

230-RICR-80-05-4

TITLE 230 – DEPARTMENT OF BUSINESS REGULATION

CHAPTER 80 – MARIJUANA

SUBCHAPTER 05 – MEDICAL MARIJUANA

PART 4 – Minimum Requirements for Departmental Approval of Volatile Solvent-Based Hydrocarbon Extraction Operations

4.1 Authority

This Part is promulgated in accordance with R.I. Gen. Laws § 21-28.6-1, *et seq.*, and supplements the Rules contained in § 1.6.10 of this Subchapter.

4.2 Purpose

The purpose of this Part is to supplement the requirements contained in the Manufacturing and Extraction Regulations promulgated by the Department of Business Regulation in § 1.6.10 of this Subchapter by articulating the minimum standards for Volatile Solvent-Based Hydrocarbon Extraction of Marijuana and the two (2) phase application process for obtaining the Department’s required approval to begin Volatile Solvent-Based Hydrocarbon Extraction operations.

4.3 Definition

A. In addition to the terms defined in R.I. Gen. Laws § 21-28.6-3 and Part 1 of this Subchapter, for this Part 4 the following terms shall have the corresponding meanings:

1. “Closed-loop system” means machinery in which the volatile hydrocarbon substances are self-contained without the loss/escape of said substances.
2. “Design plans” means all relevant engineering and/or architectural graphics, blueprints, construction phasing schedules, or any other documentation produced or relied upon by the Rhode Island Registered Professional Engineers and Registered Architects, as applicable, identified in §§ 4.5(B)(1)(e) and 4.5(D)(1) of this Part.
3. “Final certification” means the ultimate approval given by the Department to a Licensee which is required prior to commencing Volatile Solvent-Based Hydrocarbon Extraction operations.
4. “Standard operating procedures” or “SOPs” means step-by-step instructions which explain the order of tasks required to safely and properly conduct a specific activity.

5. "Volatile hydrocarbon substances" are those likely to change into gases and, pursuant to § 4.4(B)(2) of this Part and for the purposes of this Part, are limited to butane, propane, ethanol, or a different volatile hydrocarbon substance which is preapproved by the Office of Cannabis Regulation.
6. "Volatile solvent-based-hydrocarbon extraction" means a manufacturing process in which a volatile hydrocarbon substance, as permitted in § 4.4(B)(2) of this Part, is combined with Marijuana within pre-approved machinery to produce Marijuana Concentrate.

4.4 Requirements for Volatile Solvent-Based Hydrocarbon Extraction

- A. Except where expressly prohibited by R.I. Gen. Laws § 21-28.6-16(h), eligible licensees may submit applications to the Department, on forms prescribed by the Department pursuant to § 4.5 of this Part, for the implementation and use of Volatile Solvent-Based Hydrocarbon Extraction machinery subject to the requirements contained in this Part and all applicable zoning, building, fire, testing, workplace safety laws, Regulations, ordinances, court orders, and/or as otherwise legally required. All Volatile Solvent-Based Hydrocarbon Extraction Applications must demonstrate compliance with all applicable requirements including but not limited to the operational requirements contained in § 4.4(B) of this Part.
- B. All Volatile Solvent-Based Hydrocarbon Extraction manufacturing shall:
 1. Be a Closed-Loop System;
 2. Utilize the following permissible Volatile Solvent-Based Hydrocarbon Extraction Substances and be accompanied by a Certificate of Analysis, maintained in accordance with § 4.6(A)(5) of this Part, which establishes that said substances have a minimum purity level of ninety-nine percent (99.0%):
 - a. Butane;
 - b. Propane;
 - c. Ethanol; or
 - d. A different volatile hydrocarbon substance which is preapproved by the Office of Cannabis Regulation.
 3. Be conducted by employees adequately trained in the operation of the Hydrocarbon Extraction machinery to be utilized; and
 4. Follow preapproved Standard Operating Procedures ("SOPs") in accordance with § 4.6 of this Part;

- C. All final products created or partially produced via Volatile Solvent-Based Hydrocarbon Extraction must satisfy testing requirements contained in Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana, 216-RICR-60-05-6.

4.5 Volatile Solvent-Based Hydrocarbon Extraction Applications

- A. The Department's approval process for Volatile Solvent-Based Hydrocarbon Extraction applications shall consist of:
1. A Pre-Approval Phase, wherein the Department issues a letter stating that the applicant may proceed with implementing its proposed Volatile Solvent-Based Hydrocarbon Extraction system; and
 2. A Final Approval Phase, wherein the Department approves an applicant to commence Volatile Solvent-Based Hydrocarbon Extraction operations.
- B. Pre-Approval
1. Licensees eligible to perform Volatile Solvent-Based Hydrocarbon Extraction may apply to the Department on forms prescribed by the Department which include but not limited to the following:
 - a. The licensed facility address and identification of the specific location within the facility at which the Volatile Solvent-Based Hydrocarbon Extraction machinery will be utilized;
 - b. The manufacturer(s) of any and all Volatile Solvent-Based Hydrocarbon Extraction equipment intended to be utilized;
 - c. The model(s) of any and all Volatile Solvent-Based Hydrocarbon Extraction equipment intended to be utilized;
 - d. Copies of the User Manual(s) for any and all Volatile Solvent-Based Hydrocarbon Extraction equipment intended to be utilized;
 - e. Design Plans stamped and sealed by Rhode Island Registered Professional Engineer(s) and a Rhode Island Registered Architect, where applicable, who will ultimately provide a Final Certification pursuant to § 4.5(D)(1) of this Part, for any and all modifications and/or additions to the Licensee's facility including but not limited to:
 - (1) A written summary of any and all modifications and/or additions which would be made to the facility prior to the utilization/implementation of any and all Volatile Solvent Based Hydrocarbon Extraction equipment.

- (2) The identification of all Volatile Solvent-Based Hydrocarbon Extraction equipment intended to be installed;
 - (3) The identification of all other related equipment and/or hardware (e.g., hazardous materials storage, signage, plumbing, electrical, mechanical, etc.);
 - (4) Compliance with all applicable Fire Safety Code (R.I. Gen. Laws Chapter 23-28.1 and RICR Title 450) and Building Code requirements (R.I. Gen. Laws Chapter 23-27.3 and RICR Title 510) including a description of all changes to electrical, fire safety, and/or HVAC system(s), structural modifications, etc.; and
 - (5) Any and all other related additions/modifications/changes made to Licensee's facilities.
- f. Copies of all Standard Operating Procedures for the safe and proper utilization of the Volatile Solvent-Based Hydrocarbon Extraction machinery pursuant to § 4.6(A) of this Part; and
- g. A letter from the city or town zoning official stating that the proposed Volatile Solvent-Based Hydrocarbon Extraction method(s) is permitted for the intended facility location.
2. The Department will review all required pre-approval applications and may conduct an inspection of the proposed location/facilities for hydrocarbon extraction.
3. Upon the Department's determination that the requirements in § 4.5(B)(1) of this Part have been satisfied, the Department may issue a Pre-Approval Letter to the Applicant.
- C. An Applicant which obtains Pre-Approval from the Department pursuant to this Part must promptly notify the Department of any material deviations between the Pre-Approved Design Plans and the actual implementation of the Pre-Approved Design Plans. The Department reserves the right to revoke the Pre-Approval if the material deviations substantially change the nature and/or scope of the Design Plans and/or if the material deviations could have a negative impact upon public health, welfare, and/or safety.
- D. Final Approval: An eligible licensee which has obtained the Department's Pre-Approval and has implemented the facility modifications pursuant to the Design Plan may apply for Final Approval on forms prescribed by the Department which include but are not limited to the following requirements:
 1. A Final Certification from the Rhode Island Registered Professional Engineer(s) and Rhode Island Registered Architect(s), as applicable, who

approved the Design Plans identified in § 4.5(B)(1)(e) of this Part stating that the implementation of Design Plans was materially consistent with said Design Plans;

2. A letter from the State Fire Marshal, or her or his designee, stating that she or he has conducted a final inspection of the facility changes and that the Licensee has demonstrated compliance with all applicable Fire Codes and/or Regulations; and
3. A certificate of use and occupancy, or equivalent document, from the local building official that all permits have been closed as applicable.

E. Upon the Department's determination that the requirements of this Part have been satisfied, the Department may issue a Final Approval Letter.

4.6 Standard Operating Procedures

A. All licenses conducting Volatile Solvent-Based Hydrocarbon Extraction shall develop Standard Operating Procedures ("SOPs") which demonstrate compliance with all applicable laws and Regulations and specifically address the following:

1. Safe and proper operation of the Volatile Solvent-Based Hydrocarbon Extraction substances, machinery, and/or equipment;
2. Safe and proper handling and storage of Volatile Hydrocarbon Substances.
3. Adequate cleaning and maintenance of the Volatile Solvent-Based Hydrocarbon Extraction machinery and/or equipment;
4. Incident reporting for instances where the operator does not follow the stated SOPs which identifies:
 - a. The operator's name;
 - b. The date and time of the incident;
 - c. To which supervising employees the incident report will be sent; and
 - d. An incident summary including whether any Marijuana or other substances escaped from the Volatile Solvent-Based Hydrocarbon Extraction machinery and/or was destroyed and, if so, the amount(s) of said material and how the incident was resolved.

5. How to safely and properly dispose of any waste created in the operation of the Volatile Solvent-Based Hydrocarbon Extraction equipment and/or in preparation or clean-up of said equipment; and
6. Record-keeping of:
 - a. All Volatile Solvent-Based Hydrocarbon Extraction substances and the corresponding Certificates of Analysis demonstrating sufficient purity pursuant to § 4.4(B)(3) of this Part; and
 - b. The Certificates of Analysis for all Volatile Solvent-Based Hydrocarbon Extraction Substances.
 - c. All Incident Reports and related materials/documentation.
- B. Standard Operating Procedures for Volatile Solvent-Based Hydrocarbon Extraction shall be included in the Licensee's Operations Manual pursuant to § 1.6.6 of this Subchapter.
- C. Standard Operating Procedures and all records relating to the requirements of this Part shall be maintained by the Licensee for a minimum of five (5) years. All records shall be readily available to the Department upon request.

4.7 Compliance with Applicable Laws

Compliance with these Regulations does not absolve Applicant/Licensee of any other legal requirements and/or responsibilities.

4.8 Severability

If any section, term, or provision of this Regulation is adjudged invalid for any reason, all remaining sections, terms, and provisions shall remain in full force and effect.