maine OFFICE OF CANNABIS POLICY
DEPARTMENT OF ADMINISTRATIVE AND FINANCIAL SERVICES

Maine Medical Use of Cannabis Program
Inherently Hazardous Substances Manufacturing Facility Registration Certificate Application

An applicant for authorization for medical cannabis extraction using inherently hazardous substances (IHS) must apply for an inherently hazardous substances manufacturing facility registration certificate using this form.

This IHS Manufacturing Facility Registration Certification will not be issued prior to the applicant's caregiver registry identification card or dispensary registry certificate being issued.

Section 1. Applicant information. Caregiver applicants complete Section 1(a) only. Dispensary Applicants complete Section 1(b) only.			
Section 1(a). Caregiver Applicants. Complete this section to apply for an IHS Manufacturing Facility Registration Certificate with a caregiver registry identification card.			
Applicant's Legal Name:	DOB:	Caregiver Registration: CGR	
Trade Name/DBA: (if applicable)	Website: (if applicable)		
Applicant Phone:	E-mail Address:		
Mailing Address:	City:	State:	Zip:

Section 1(b). Dispensary Applicants. Complete this section to apply for an IHS Manufacturing Facility Registration Certificate with a dispensary registry certificate. You must apply with the same legal name as dispensary registry certificate.			
Business Legal Name:	Federal EIN:	Dispensary Registration: DSP	
Trade Name/DBA: (if applicable)	Website: (if applicable)		
Primary Contact Name:	Title/Relationship to Applicant:		
Phone:	E-mail Address:		
Mailing Address:	City:	State:	Zip:

Section 2. Inherently hazardous substance manufacturing facility premises information.	
Section 2(a). Location where IHS manufacturing activities will be conducted. The address provided in this section must match the address provided in Section 2 of the Inherently Hazardous Substances Manufacturing Facility Local Authorization Form.	
Physical Address:	Municipality:
Property Owner Name:	Property Owner Phone:
Is the premises at least 500 feet from the property line of any preexisting public or private school? ☐ Yes ☐ No	

Section 2(b). Facility diagram of premises where IHS manufacturing activities will be conducted.

Provide a facility diagram with sufficient detail and clarity to indicate the following:

- A floor plan showing the proposed size (in square feet) and layout of the registered premises, including an indication of the primary activities to be conducted in each area of the registered premises;
- An indication of where solvents, chemicals and inherently hazardous substances will be stored;
- An indication of where waste containing cannabis will be stored;
- An indication of all external windows and doors;
- An indication of all points of ingress and egress within the registered premises;
- An indication of any areas of the registered premises open to qualifying patients, caregivers, or the public;
- An indication of the location of all security measures required by 18-691 CMR, ch. 4, including:
  - Exterior lighting sufficient to deter nuisance activity and facilitate surveillance;
  - Access-control-card system;
  - Actively monitored alarm system;
  - Security cameras at all access points to the premises and storage areas containing cannabis;
  - Visitor arrival and departure log;
  - Any other interior or exterior security devices;

Section 2(c). Other uses of premises where IHS manufacturing activities will be conducted.

Is the property where IHS manufacturing activities will be conducted also used as a residence? ☐ Yes ☐ No

If yes:

- Indicate on the facility diagram provided for Section 2(b) the location of that residence within the property and the location of the entirely separate entrance from a public right of way;
- Will IHS extraction occur in the same building or structure where the residence is located? ☐ Yes ☐ No

Will IHS manufacturing activities be co-located with applicant's caregiver or dispensary activities? ☐ Yes ☐ No

If yes:

- Which authorized caregiver or dispensary activities will be conducted at this premises?
  - ☐ Cultivation activities.
  - ☐ Manufacturing activities other than IHS manufacturing.
  - ☐ Manufacturing edible cannabis products.
  - ☐ Transfer, donation and/or sale of medical cannabis, concentrate and products to patients.
  - ☐ Operation of a retail store.
  - ☐ Purchase, sale or other transfer of wholesale cannabis.
- Indicate on the facility diagram provided for Section 2(b) the location of the authorized caregiver/dispensary activities.
- How will applicant distinguish between the cannabis authorized to possess with caregiver or dispensary registration and the up to 40 pounds of harvested cannabis authorized with this certificate?

Is this IHS Manufacturing Facility co-located with an Adult Use Products Manufacturing Facility? ☐ Yes ☐ No

If yes:

- Indicate which adult use establishment: Adult Use Establishment Licensee Name:
  Adult Use Establishment License Number: AMF
- Indicate on the facility diagram provided for Section 2(b) the location of the adult use activities.
- Describe the plans to ensure that all cannabis, concentrate and other cannabis products are correctly packaged and labeled for medical use or adult use:
- Describe the plans to separately track, including input to the tracking system, cannabis, cannabis concentrate and cannabis products for medical use separately from adult use and will otherwise keep them from becoming intermixed:
- Describe how the licensee will ensure that each piece of equipment is not used simultaneously on medical cannabis and adult use cannabis, with the purpose of ensuring that medical and adult use cannabis, cannabis concentrate, and other cannabis products will remain separate:

Section 3. Inherently hazardous substances manufacturing facility activities.

Section 3(a). Inherently hazardous substances and equipment to be used.

Indicate which inherently hazardous substances are to be used:

- ☐ Butane
- ☐ Propane
- ☐ Acetone
- ☐ Heptane
- ☐ Pentane
- ☐ CO_2
- ☐ Other liquid chemical, compressed gas, or commercial product with a flash point at or below 100°F
  Which other liquid chemical, compressed gas, or commercial product:

I understand that I am only permitted to perform IHS extraction using a 99% or greater purity of the solvent(s) indicated in this section.

☐ Agree ☐ Disagree

I understand that all flammable gas that must be odorized in compliance with state and federal regulations is.

☐ Agree ☐ Disagree

List all equipment to be used to conduct manufacturing activities using IHS, including UL or other safety listing:

List of all safety and personal protective equipment to be used on the premises:

Section 3(b). Facility Management.

Manufacturing Facility Director. An IHS manufacturing facility must designate a manufacturing facility director*.
*If the applicant is an individual applying in connection with a caregiver registration, the caregiver must be the manufacturing facility director.

Legal Name:	RIC or CGR Number: RIC or CGR

Principal Officer(s). An IHS manufacturing facility that will employ more than 5 assistants, must designate a Principal Officer, and may designate more than one if desired, who cannot also be the Manufacturing Facility Director.

Legal Name:	RIC Number: RIC
Legal Name:	RIC Number: RIC

Additional Person(s)-in-Charge. An IHS manufacturing facility must at all times have a person-in-charge, present on the premises of the facility during hours of operation or apparent activity, who can cooperate with any inspection, on-site assessment or complaint response. The facility may designate other Person(s)-in-Charge for times the Manufacturing Facility Director or Principal Officer(s) are not on site.

Do you wish to name any additional persons-in-charge? ☐ Yes ☐ No

If yes:

Legal Name:	RIC Number: RIC
Legal Name:	RIC Number: RIC
Legal Name:	RIC Number: RIC

Additional Key Personnel. An IHS manufacturing facility must identify key personnel in the organization who will be engaging in extraction using IHS. If there are key personnel who will be engaging in extraction using IHS not already listed in this Section, list those individuals here.

Legal Name:	RIC Number: RIC
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Legal Name:	RIC Number: RIC

Section 3(c). Public safety.

Will qualifying patients, caregivers, caregiver assistants, dispensary assistants or the public be allowed on the premises?
☐ Yes ☐ No

If yes:

- Indicate on the facility diagram provided for Section 2(b) any areas open to qualifying patients, caregivers, caregiver assistants, dispensary assistants, or the public.
- Describe safety measures to protect the health and safety of these visitors:

Section 3(d). Waste disposal.

Indicate how cannabis waste will be rendered unusable and indistinguishable from non-cannabis waste:
☐ by breaking up, ☐ by grinding, ☐ by unpackaging, or ☐ by combining and mixing with other solid waste
Identify other solid waste to be used:

Section 3(e). Additional requirements for a renewal application.

Annual revenue for the last fiscal year:

Provide the following numbers for the last year: (date of license issuance to date of renewal):

The number of samples tested by a cannabis testing facility:

The number of samples that failed testing standards:

The number of batches destroyed:

The number of batches remediated:

Provide the results of the annual internal audit conducted by the manufacturing facility:

If a report was created with the annual internal audit, you may attach a copy of that report.

Section 3(f). Required documents.

In accordance with 18-691 CMR, ch. 4, the applicant must provide, at a minimum, the following documents with this application form.

- Certification by a professional engineer licensed in the State of Maine pursuant to 32 MRS, chapter 19 of the safety and location of the professional grade closed loop equipment used for cannabis extraction and the professional engineer's approval of the standard operating procedures for the cannabis extraction;
- Certification by a professional engineer licensed in the State of Maine pursuant to 32 MRS, chapter 19, or a State or authorized local official, that the equipment used for cannabis extraction and the location of the equipment comply with state law and all applicable local and state building codes, electrical codes and fire codes, including the chapters of the most recent National Fire Protection Association Fire Code relating to cannabis extraction facilities;
- Documentation from the manufacturer of the cannabis extraction system, or certification by a professional engineer licensed in the State of Maine, showing that a professional grade, closed-loop extraction system that is capable of recovering the solvents used to produce cannabis concentrate is being used by the applicant;
- A Maine Medical Use of Cannabis Program Inherently Hazardous Substance Manufacturing Local Authorization Form from the municipality where the applicant's registered premises will be used is located;
- If property owner is other than the applicant, a copy of the lease agreement between the applicant and the property owner.

In accordance with 18-691 CMR, ch. 4 (the Rule), the applicant must have the following documents on site and available on demand of the Department for inspection. If this is an application for renewal, only check the box of the documents below have been modified in the last year.

Standard Operating Procedures. The facility must maintain standard operating procedures that are easily accessible to on-site personnel for each product or concentrate it manufactures. Standard operating procedures should include, at a minimum:

☐ Step-by-step instructions of each required process to manufacture cannabis concentrate or cannabis products, including but not limited to methods, use of equipment in accordance with manufacturer's instructions, and applicable sanitary rules and safety measures;

☐ Detailed instructions to conduct all necessary safety checks prior to commencing production;

☐ Detailed instructions to prepare cannabis for manufacturing;

- ☐ Detailed instructions to extract cannabinoids and other essential comments of cannabis;
- ☐ Detailed instructions to purge any solvent or other unwanted components from a cannabis concentrate;
- ☐ Detailed instructions to clean all equipment, counters and surfaces thoroughly;
- ☐ Policies and procedures developed in accordance with the security requirements of the Rule, Section 6;
- ☐ Emergency response procedures, including in case of a fire, chemical spill or other emergency;
- ☐ Inventory control procedures for preventing unlawful diversion of cannabis products and concentrates and for tracking the amount of cannabis in possession of the facility, which includes tracking and reporting weight and/or count;
- ☐ Waste management procedures in compliance with the Rule, Section 13;
- ☐ Policies and procedures for taking cannabis samples for required testing specified in the Rule, Section 10;
- ☐ Defined responsibilities of key personnel in the organization who have a management role; and
- ☐ Policies and procedures to ensure the protection of its qualifying patients' confidential information, including procedures for protecting the electronic storage of confidential information.

Director, Principal Officers, and Personnel Qualifications, Training and Supervision Documentation Requirements

- ☐ Documentation that the facility director, principal officers and personnel meet the employment requirements of the Rule;
- ☐ Documentation of responsibilities, training and supervision requirements of the Rule, Sections 7.1 and 7.4;
- ☐ Policies and procedures for identifying training needs and providing training of personnel;
- ☐ Training documentation on equipment, techniques, standard operating procedures and security protocols; and
- ☐ Training documentation in ethical and legal responsibilities.

☐ Educational materials related to the cannabis product or concentrate, and any solvents used by the facility, that meets the requirements of the Rule, Section 8.3.

Section 4. Affirmations.

I,__ _____, affirm that the entire Maine Medical Use of Cannabis Program Inherently Hazardous Substances Manufacturing Facility Registration Certificate Application, statements, attachments, and supporting documents are true and correct to the best of my knowledge and belief, and that this statement is executed with the knowledge that misrepresentation or failure to reveal information requested may be deemed good cause for denial to issue an Inherently Hazardous Substances Manufacturing Facility Registration Certificate by the Department.

I understand and acknowledge that the applicant and its agents, officers, directors and employees are responsible for knowing and complying with all state laws and rules governing the Maine Medical Use of Cannabis Program.

I understand the Department does not mail out a renewal application; and therefore, I am responsible for obtaining and submitting an application to renew my certification no less than 60 days prior to its expiration.

I understand that IHS Manufacturing Facility Registration Certificates are valid for one year from the date of issuance and shall be renewed on forms provided by the Department.

I understand that if I allow the IHS Manufacturing Facility Registration Certificate to expire for even one day and then reapply, I must submit a new application along with another annual fee.

I understand I am responsible for notifying the Office of Cannabis Policy, in writing, upon any change in mailing address, phone number or email address, since all correspondence will be sent to my last known address or email address. Failure to notify the Office of Cannabis Policy could result in not receiving my physical registry identification certificate and other correspondence.

I understand that any change in physical address of the facility must be reported to the Department at least 30 days before such relocation.

I understand that a change in officers or directors, facility director or principal officer(s) must be reported to the department within 3 days.

I understand that I may employ assistants to assist in performing the duties of the facility and they must be registered with the State of Maine, Office of Cannabis Policy in accordance with state law.

I understand that I am prohibited from modifying equipment after a professional engineer certifies the equipment as approved in writing by the engineer.

I understand that use of unauthorized solvents by the registrant may result in an immediate revocation of registration.

I understand that I must maintain records of all transfers, inventory, transactions and chain of custody forms for a minimum of one year and all records must be made available to the Department upon request.

I understand I must conduct an internal audit at least once per year in accordance with 18-691 CMR, ch. 4, Section 5.2.2, reporting any material deficiencies and non-complaint findings to the Department along with a plan of correcting deficiencies and gaining compliance.

I agree to abide by packaging, labeling and marketing requirements of 18-691 CMR, ch. 4, Section 8.

I understand that an IHS Manufacturing Facility Registration Certificate issued by the Office of Cannabis Policy is a revocable privilege, and that the burden of proving an Applicant's qualifications for an IHS Manufacturing Facility Registration Certificate rests at all times with the Applicant.

I understand that I may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

Section 5. Fees. This application will not be considered complete until the annual fee is remitted by the applicant.

Annual Fee: **$350.00**

Cash and personal checks are <u>not</u> accepted by the Office of Cannabis Policy. Please submit a cashier's check or money order made payable to "Treasurer, State of Maine." Include name and license number, if applicable, on the payment.

All fees are non-refundable.

Section 6. Acknowledgement and signature. This application must be acknowledged and signed by the applicant, if the applicant is an individual, or by an agent of the applicant who is authorized to represent and legally bind the applicant, if the applicant is a business entity.

I understand and agree to provide documents, if requested, to clarify or support information provided in this application and supporting documents. I understand and agree that federal, state and local officials or other persons and organization may verify the information I have given, except as limited by the confidentiality provisions of 22 MRS § 2425-A. I agree that I have read and understand the affirmations provided above in Section 4.

Signature:	Date:
Printed Name and Title:	