemp finished products intended for human consumption or hemp products that will be utilized as ingredients in hemp finished products intended for human consumption shall transport such items under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container in accordance with the New Mexico Food Service Sanitation Act and the New Mexico Food Act.

E. Hemp facilities transporting small amounts of hemp to approved laboratories or research facilities in accordance with practices approved under this part and the Act shall have a hemp harvest certificate and a hemp transportation manifest containing the following information:

- (1) Batch/lot ID of the hemp product;
- (2) Item(s) description;
- (3) Origin and destination; and
- (4) Total volume/weight of each hemp product.

F. Hemp facilities transporting small amounts of hemp extract, hemp-derived material, or hemp finished product to approved laboratories or research facilities in accordance with practices approved under this part and the Act shall have a hemp transportation manifest containing the following information:

- (1) Batch/lot ID of the hemp product;
- (2) Item(s) description;
- (3) Origin and destination; and
- (4) Total volume/weight of each hemp product.

[20.10.2.10 NMAC - N, 1/28/2020]

20.10.2.11 HEMP FACILITY REQUIREMENTS:

A. After the effective date of this part and unless otherwise provided, it is illegal to operate a hemp facility which does not meet the requirements of this section.

B. Adoption of 21 CFR 117 Subparts A, B, and F. Except as otherwise provided, Subparts A, B, and F of the United States code of federal regulations, title 21, part 117 are hereby adopted and incorporated in their entirety.

C. 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 regulatory authority for official review and copying upon oral or written request.

D. Omissions. The following provisions are omitted from the incorporated subparts of 21 CFR 117:

- (1) 117.1;
- (2) 117.5;
- (3) 117.7;
- (4) 117.8;
- (5) 117.310;
- (6) 117.315(d);
- (7) 117.325; and
- (8) 117.335.

E. The current 21 CFR 111 and United States federal food, drug, and cosmetic act, title 21, chapter 9 are hereby adopted as a technical reference and interpretation guide.

F. Hemp and Hemp Product Source and Hemp Product Transportation.

(1) Hemp facilities shall not receive hemp without a hemp harvest certificate issued by NMDA or a person approved by the regulatory authority verifying the hemp being transported has a THC concentration of not more than three-tenths of one percent (0.30%) on a dry weight basis.

(2) Hemp facilities shall not receive hemp-derived material, hemp extract, or hemp finished product unless:

- (a) it is received from an NMED permitted hemp facility or a person approved by the regulatory authority;
- (b) it is accompanied by a hemp transportation manifest; and
- (c) hemp finished products intended for human consumption or hemp products that will be utilized as ingredients in hemp finished products intended for human consumption were transported under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container in accordance with the New Mexico Food Service Sanitation Act and the New Mexico Food Act.

G. Records and Traceability.

(1) Hemp facilities shall implement the approved record keeping system at all times and shall maintain traceability records for a period of two years.

(2) Hemp facilities shall maintain all shipping records and records of receipt for all hemp products for a period of two years, including but not limited to:

- (a) Hemp harvest certificate;
- (b) Hemp transportation manifest;
- (c) Date of receipt; and

(d) Certificate of analysis, if hemp finished product.

H. Hemp facilities shall maintain the operational plans and recall plan, accepted by the regulatory authority, onsite during all hours of operation and shall make them available for review by the regulatory authority.

I. The final disposition of all unused hemp product and residual solvents shall be conducted as approved by the regulatory authority in Subsection C of 20.10.2.8 NMAC.

J. The permit holder shall be responsible to ensure the security of, and limit access to, hemp-derived material with a THC concentration of greater than three-tenths of one percent (0.30%).

[20.10.2.11 NMAC - N, 1/28/2020]

20.10.2.12 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-hemp 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 hemp 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.

[20.10.2.12 NMAC - N, 1/28/2020]

20.10.2.13 HEMP FINISHED PRODUCT LABELING:

A. After the effective date of this part and unless otherwise provided, hemp finished products produced for:

(1) human consumption shall meet the applicable labeling requirements of 21 CFR 101 and the New Mexico Food Act; and

(2) absorption by humans shall meet the applicable labeling requirements of 21 CFR 701 and 740.

(3) inhalation by humans shall meet applicable state and federal labeling requirements.

B. In addition to the labeling requirements specified in Subsection A of this section, hemp finished products shall clearly identify on the principle display panel of the label:

(1) CBD content in the package and/or container, labeled in milligrams; and

(2) Total THC content in the package and/or container, labeled in milligrams.

C. In addition to the labeling requirements specified in Subsections A and B of this section, hemp finished products shall include the following statement on the label: "FDA has not evaluated this product for safety, effectiveness, and quality".

D. Unless otherwise approved, statements representing or inferring a hemp finished product contains no THC are prohibited.

E. Hemp facilities shall design, maintain and use a coding system that will identify the date and place of manufacture of each hemp product and shall be clearly visible on the product label or securely affixed to the body of the container.

F. Except as specified in paragraph (1) of Subsection D of 20.10.2.14 NMAC, product concentration and content stated on a hemp finished product label shall not deviate by more than ten percent of what is stated on the label.

G. Hemp finished products shall not contain medical, health, or benefit claims on the label.
[20.10.2.13 NMAC - N, 1/28/2020]

20.10.2.14 HEMP FINISHED PRODUCT TESTING:

A. After the effective date of this part and unless otherwise provided, hemp finished products that will be used for human consumption, absorption, or inhalation shall be tested by an approved laboratory and meet the requirements of this section before they leave the hemp facility and are transported, distributed, sold or otherwise made available to consumers.

B. Except as otherwise provided, each batch/lot of hemp finished product shall be tested as follows:

- (1) Cannabinoid profile, including at a minimum the concentration of the following:
 - (a) Total THC calculated as $THC = (0.877 \times THCA) + THC$;
 - (b) D9-THC;
 - (c) THCA;
 - (d) CBD; and
 - (e) CBDA;
- (2) Solvents (volatile organic compounds) utilized throughout the processing of the hemp product;
- (3) Content of CBD, total THC, and other compounds derived from hemp stated on the label of the hemp finished product; and
- (4) If dried usable hemp finished product:
 - (a) Water content;
 - (b) Total aerobic microbial count;
 - (c) Total combined yeast and mold count;
 - (d) Bile-tolerant gram-negative bacteria;
 - (e) Salmonella spp. and E. coli; and
 - (f) Total coliforms count.

C. Hemp processed or dried as a hemp finished product or hemp product that does not require further processing before being offered as a hemp finished product shall:

- (1) meet the requirements of this section for hemp finished product; and
- (2) be prepared for testing, as required in Subsection B of this section, as follows:
 - (a) Blending of the entire batch/lot prior to testing; or
 - (b) Tested in accordance with a testing plan approved by the regulatory authority.

D. Testing limits for hemp finished product shall be as follows:

- (1) Total THC concentration shall not exceed more than three-tenths of one percent (0.30%);
- (2) Solvents (volatile organic compounds) utilized throughout the processing of the hemp finished product shall not exceed the current United States Pharmacopeia recommended limits for residual solvents; and
- (3) If dried usable hemp finished product:
 - (a) Water content shall be less than fifteen percent by weight;
 - (b) Total aerobic microbial count shall be less than 100,000 colony forming units per gram (cfu/g) or colony forming units per milliliter (cfu/mL);
 - (c) Total combined yeast and mold count shall be less than 10,000 cfu/g or cfu/mL;
 - (d) Bile-tolerant gram-negative bacteria shall be less than 1,000 cfu/g or cfu/mL;
 - (e) Salmonella spp. and E. coli shall be absent in 10 grams cfu/g or cfu/mL; and
 - (f) Total coliforms count shall be less than 1,000 cfu/g or cfu/mL.

E. Hemp finished product that exceeds the testing limits specified in Subsection D of this section, or the testing results specified in Paragraph 3 of Subsection B of this section do not meet the requirements of Subsection E of 20.10.2.13 NMAC, may undergo a confirming test by a hemp laboratory. If the confirming test confirms the initial test results, the permit holder shall report the results to the regulatory authority within 24 hours.

F. Hemp finished products that exceed the testing limits specified in Subsection D of this section, or the testing results specified in Paragraph 3 of Subsection B of this section do not meet the requirements of Subsection E of 20.10.2.13 NMAC, shall not be distributed and shall be:

- (1) disposed of in an approved manner; or
- (2) re-worked in an approved manner.

G. Hemp finished product that is re-worked as specified in Paragraph 2 of Subsection F of this section shall meet requirements of this section before they are transported, distributed, sold or otherwise made available to consumers.

H. Hemp facilities shall obtain a certificate of analysis for each hemp finished product batch/lot from an approved laboratory. The certificate of analysis shall include the results of the required testing required in this section and shall include the following information:

- (1) The batch identification number;
- (2) The date received;
- (3) The date of testing completion;
- (4) The method of analysis for each test conducted; and
- (5) The signature of an authorized official of the hemp laboratory that guarantees the results of the laboratory's testing of a sample.

I. Hemp facilities shall provide the certificate of analysis with hemp finished products as follows:

- (1) If shipped to another business entity, the certificate of analysis for each hemp finished product shall be provided to the business entity; or
- (2) If shipped directly to the consumer, shall be provided to the consumer upon request.

[20.10.2.14 NMAC - N, 1/28/2020]

20.10.2.15 HEMP LABORATORIES: Testing required in 20.10.2.14 NMAC shall be conducted by an approved laboratory that has no direct ownership or financial interest in the hemp facility for which the testing is being conducted.

[20.10.2.15 NMAC - N, 1/28/2020]

20.10.2.16 INSPECTION BY REGULATORY AUTHORITY:

A. The regulatory authority shall conduct inspections of hemp facilities to determine compliance with the act, Food Service Sanitation Act, the New Mexico Food Act, and this part.

B. When an inspection conducted by the regulatory authority reveals a violation or repeat violation of this part, and a re-inspection is scheduled by the regulatory authority, a re-inspection penalty fee shall be assessed by the regulatory authority and paid by the operator as specified in Paragraph 5 of Subsection D of 20.10.2.8 NMAC.

C. After the regulatory authority presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the regulatory authority to determine if the hemp facility is in compliance with this part and the act by allowing access to the facility to make an inspection, interview employees, and take photos, and providing information and records requested and to which the regulatory authority is entitled according to law, during the hemp facility's hours of operation and other reasonable times.

D. The regulatory authority shall be allowed to copy any records pertaining to the manufacture, processing, packing, distribution, receipt, holding, or importation of hemp product maintained by or on behalf of a hemp facility in any format, including paper and electronic formats, and at any location. Proprietary documents shall be protected by the regulatory authority according to law.

E. If a person in charge denies access to the regulatory authority, the regulatory authority shall:

- (1) inform the person that:
 - (a) the permit holder is required to allow access to the regulatory authority as specified in Subsection F of this section;
 - (b) access is a condition of the acceptance and retention of a hemp facility permit to operate as specified in Paragraph 3 of Subsection E of 20.10.2.8 NMAC;
 - (c) if access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to law; and
 - (d) refusal to allow access is grounds for immediate permit suspension or

revocation; and

- (2) make a final request for access.

F. If after the regulatory authority presents credentials and provides notice as specified in Subsection C of this section, explains the authority upon which access is requested, and makes a final request for access as

specified in Subsection E of this section, the person in charge continues to refuse access, the regulatory authority shall provide details of the denial of access on an inspection report form.

G. If denied access to a hemp facility for an authorized purpose and after complying with Subsection E of this section, the regulatory authority may issue, or apply for the issuance of, an inspection order to gain access as provided in law.

H. The regulatory authority shall document on an inspection report form:

(1) Specific factual observations of violative conditions or other deviations from this part that require correction by the permit holder; and

(2) Time frame for correction of the violations observed and documented.

I. Except as otherwise provided, a permit holder shall at the time of inspection correct violations of this part.

J. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame.

K. After observing at the time of inspection a correction of a violation, the regulatory authority shall enter the violation and information about the corrective action on the inspection report.

L. As specified in Subsection J of this section, after receiving notification that the permit holder has corrected a violation, or at the end of the specified period of time, the regulatory authority shall verify correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

M. The regulatory authority shall request a signed acknowledgment of receipt and provide a copy of the completed inspection report and the notice to correct violations, as soon as possible after the inspection, to the permit holder or to the person in charge.

N. The regulatory authority shall inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in Subsection I of this section that:

(1) An acknowledgment of receipt is not an agreement with findings;

(2) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified;

(3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the regulatory authority's historical record for the hemp facility; and

(4) A final request to sign an acknowledgement receipt of inspectional findings will be made to the person in charge.

[20.10.2.16 NMAC - N, 1/28/2020]

20.10.2.17 CEASING OPERATIONS AND REPORTING:

A. Except as specified in Subsections B and C of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority 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 hempborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health, employees, or the environment.

B. A permit holder need not discontinue operations in an area of an establishment 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 regulatory authority may allow the permit holder 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;

(2) immediate corrective action is taken to eliminate, prevent, or control any food safety risk and imminent health hazard associated with the electrical or water service interruption; and

(3) the regulatory authority 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 permit holder shall obtain approval from the regulatory authority before resuming operations.

[20.10.2.17 NMAC - N, 1/28/2020]

20.10.2.18 PERMIT SUSPENSION AND REVOCATION:

A. The regulatory authority may immediately suspend a permit, without prior warning, notice of a hearing, or a hearing, if it determines through inspection, examination of employees, hemp product records, or other means as specified in this part, if:

- (1) an imminent health hazard exists; or
- (2) the permit holder:

(a) allows serious or repeated violations of the Food Service Sanitation Act, the New Mexico Food Act, the act, or this part;

(b) allows violations of this part to remain uncorrected beyond time frames for correction approved, directed, or ordered by the regulatory authority;

(c) violates any term or condition of a permit as specified under Paragraph 3 of Subsection E of 20.10.2.8 NMAC;

(d) fails to comply with Subsection C of 20.10.2.16 NMAC;

(e) fails to comply with a regulatory authority order issued concerning an employee or conditional employee suspected of having a disease transmissible through hemp products by infected persons; or

(f) fails to comply with a hold order as specified in Subsection A of 20.10.2.21 NMAC;

B. The regulatory authority shall provide written notice of the immediate suspension to the permit holder or person in charge.

C. After receiving a written request from the permit holder stating that the conditions cited in the immediate suspension notice no longer exist, the regulatory authority shall conduct a reinspection of the hemp facility for which the permit was summarily suspended.

D. A permit suspension shall remain in effect until the conditions cited in the immediate suspension notice no longer exist and their elimination has been confirmed by the regulatory authority through re-inspection and other means as appropriate as described in Subsection C of this section.

E. If a permit has been suspended more than one time, the regulatory authority may revoke the permit.

F. If a hemp facility fails to comply with an employee restriction order, an order to hold and not transport hemp product, or an immediate suspension notice, the regulatory authority may revoke the permit.

G. The regulatory authority shall conduct a hearing as specified in 20.10.2.19 NMAC prior to revoking a permit.

H. A permit that has been revoked shall not be considered for reapplication until the permit holder has demonstrated to the satisfaction of the regulatory authority that the hemp facility will comply with this part. [20.10.2.18 NMAC - N, 1/28/2020]

20.10.2.19 APPEAL HEARINGS:

A. A permit holder may request an appeal hearing to address concerns about the regulatory authority's denial of an application for permit, suspension or revocation of a permit, or an enforcement action taken by the regulatory authority. A hearing request does not stay the regulatory authority's immediate suspension as specified in Subsection A of 20.10.2.18 NMAC.

B. The permit holder shall submit a written hearing request to the secretary within 10 calendar days from the date of receipt of the denial of an application for permit, permit suspension, permit revocation, or enforcement action.

C. The written request for hearing as specified in Subsection B of this section shall contain the following information:

(1) A statement of the issue of fact for which the hearing is requested;

(2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact;

(3) A statement indicating whether witnesses will be utilized during the hearing; and

(4) The name and address of the respondent's or requestor's legal counsel, if any.

D. If the regulatory authority receives a hearing request within the required timeframe, the regulatory authority shall issue a notice of hearing. The secretary may designate a person to conduct the hearing and make a final decision or make recommendations for a final decision. The secretary's hearing notice shall indicate who will conduct the hearing and make the final decision.

E. A notice of hearing shall contain the following information:

(1) Time, date and place of the hearing;

(2) Purpose of the hearing;

(3) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in Subsection M of this section; and

(4) The consequences of failing to appear at the hearing.

F. In the appeal hearing, the burden of proof is on the person who requested the hearing.

G. A complete digital recording of a hearing shall be made and maintained as part of the regulatory authority's records.

H. The rules of civil procedure and the rules of evidence shall not apply, but a hearing shall be conducted so that all relevant views, arguments, and testimony are amply and fairly presented.

I. Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

J. The regulatory authority shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

K. Evidence shall be excluded that is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds, or on the basis of evidentiary privilege.

L. Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

M. Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

N. Documentary evidence may be received in the form of a copy or excerpt.

O. At the end of the hearing, the secretary shall decide and announce if the hearing record will remain open and for how long and for what reason it will be left open. Based upon the evidence presented at the hearing, the secretary shall sustain, modify, or reverse the action of the regulatory authority. The secretary's decision shall be by written order within 15 working days following the close of the hearing record. The decision shall state the reasons therefore and shall be sent by certified mail to the hearing requestor and any other affected person who requests notice. Appeals from the secretary's final decision are by Rule 1-075 NMRA.

P. The regulatory authority may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

Q. Respondents accepting a consent agreement pursuant to Subsection P of this section waive their right to a hearing on the matter.

R. Failure by the permit holder to appear at the hearing shall result in the secretary upholding the regulatory authority's initial decision which led to the permit holder's hearing request.

[20.10.2.19 NMAC - N, 1/28/2020]

20.10.2.20 REMEDIES: The regulatory authority may seek an administrative or judicial remedy to achieve compliance with the provisions of this part if a person operating a hemp facility:

A. fails to have a valid permit to operate a hemp facility as specified in Subsection A of Section 20.10.2.8 NMAC;

B. fails to comply with an employee restriction or exclusion order, an order to hold and not transport hemp product, or an immediate suspension notice issued by the regulatory authority as specified in Subsection A of 20.10.2.18 NMAC; or

C. denies the regulatory authority access to the premises of a hemp facility to:

(1) make an inspection, including taking photographs;

(2) examine and sample hemp products or other substances found on the premises; or

(3) examine and copy the records on the premises relating to hemp products as specified in

Subsection C of 20.10.2.16 NMAC.

[20.10.2.20 NMAC - N, 1/28/2020]

20.10.2.21 HOLDING, EXAMINATION, AND DESTRUCTION OF HEMP PRODUCTS:

A. The regulatory authority may place a hold order on hemp products in a permitted hemp facility that:

(1) originated from an unapproved source;

(2) may be adulterated, misbranded, or otherwise unsafe for human consumption, or not

accurately presented;

(3) are not labeled according to law;

(4) have a THC concentration of more than three-tenths percent, in hemp finished product; or

(5) are otherwise not in compliance with this part or the act.

B. If the regulatory authority has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the regulatory authority may remove the hemp products that are subject to the order to a place of safekeeping.

C. The regulatory authority may issue a hold order to a permit holder or to a person who owns or controls the hemp products, as specified in Subsection A of this section, without prior warning, notice of a hearing, or a hearing on the hold order.

D. If the suspected hemp products have been transported, the permit holder shall be given the opportunity to recall the hemp products voluntarily at the permit holder's expense.

E. If the permit holder refuses to recall the suspected hemp products, the regulatory authority may order a mandatory recall of the suspected hemp products at the permit holder's expense.

F. The hold order notice shall:

(1) state that hemp products subject to the order may not be used, sold, moved from the hemp facility, or destroyed without a written release of the order from the regulatory authority;

(2) state the specific reasons for placing the hemp products under the hold order with reference to the applicable provisions of this part and the hazard or adverse effect created by the observed condition;

(3) completely identify the hemp products subject to the hold order by the common name, the label information, a container description, the quantity, regulatory authority's tag or identification information, and location;

(4) state that the permit holder has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in 20.10.2.19 NMAC;

(5) state that the regulatory authority may order the destruction of the hemp products if a timely request for an appeal hearing is not received; and

(6) provide the name and address of the regulatory authority representative to whom a request for an appeal hearing may be made.

G. The regulatory authority shall securely place an official tag or label on the hemp products or containers or otherwise conspicuously identify hemp products subject to the hold order.

H. The tag or other method used to identify a hemp product that is the subject of a hold order shall include a summary of the provisions specified in Subsection F of this section and shall be signed and dated by the regulatory authority.

I. Except as otherwise provided, hemp products placed under a hold order may not be used, sold, served, or moved from the establishment by any person.

J. The regulatory authority may allow the permit holder the opportunity to store the hemp products in an area of the hemp facility if the hemp products are protected from subsequent deterioration and the storage does not restrict operations of the establishment.

K. Only the regulatory authority may remove hold order tags, labels, or other identification from hemp products subject to a hold order.

L. The regulatory authority may examine, sample, and test the hemp products in order to determine its compliance with the Food Service Sanitation Act, the New Mexico Food Act, the act, and this part.

M. When hemp products are found to be adulterated, misbranded, or otherwise unsafe for human consumption, or not accurately presented; or found in any room, building, vehicle of transportation or other structure, any hemp products which are unsound or contain any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the procedures outlined in Section 25-2-6 NMSA 1978 shall be followed.

N. When any product is found, by examination or laboratory analysis, to be in violation with this part or the act, the regulatory authority may order condemnation and disposal of the product lot, at the expense of the permit holder.

O. The regulatory authority shall issue a written notice of release from a hold order and shall remove hold tags, labels, or other identification from the hemp product if the hold order is vacated.

[20.10.2.21 NMAC - N, 1/28/2020]

20.10.2.22 SERVICE OF NOTICE:

A. A notice issued in accordance with this part shall be considered to be properly served if it is served by one of the following methods:

(1) The notice is personally served by the regulatory authority, a law enforcement officer, or a person authorized to serve a civil process to the permit holder, the person in charge, or person operating a hemp facility without a permit; or

(2) The notice is sent by the regulatory authority to the last known address of the permit holder or the person operating a hemp facility without a permit, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired.

B. An employee restriction or exclusion order, an order to hold and not transport hemp product, or an immediate suspension order shall be:

(1) served as specified in Paragraph (1) of Subsection A of this section; or

(2) clearly posted by the regulatory authority at a public entrance to the hemp facility and a copy of the notice sent by first class mail to the permit holder or to the owner or custodian of the hemp product, as appropriate.

C. Service is effective at the time of the notice's receipt or if service is made as specified in Paragraph (2) of Subsection B of this section, at the time of the notice's posting.

D. Proof of proper service may be made by affidavit of the person making service or by admission of the receipt signed by the permit holder, the person operating a hemp facility without a permit to operate, or an authorized agent.

[20.10.2.22 NMAC - N, 1/28/2020]

20.10.2.23 VARIANCES:

A. The regulatory authority may grant a variance by modifying or waiving the requirements of this part if the regulatory authority determines that no hazard to human health or the environment will result from the modification or waiver.

B. The person requesting a variance shall submit a written application on a form provided by the regulatory authority. The following information shall be provided by the person requesting the variance:

(1) A statement of the proposed variance;

(2) The applicable code citations from which the variance is requested;

(3) A detailed rationale for how the potential hazards to human health or the environment addressed by the applicable code citations will be alternatively addressed by the proposal; and

(4) If applicable, documentation supporting the rationale provided.

C. The regulatory shall grant the variance, grant the variance subject to conditions, or deny the variance within 15 working days following the receipt of the variance request.

D. If the regulatory authority grants a variance as specified in this section, the permit holder shall:

(1) comply with the procedures that were approved; and

(2) when required as a condition of the variance, maintain and provide to the regulatory authority, upon request, records that demonstrate compliance with the approved variance.

[20.10.2.23 NMAC - N, 1/28/2020]

HISTORY OF 20.10.2 NMAC:

20.110.2 NMAC, Hemp Extraction, Production, Transportation, Warehousing, and Testing, filed and effective August 1, 2019, duration expired by operation of law, January 27, 2020.