3796:3-2-01 **Processor operations and quality assurance.**

(A) A processor shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the processor as part of the application that was approved by the department. The operations plan shall include policies and procedures for the production, storage, inventory, and transportation of plant material, medical marijuana extract, and medical marijuana products. At a minimum, a facility's operations plan shall accomplish the following:

(1) Designate areas in the facility that are compartmentalized based on function, such as the marijuana extraction area, with restricted access between the different areas based on access credentials assigned by the facility;

(2) Implement policies and procedures that provide best practices for safe, secure, and proper processing of medical marijuana, which includes restricted movement between the different production areas by personnel;

(3) Establish training and safety policies and procedures to ensure that any person involved in processing medical marijuana:

(a) Has been fully trained in the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana, with supporting documentation of the training;

(b) Has been fully trained in the safe use, handling, and storage of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols, with supporting documentation of the training;

(c) Has been fully trained in the safe and sanitary execution of any applicable post-extraction refining protocols;

(d) Has been fully trained in the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter 901:3-1 of the Administrative Code;

(e) Has direct access to applicable material safety data sheets and labels;

(f) Has been fully trained regarding compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.

(4) Document the chain for all medical marijuana in the inventory tracking system;

(5) Establish sanitary operating procedures for the facility to be maintained in a clean and orderly condition, which includes free from infestation by rodents, insects, birds, and other animals of any kind; and

(6) Maintain a facility with adequate lighting, ventilation, temperature, sanitation, equipment, and security for the processing of medical marijuana.

(B) A processor shall acquire plant material from a cultivator or dispensary licensed under Chapter 3796. of the Revised Code. Plant material may only be acquired from a dispensary under the following conditions:

(1) The plant material has reached or exceeded the expiration date listed on the label;

(2) The plant material shall be processed into medical marijuana extract for use in the manufacture of medical marijuana products;

(3) The plant material acquired from the dispensary shall not be combined with other batches of plant material during processing;

(4) The medical marijuana products manufactured using the plant material shall not be identified as or associated with the brand, cultivator, or processor that originally packaged and sold the plant material to the dispensary; and

(5) The medical marijuana products manufactured using the plant material shall be subject to laboratory testing pursuant to rule 3796:3-2-06 of the Administrative Code.

(C) A processor may only use the methods, equipment, solvents, and gases set forth in this paragraph in the manufacture of medical marijuana products.

(1) A processor may use hydrocarbon solvent-based extraction methods in a spark-free and properly ventilated environment, isolated from any open flame or ignition source, and may use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade, closed-loop extraction system designed to recover the solvents:

(a) Propane;

(b) N-butane;

(c) Isobutane;

(d) Heptane; or

(e) Other solvents exhibiting minimal potential toxicity to humans with the approval of the department.

(2) A processor may use carbon dioxide-based extraction methods using food grade carbon dioxide at a minimum of ninety-nine per cent purity in a professional

grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.

(3) A processor may use ethanol at a minimum of ninety-nine per cent purity to produce extracts for use in the manufacture of medical marijuana products.

(4) A processor may use food grade glycerin and propylene glycol in the manufacture of medical marijuana products.

(5) A processor may use non-solvent extraction methods involving the mechanical separation of cannabinoids from plant material to produce medical marijuana extracts for use in the manufacture of medical marijuana products.

(6) A processor may use non-marijuana ingredients in the manufacture of medical marijuana products that meet the following conditions:

(a) The non-marijuana ingredients must be obtained from licensed and regulated sources that comply with the requirements of federal and state laws and regulations;

(b) The non-marijuana ingredients are nontoxic and safe for human consumption; and

(c) The non-marijuana ingredients were not prepared or stored in a private residence.

(7) A processor shall comply with all applicable OSHA regulations as well as comply with and pass inspection for any applicable fire, safety, and building codes pertaining to the use and storage of the equipment and solvents used in the manufacture of medical marijuana products.

(D) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one individual to train and supervise employees in the use of extraction equipment and associated solvents who has earned, at minimum, a Bachelor's Degree in engineering or physical sciences from an accredited university, or who has at least three years of experience in the operation of the equipment being used in the facility or similar equipment.

(E) A processor shall submit, as part of the application process, and maintain an operations plan and quality control plan for the processing of medical marijuana in its facility. The purpose of these plans is to ensure a safe, consistent product supply and minimize the deviation in quality of the production lots of medical marijuana products

(1) A processor shall submit to the department any proposed changes to its plans approved as part of its application submitted under rule 3796:3-1-02 of the

Administrative Code.

(2) The department shall review and approve or reject the proposed changes before the proposed changes can be made.

(F) A processor shall maintain a facility in the following manner:

(1) A processor shall keep all floors and benches free of debris, dust, and any other potential contaminants, and shall control rodents and other pests.

(2) A processor shall use chemicals, cleaning solutions, and other sanitizing agents approved for use around vegetables, fruit, medicinal plants, or food contact surfaces, and shall store them in a manner that protects against contamination.

(3) A processor shall keep its equipment in a clean environment and maintain a cleaning and equipment maintenance log at the facility.

(4) The processor shall have its scales, balances, or other weight and/or mass measuring devices routinely calibrated using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least once each calendar year, by an independent third party approved by the department.

(5) The water supply shall be derived from a source that is compliant with rule 901:3-1-05 of the Administrative Code.

(6) A processor shall implement policies and procedures related to receiving, inspecting, transporting, segregating, preparing, packaging, and storing plant material, medical marijuana extract, and medical marijuana products in accordance with adequate sanitation principles.

Effective:

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