This is **Exhibit "I"** referred to in
the Affidavit of **TODD CAIN**
Affirmed before me at the City of
Ottawa, in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Sherri Laureen Szabados, a Commissioner, etc.,
Province of Ontario, for the Government of Canada,
Department of Health.
Expires December 2, 2015

Controlled Substances Program

STANDARD OPERATING PROCEDURE

Conducting the Initial Inspection of a Licensed Producer under the *Marihuana for Medical Purposes Regulations*	**Doc. Number: CS-SOP-022** **Version:** 1

Bureau/Office/Area: OCS & RAPB	**Status:** DRAFT	**Effective Date:**

Approved by:	**Date: March**, 2014

The Office of Controlled Substances ensures that precursors and controlled substances are handled effectively and remain in legal distribution channels. This involves developing legislation, regulations, policies and implementing operations that support the control of illicit drugs and other substances.

The regional Controlled Substances Program is the compliance and enforcement arm of the Office of Controlled Substances, who conducts compliance and monitoring activities to enforce the *Controlled Drugs and Substances Act* (CDSA) and its associated regulations including but not limited to the *Precursor Control Regulations*, the *Narcotic Control Regulations*, and the *Marihuana for Medical Purposes Regulations* (MMPR).

Inspectors conduct on-site inspections of regulated parties who perform activities such as importation, production and distribution of narcotics, targeted substances, restricted drugs, marihuana for medical purposes, industrial hemp, controlled drugs and precursors.

Health Canada staff work closely with both our internal partners within Health Canada and external partners including the RCMP, local law enforcement, the Canada Border Services Agency and provincial licensing bodies through joint training initiatives and other collaborative efforts.

FOREWORD

Standard Operating Procedure (SOP) documents are meant to provide guidance to Health Canada employees on how to perform specific tasks to ensure that the requirements of all governing legislation and regulations are met. They also serve to familiarize employees with the applicable tools and record keeping methods and requirements for a specific task. SOP documents provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

SOP documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may* be acceptable if they are supported by adequate justification and applicable legislative or regulatory requirements have been met. Alternate approaches should be discussed in advance with the relevant program area.

This document is dynamic in nature, and is offered without prejudice to future measures, which Health Canada might take in this area.

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1. PURPOSE

The purpose of this SOP is to establish a pre-defined procedure. SOPs are written instructions that are necessary to achieve and maintain a consistent approach to a process. This SOP also provides a platform for training and assessing quality.

Inspections are conducted to monitor and verify compliance with the requirements of the *Controlled Drugs and Substances Act* (CDSA) and the Marihuana for Medical Purposes (MMPR). The procedures described herein are intended to ensure uniformity of action within the CSP and the OCS.

This document has been developed to:

- Outline the steps followed during the first full inspection, referred to as the initial inspection, of a Licensed Producer's activities and facility;
- Provide direction to Regional Managers (RM), Section Heads (SH), and Inspectors regarding full inspections of a licensed producer (LP) under the *Marihuana for Medical Purposes Regulations* (MMPR); and
- Assist in ensuring a consistent approach and uniformity to the inspection program.

This document will evolve, guided by information collected through compliance and enforcement activities conducted under the new MMPR.

2. SCOPE

This procedure applies to the initial inspection of Licensed Producers under the MMPR. These inspections are conducted under Section 9 of the MMPR and Section 31 of the CDSA.

PLEASE NOTE:
In addition to the collection of information and verifications that reflect regulatory requirements of the MMPR, this SOP also includes related questions, considered to be best practices by Health Canada that Inspectors may use during an inspection.

Any observation or recommendation (i.e. refusal or that a condition be included on the licence) made by the Inspector, must be clearly linked to a deficiency in a regulatory requirement and must reference the applicable section of the MMPR.

3. DEFINITIONS and ACRONYMS

The following terms are found in this document:

INITIAL INSPECTION	Initial inspections are comprehensive inspections that include the breadth of the requirements of the MMPR
A/RPIC	Alternate Responsible Person in Charge
AUTHORIZED PARTY	Individuals authorized under subsection 12.(4) of the MMPR to purchase or receive dried marihuana from a licensed producer
CDSA	*Controlled Drugs and Substances Act*
CSP	Controlled Substances Program
DESIGNATED PERSONNEL	Includes any of the following individuals: the Senior Person in Charge, the Responsible Person in Charge, or the Alternate Responsible Person(s) in Charge
FDA	*Food and Drugs Act*
FDR	*Food and Drug Regulations*
IMMEDIATE CONTAINER	The container in direct contact with the dried marihuana
INSPECTOR	Any person designated as an Inspector under section 30 of the CDSA
IUMMP	Information on the Use of Marihuana for Medical Purposes: Consumer Information Sheet
LICENSED PRODUCER	The holder of a licence issued under the MMPR
LPD	Licences and Permits Division
MMPR	*Marihuana for Medical Purposes Regulations*
NCED	National Compliance and Exemption Division
NCPR	*New Classes of Practitioners Regulations*
NCR	*Narcotic Control Regulations*
PCPA	*Pest Control Products Act*
PPE	Personal Protective Equipment
RPIC	Responsible Person in Charge

REGULATED PARTY	Individuals authorized under subsection 12.[2] of the MMPR to purchase or receive marihuana; and cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting in vitro testing that is necessary to determine the percentage of cannabinoids in dried marihuana from a licensed producer
RM	Regional Manager
SECURITY DIRECTIVE	Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the storage of Controlled Substances)
SECURITY GUIDE	Guidance Document: *Building and Production Security Requirements for Marihuana for Medical Purposes*
SOP	Standard Operating Procedure
SENIOR PIC	Senior Person in Charge
TECHNICAL GUIDE	Guidance Document: *Technical Specifications for Testing Dried Marihuana for Medical Purposes*
THC	Delta-9-tetrahydrocannabinol

4. ROLES AND RESPONSIBILTIES

The planning and execution of MMPR inspections is a shared responsibility between the Inspector(s) and the RM. The Licences and Permits Division (LPD) and the National Compliance and Exemption Division (NCED) are responsible for coordinating the scheduling of all MMPR inspections.

The RM is responsible for assigning an inspection team to conduct inspections and will identify a Lead Inspector. To the extent possible, Inspectors will be rotated through the inspection schedule and inspect a variety of companies. RM's are responsible for ensuring Inspectors follow these procedures.

Inspectors are responsible for observing and applying them.

The Lead Inspector is responsible for ensuring that all aspects of the inspection are addressed, including:

- ensuring that all information with regards to the file has been received and is available for the inspection;
- reviewing all of the file history of the licensed producer
- developing an inspection plan;
- coordinating all aspects of the inspection;
- assigning tasks and responsibilities amongst the team, as required;
- ensuring that inspection notes are taken by each team member according to shared responsibilities;
- acting as the spokesperson for the team;
- organizing the exit interview;
- coordinating the writing of the report;
- recommending follow-up actions;
- assigning a risk level to the LP based on the inspection findings;
- signing the inspection report, and submitting it to the RM for review;
- determining if the LP's response to any observations found during the inspection are sufficient; and
- recommending that a final monitoring letter be issued to the LP and no further action is required.

Within the context of an administrative inspection and the normal execution of their duties, Inspectors may review files that contain personal information. For example, inspections of licensed producer applicants and licensed producers will require Inspectors to access to records to verify that client registration and other record

keeping systems meet the requirements of the MMPR. There may be circumstances where in order to perform their duties (i.e., to document potential diversion of controlled substances, suspected fraudulent activities) the Inspector may need to reproduce or make note of client information, of an individual applying to be a client, or a health care professional. Under these circumstances, Inspectors should contact their Section Head or Regional Manager to discuss, taking into consideration an individual's right to privacy, the appropriate approach to collecting this information for compliance management purposes.

Inspectors will only collect information as required when exercising their duties as an Inspector. Inspectors must ensure that all information is safeguarded and protected in accordance with the *Privacy Act*. Generally, Inspectors should not reproduce or make note of client information including the client's unique identifier, of an individual applying to be a client, or a health care professional. An inspection report, with the exception of an inspection report related to suspected diversion of controlled substances, fraudulent activities, or serious contraventions of the regulations must not include any information pertaining to clients, individuals applying to become clients or health care professionals or any information that could potentially identify these individuals.

5. BACKGROUND

The MMPR provides a regulatory framework whereby Canadians who are deemed to benefit from access to marihuana for medical purposes can have access to it. The MMPR replaces the *Marihuana Medical Access Regulations* which will be repealed on March 31, 2014.

Health Canada plays a role in protecting the health of Canadians who are prescribed marihuana for medical purposes, by ensuring they receive the medication deemed necessary. A second objective is to ensure the supply of marihuana for these Canadians meets their prescribed requirements.

Health Canada is a regulatory department, and C&E activities are essential to the success of regulatory activities. The operational framework and strategic direction for C&E activities to be conducted under the MMPR is set out in CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*, CS-POL-001 *CDSA Compliance and Enforcement Policy*, and CS-GD-010 *MMPR Compliance Management and Endpoints.*

The role of Inspectors includes performing on-site inspections, sharing compliance promotion materials, communicating with LPs and LP applicants, and conducting compliance monitoring and enforcement activities.

Section 30 of the CDSA covers the designation of Inspectors and their duty to identify themselves when entering a place under the authority of this Act.

Section 31 of the CDSA describes the places an Inspector may enter, the powers granted to them, and the use of computers and copying equipment in carrying out an inspection. Subsection 31.(2) of the CDSA covers the entry into a dwelling-place and the conditions attached to that activity.

Section 9 of the MMPR authorizes inspections to be conducted to confirm information submitted in support of an application, amendment or renewal of a licence.

5.1 Resources and Equipment

During an inspection, each Inspector must carry their badge and Inspector identification card, and must use PPE as required. In addition the following materials may be useful:

- Inspection plan
- Notebook and pens
- Cellular phone
- Measuring tape
- Business cards
- CSP/ OCS telephone contact list
- MMPR PLI Questionnaire
- Sample Medical Document for the MMP
- MMPR
- IUMMP
- NCR and NCPR
- CDSA and FDA Schedule B
- Security Directive
- Security Guide
- Technical Guide
- Industrial Hemp Technical Manual – Standard Operating Procedures for Sampling, Testing and Processing Methodology

6. PROCEDURE

An Initial inspection is a full inspection. The Licensed Producer (LP) will be assessed against all applicable requirements of the MMPR.

Initial inspection will be scheduled once the licensed producer has final product that is ready for sale (including the testing of the contaminants and percentage of THC and CBD as required under Division 4 of the MMPR). An initial inspection will be conducted to ensure that the licensed producer complies with all the provisions under the MMPR. Typically, an initial inspection would occur within a 3-6 month timeframe depending upon factors such cultivation of the crop, the drying process, testing of the products etc. The results of the initial inspection will contribute to demonstrated that the proposed site meets the all of the requirements of the MMPR, the licensed producer licence may be amended to include the activity of sale. It is only at this point the licensed producer will be able to start registering clients and selling or providing Cannabis.

Each initial inspection consists of five phases: preparation and planning, introductory meeting, verification of requirements, exit meeting, and reporting.

The on-site portion of the initial inspection, (introductory meeting, verification of requirements, exit meeting) should be completed within five (5) days depending upon the activities being conducted by the LP. The number of Inspectors assigned to complete an initial inspection will be determined by the RM.

All initial inspections will be unannounced. If it is deemed necessary to announce the inspection date in advance, this must be approved by the RM prior to announcing the inspection. If approval is obtained, the Senior PIC will be notified the day before the inspection. If the Senior PIC cannot be reached, the RPIC or, if not available, the A/RPIC will be informed.

Except under extraordinary circumstances, the initial inspection shall not be postponed. If such a condition appears to exist, prior approval from RM must be obtained. The inspection should then be re-scheduled for the next business day or as soon as possible. The OCS should also be notified of the new inspection date.

6.1 Preparation and Planning

This phase of the inspection commences approximately 3 weeks prior to the inspection and consists of three main tasks: gathering information, reviewing documentation, and creating the inspection plan.

6.1.1 Pre-Inspection Information Gathering

The RM will determine whether measures to mitigate risks to personal safety are required in accordance with CS-SOP-016 *Safety and Security of Inspectors.*

The RM is responsible for considering all available information including intelligence received from a police force that may not be present in the LP file to identify potential risks that may impact on the safety or security of the Inspector.

The Compliance and Enforcement Section Head is responsible for communicating any information related to potentially high-risk inspections immediately to the RM responsible for the province in which the company resides.

The Lead Inspector should contact the National Compliance Section (NCS) three weeks in advance of the inspection to request the LP file for their review. The NCS should provide the LP file including information regarding adverse reactions reports, compliance verifications, and recalls involving the LP, to the Lead Inspector within one week of their request.

6.1.2 Pre-inspection Document Review

The Inspectors will examine the LP file provided by the OCS and any other pertinent information, including the following:

- the producer's licence;
- import/export permits and applications;
- floor plans, organizational chart and list of designated personnel;
- description of the security measures and internal controls including record keeping, good production practices, quality assurance, etc.;
- any pertinent correspondence;
- loss and theft reports, compliance verifications, recall reports, adverse event reports and other pertinent information; and;
- pre-licence inspection reports, follow-up letters, and responses.

The Inspector will identify any safety concerns. If serious concerns are noted, police accompaniment should be discussed with the RM. Please refer to CS-SOP-016 *Safety and Security of Inspectors* for more information.

6.1.3 Preparing the Inspection Plan

The Lead Inspector will create an inspection plan that identifies the:

- scope of the initial inspection;
- objectives of the inspection
    - verification of compliance with the applicable requirements of the MMPR (see section 6.6 of this document for detailed information);
    - visual inspection and confirmation of inventory;
    - review of records related to client registrations, sales, complaints, adverse events, recalls, loss and theft; and
    - sharing of compliance promotion materials
- role of each Inspector;
- Inspector who will conduct the inventory reconciliation; and
- PPE that may be required must be listed.

Modification to the inspection plan may be required once the Inspectors are on the premises.

6.2 Introductory Meeting

Upon arriving at the site, the Inspectors will introduce themselves and present their identification cards. The Inspectors will not allow anyone to handle their identification cards.

The Inspectors will confirm site is not a dwelling-place and whether there is more than one building at the site. If the site is a dwelling-place the Inspector(s) should contact the RM immediately.

The Inspectors will then present their business cards and request to speak with the Senior PIC.

The Inspectors will identify themselves to the designated personnel as above.

If the Senior PIC is not present, the Inspector will ask one of the designated persons present to advise the Senior PIC of the inspection.

If the RPIC is also absent and there is no A/RPIC, the Inspector must:

1) ensure that no transactions are allowed to take place until either the RPIC or A/RPIC is on the premises; and 2) contact the RM immediately.

The RPIC may be contacted by phone, and may designate an individual to assist with the inspection until he or she arrives at the site.

The Inspectors will hold a brief meeting with the available designated personnel to explain the purpose of the inspection and under what statute and regulations it is being conducted. The names and titles of all individuals attending the meeting will be documented. CS-FRM-0220 *Inspection Attendance Record* may be used to document attendance.

The following should be accomplished during the introductory meeting:

- General information on how the inspection will be conducted should be provided to company personnel.
- Advise the company that if observations of a critical nature (more likely to cause a risk to health or pose a risk of diversion) the Senior/ PIC will be notified as soon as possible.
- Compliance promotion material (FAQs, information sheets) should also be provided to company personnel;
- Identification of any potential personal health and safety concerns found at the site and, if applicable, any health and safety procedures that must be followed.
- The Inspector assigned to inventory reconciliation should request an up to date inventory report that includes the inventory of all stages of production, It is critical that the Inspector receives the inventory report prior to commencing the inspection. If possible this Inspector should leave the meeting in order to immediately start the inventory reconciliation (see Section 6.3.1 of this document).
- Verification of the following information:
  - List of all designated personnel and other personnel including names, titles, contact information and hours of work. Any changes to designated personnel should be noted;
  - Civic address(es) of all sites where any aspects of licensed activities are located;
  - The licensed producer's clientele;
  - Whether any other entities are operating on the site;
  - Overall hours of operation including office area, production area, storage area, shipping /receiving area, etc.;
  - All activities and substances on site are permitted according to licence;

- Any changes to existing floor plan and if so, a new floor plan should be requested;
- If or when pesticides were applied and the names of applied pesticides; and
- Production of CO_2 and whether CO_2 and CO levels are monitored.

In order to facilitate the inspection, the Inspector should request documentation at the beginning of the inspection to give the LP time to obtain the information.

6.3 Verification of Regulatory Requirements

The inspection can generally be divided into three parts – inventory reconciliation, physical inspection, and a document review or audit.

Inspectors will note any observed non-compliance with the MMPR as well as discrepancies between observed practices and records and those on file with OCS. In addition, the Inspectors will document any opportunities for diversion and assess the security measures for effectiveness and sufficiency.

The Inspector, at their discretion, may review any written SOPs the company has developed. The SOPs related to concerns identified during 6.1.2 (pre-inspection document review) and through discussions with designated personnel during the introductory meeting should be reviewed.

6.3.1 Inventory Reconciliation

With the up-to-date inventory in hand, the Inspector will proceed with a physical inventory reconciliation of a representative sample of the inventory. The inventory must be verified as soon as possible after arriving on-site.

The sample selected must be:

- proportional to the total inventory;
- representative of the products handled by the LP; and
- must reflect all activities conducted by the LP.

For the selected sample, the Inspector will proceed with a complete review of all phases of operations, including all production phases packaging, retained samples, waste material, distribution, returns and destruction.

The Inspector will verify inventory of various forms of cannabis,(i.e., plants, bulk dried marihuana, dried marihuana packaged for sale for medical purposes, samples, reference standards and unservicable product/waste), as well as a representative sample of dried marihuana products, based on the activities conducted by the licensed producer.

The Inspector must reconcile the information collected at different steps of the process. In order to reconcile transactions and inventory of a particular product, the Inspector will establish a starting date for the verification. This starting date must be the date a physical inventory was taken. The Inspector will check the receipts and disbursements from that date onwards up to the day the inventory was taken which should be the first day of inspection.

Expired or damaged products to be destroyed should already have been removed from the saleable inventory and listed in a separate record. Returned products should be listed in a separate record as well. Final disposition of the returned product should be identified (i.e., sale to another LD for destruction). The theoretical yield and loss of weight from drying will be determined based on the grower's inventory system (i.e., their predicted, documented and historical yield).

The Inspector will note any discrepancy between the theoretical inventory and the physical count and will ask for explanations. If significant discrepancies are found for which no satisfactory explanations can be provided by the designated representatives, the Inspector shall contact the RM to discuss how to proceed.

6.3.2 Diversion Indicators

The following list represents possible signs that may indicate a diversion issue at the licensed producer's site. Inspectors should be aware that any of the signs listed may also have a legitimate explanation. The list is intended to cover circumstances where additional questions should be asked:

- Missing product
- Sales to patients that do not correspond to the registered client list
- Sales above the 150 grams indicated in the MMPR
- Havest records that are greatly different from typical production
- Culling "male" plants close to the harvest time
- Unusual loss of material
- Evidence of production of derivatives of marihuana (hasish, etc.)

- Lack of production records

6.3.3 Security

Verify the accuracy of the floor plan on file or provided at the time of the inspection and record the location of the areas within the site where cannabis is present.

Review the ventilation.

Review the flow of material through the site.

6.3.3.1 Site Perimeter

- Verify that a system is in place to control the distribution of the codes, keys, and other elements of the security system.
- Review personnel that have access to keys and codes and how this information is tracked.
- Verify whether the perimeter of the site prevents unauthorized access.
- Assess the perimeter of the site to ensure that there are sufficient visual recording devices to visually monitor the perimeter at all times in order to detect attempted or actual unauthorized access.
- Assess whether the visual recording devices, in the conditions under which they are used, are capable of recording in a visible manner any attempted or actual unauthorized access.
- Test the intrusion detection system that is used to detect:
  - attempted or actual unauthorized access to, or
  - movement around the perimeter, or
  - tampering with the system.
- Verify that the intrusion detection system operates and is monitored at all times.
- Verify that records of breaches of the intrusion detection system are kept and contain all required information.

6.3.3.2 Area(s) within the Site where Cannabis is Present

- Verify that the area(s) within the site where cannabis is present (referred to in section 6.2.2 as "those area(s)") is restricted to persons whose presence in those area(s) is required by their work responsibilities.
- Verify that the RPIC or A/RPIC, if applicable, is physically present while other persons are in those area(s).

- Verify that a system is in place to control the distribution of the codes, keys, and other elements of the security system.
- Verify if those area(s) have any physical barriers or signage posted to prevent unauthorized access.
- Verify if there are sufficient visual recording devices to visually monitor the area(s) at all times to detect illicit conduct.
- Assess whether the visual recording devices, in the conditions under which they are used, are capable of recording in a visible manner illicit conduct.
- Assess/test the intrusion detection system that is used to detect:
  - attempted or actual unauthorized access to, or
  - movement in the area(s), or
  - tampering with the system.
- Verify that the intrusion detection system operates and is monitored at all times.
- Verify that records of breaches of the intrusion detection system are kept and contain all required information.
- Assess the systems in place that filter air to prevent the escape of odour and, if present, pollen in these areas. Verify whether odour is detectable outdoors.

6.3.3.3 Storage

PLEASE NOTE:
These additional requirements apply to the storage of controlled substances which includes dried marihuana, marihuana seeds and cannabis used solely for the purpose of testing in order to determine the percentage of cannabinoids in dried marihuana (both packaged and unpackaged). These requirements also apply to all waste cannabis material from cultivation or production with the exception of mature cannabis stalks that do not include leaves, flowers, branches or seeds; and fibers derived from the stalks, as well as, any non-viable cannabis seeds. Additionally, these requirements do not apply to plants or cannabis material undergoing the drying process.

- Verify that only the RPIC, A/RPIC(s) and persons whose presence is required by their work responsibilities have access to the vault/safe or cage.
- Verify that an appropriate system is in place to control the distribution of the codes, keys, combinations, etc.
- Verify that the illicit value of stored cannabis does not exceed the approved security level as indicated on their license.
- Verify that only cannabis is kept in these areas.
- Verify the in-house laboratory, if applicable, stores reference standards and samples as required by the Security Directive.
- Verify that the RPIC or A/RPIC, if applicable, are physically present while other persons are handling controlled substances.

- Verify that only the RPIC and/or A/RPIC(s) have the authorization to disarm a vault/safe or cage.
- Verify that only the RPIC and A/RPIC(s) have the key to the cage and the combination for the safe/vault.
- Verify the storage conditions (vault or safe and cage, if applicable) against the measures submitted and the Security Directive.
- Verify that the combination is changed at regular intervals (at least once a year) and/or when a person having the combination is no longer a designated RPIC or A/RPIC. (This requirement only applies to Security Level 8 and higher.)
- Conduct an alarm test of the intrusion detection devices and system required by the Security Directive. Request an incident report from the monitoring firm to ensure that the firm is able to report all incidents related to the safety devices.

6.3.4 Good Production Practices

- Verify that SOPs have been implemented at the site regarding the production, packaging, labelling, and storage of the dried marihuana.
- Verify that any changes to SOPs have been implemented and documented appropriately.
- Review records of THC and cannabidiol content from various batches to verify uniformity.
- Verify that the licensed producer has developed a sampling plan to verify uniformity of THC and cannabidiol content of the finished products. Review records of this sampling plan.

6.3.4.1 Premises for Production, Packaging, Labelling, and Storing of Dried Marihuana

- Verify that the areas permit activities to be conducted under sanitary conditions.
- Verify that the storage conditions of the dried marihuana maintain its quality.

6.3.4.2 Equipment to Produce, Package, Label, and Store Dried Marihuana

- Verify that equipment is designed, constructed, maintained, operated and arranged in a manner that:
  - Permits the effective cleaning of its surfaces.
  - Permits it to function in accordance with its use.
  - Prevents it from contaminating the dried marihuana.
  - Prevents it from adding extraneous substance to the dried marihuana.

6.3.4.3 Sanitation Program (Areas where the Dried Marihuana is Produced, Packaged, Labelled, and Stored)

- Verify that a written sanitation program is implemented for the areas used to produce, package, label, and store the dried marihuana.
- Observe and note any areas of sanitation concern. If any concerns are noted, review the sanitation plan to ensure they are being implemented as written and note any possible deficiencies in written plan.

6.3.4.4 Material Control

- Verify that the licensed producer has written procedures for the transportation, receipt, identification, examination, handling, sampling, testing, and approval or rejection of marihuana.
- Verify each lot of marihuana is assigned a distinctive lot number.
- Verify that containers of marihuana are inspected upon receipt for closure and physical integrity.
- Verify that dried marihuana is retested after any exposure to conditions likely to adversely affect their purity, quality or composition.
- Verify each lot of dried marihuana is identified and treated according to its quality status (i.e. quarantined, approved or rejected).
- Verify that marihuana is stored in appropriate conditions, including appropriate temperature and humidity, to protect against quality deterioration and contamination.
- Verify that outdated or obsolete printed packaging materials are destroyed.
- Verify that appropriate systems and controls are established to ensure water used to produce products is of potable quality and meets the WHO guidelines for Drinking Water Quality or other standards, as well as Guidelines for Canadian Drinking Water Quality [http://www.hc-sc.gc.ca/ewh-semt/water-eau/drink-potab/guide/index_e.html]

6.3.4.5 Process Control

- Verify that a master production document has been prepared for the production of each product, and that the quality assurance person has reviewed and approved the document.
- Verify that complete batch records are prepared and retained.
- Verify that each batch of product produced is allocated an individual batch number that can be tracked.

- Verify that deviations from written and approved production processes, standards and test methods, are recorded and evaluated with the final approval given by the quality assurance person.
- Verify that all materials, products, samples, containers, processing areas and major equipment are identified at all times to indicate their contents and/or status.
- Verify that procedures are in place to prevent extraneous materials from being included in the in process materials and the final package.
- Verify procedures are in place to identify, store and dispose of rejected or contaminated/adulterated products.
- Verify that approved written procedures are established for reprocessing batches that do not conform to finished product specifications.
- Verify labels are securely stored to prevent mix-ups (i.e. stored and withdrawn against a packaging order).
- Verify that written procedures exist and are followed to ensure the correct labels and packaging materials are issued and used.
- Verify that each package bears a lot number and expiry date, if applicable.
- Verify that written procedures are set up and followed for preparing samples, including the conditions of their storage and the duration of such storage.
- Verify that on completion of each stage of processing, the equipment and containers used during critical in-process stages are appropriately labelled.

6.3.4.6 Records

- Verify that current versions of SOP(s) are maintained on site.
- Verify records of each batch of dried marihuana produced, packaged or labelled have been done accordingly to a master production document.
- Verify that the licensed producer maintains a list of all brand names of the dried marihuana they produce, package, or label.

6.3.5 Quality Assurance

PLEASE NOTE:
This section applies to dried marihuana for sale for medical purposes, as well as to any imported marihuana when it is to be sold or provided in Canada, and to any Canadian-produced marihuana which is to be exported.

- Verify the identity of the quality assurance (QA) person, the date of appointment, qualifications, and any changes to QA staff.
- Verify that written specifications are set up and approved by the QA.

- Verify that the specifications for dried marihuana correspond with an appropriate Schedule B pharmacopoeial standard.
- Verify that every lot or batch of dried marihuana is tested for microbial and chemical contaminants as required by the Pharmacopeia selected from Schedule B to the FDA, as well as, for the THC and cannabidiol levels, and any pesticide residues, if applicable.
- Verify that a visual inspection of the dried marihuana take place to verify the absence of pests or extraneous substances (i.e. any material or substance other than dried marihuana).
- Verify that written analytical methods to perform all chemical and microbiological tests enumerated in the specification of the finished product are in place.
- Verify that the licensed producer and any external laboratory will have a technical agreement and that the QA ensures that laboratories (in-house and/or contract) are capable of performing all of the tasks and responsibilities assigned to them.
- Verify written procedures are established and followed for sampling, inspecting, and testing dried marihuana.
- Verify that the QA approves or rejects all procedures, specifications, test methods, controls and results that affect the purity, quality and composition of the product.
- Verify that every lot or batch of dried marihuana is approved by the QA prior to its sale based on its completed batch records and test results.
- Review various testing results for dried marihuana for the following information
    - Testing has been established according to section 53 of the regulations
    - Methodology for the testing has been established
    - Note whether an outside laboratory is conducting testing and verify the lab is appropriate for conducting testing (i.e. licensed facility)
    - Test result reviewed were within established limits for microbial and chemical contamination
- Verify a validated methodology has been established to determine the THC and cannabidiol content of the cannabis (including dried marihuana).
- Verify that the licensed producer has established specifications and tolerance limits for THC and cannabidiol for each brand of dried marihuana that they produce.
- Verify whether pest control products are used on marihuana.
- Verify that any pest control products are authorized or registered by Health Canada.
- If applicable, verify that the licensed producer has determined its maximum residue limit(s) specified for its pesticide control product(s). http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php

- Verify a validated methodology is established to determine the pesticide control product residues.
- Verify a process is developed to record every complaint received regarding the quality of the dried marihuana and whether any further investigations and/or corrective action required.
- Review records of complaints and written actions taken in response.
- Verify that written procedures are reviewed regularly and kept up-to-date.
- Verify that there is a system for revising the procedures and the reason for any revisions is documented.
- Verify the system will ensure that only current procedures are in use.

6.3.5.1 Retention Sample

- Verify that retention samples are maintained for at least one year after the date of the last sale or provision of any portion of the lot or batch of dried marihuana.
- Verify that the retention samples are available in sufficient quantities that would enable the Minister to make a determination of whether the lot or batch of dried marihuana meets the requirements of the laboratory tests.
- Verify the retained samples are maintained in their immediate containers or in containers of the same material and construction.
- Verify the retention samples have been stored in the environmental conditions listed on the label.
- Visually inspect a representative sampling of the LPs retention samples and verify that the retention samples meet the requirements.

6.3.5.2 Records

- Review the documentation, used to capture the approval of the dried marihuana by the quality assurance person prior to its sale.
- Verify that the quality assurance person maintains all laboratory records of tests and investigations.
- Verify that the quality assurance person maintains all records of complaints with the following information: the name and description of the product, the lot number, the source and nature of the complaint, and any response. When an investigation is conducted, verify that the quality assurance person will include in the written record the findings and any follow-up action taken.
- Verify that the licensed producer keeps records of retention samples maintained at the site.
- Verify authorized written procedures for all sections of these requirements are retained for reference and inspection.

- Verify that all written procedures have evidence of their approval for use by the quality assurance person.

6.3.6 Registration

6.3.6.1 New Applications/Amendment Applications

- Verify that all of the required registration information is being collected.
- Verify the process and/or system in place to ensure that the medical document contains all required information and was signed by an authorized healthcare practitioner.
- Verify the process and/or system in place to notify clients in writing when they have been registered. Ensure that all of the information required under subsection 111.(2) and section 116 of the MMPR is captured.
- Verify that each client will receive a unique identifier.
- Verify that registrations are assigned an appropriate expiry date.
- Verify the means of preventing a client from placing an order and receiving an order of dried marihuana after their registration has expired.
- Review samples of registration records.

6.3.6.2 Refusals

- Verify the process and/or system in place to assess applications and determine if they should refuse to amend a registration of an existing client or to register the potential client.
- Verify the process and/or system in place to notify clients or potential clients in writing that the LP is proposing to refuse or to register them as a client.
- Verify the process and/or system in place to assess the response provided by the client or potential client and the reason(s) why the LP's decision to refuse to register them is unfounded.
- Verify the process and/or system in place to return the medical document without delay to the clients or potential clients they refuse to register.
- Review samples of applications that have been refused.

6.3.6.3 Cancellation

- Verify the process and/or system in place to assess the situation and determine if a registration should be cancelled.
- Verify the process and/or system in place to notify clients in writing that their registration has been cancelled.

- Verify the process and/or system in place to assess the response provided by the client and the reason(s) why the licensed producer's decision to cancel their registration is unfounded.
- Verify that medical documents are not returned to a client whose registration has been cancelled.

6.3.7 Packaging

- Verify whether the immediate container has a security feature that satisfactorily indicates that a package has been opened.
- Verify that the immediate container is a child resistant package that meets the requirements of subsections C.01.001.(2) to (4) of the FDR.
- Verify the package sizes offered by the licensed producer and/or the process used package the product ensure that no more than 30g of dried marihuana is placed in the immediate container.
- Verify the process and/or system the licensed producer uses to ensure that the immediate container does not contain less than 95% and not more than 101% of the net weight as specified on the label.
- Verify that the package keeps dried marihuana dry and free from contamination.

6.3.8 Labelling

- Confirm that the product labels applied to the immediate container include all applicable criteria listed in s.66 of the MMPR.
- Confirm that the client label includes all of the criteria listed in s. 67 of the MMPR.
- If a combined label is used, confirm that criteria set out in s. 66 and paragraph 67(a) of the MMPR are being met.
- Verify that all information that must appear on a label is in English and in French, is clearly and prominently displayed on the label and is readily discernible under the customary conditions of use.
- Verify that if an expiry date is included on the label that the LP has submitted data to the Minister that establishes the stability period as required by the regulations, that this data has been reviewed by the Minister, and the LP has received notification from the Minister.
- Verify that the LP ensures that each shipment of the dried marihuana is accompanied by a copy of the current version of the document entitled Information on the Use of Marihuana for Medical Purposes, published by the Department of Health.

6.3.9 Ordering

6.3.9.1 Clients

- Verify that client orders contain all of the required information.
- Verify that a record is made of the information required under subsection 138.(1) of the MMPR for each order received.
- Verify the process and/or system in place to assess orders and determine if an order should be refused to be filled.
- Verify the process and/or system in place to notify clients in writing that the licensed producer is refusing to fill an order.
- Verify the process and/or system in place to prevent a client or the individual responsible for that client from being sold or provided with a total quantity of dried marihuana that exceeds 30 times their daily quantity in any 30-day period.

6.3.9.2 A Person other than a Client

PLEASE NOTE:
This applies to authorized parties (specifically hospital employees and section 56 exemption holders) and regulated parties

- Verify that before filling any written order the licensed producer verifies that it contains all of the required information as per subsection 131.(3) of the MMPR.
- Verify the licensed producer has a process and/or system in place to assess the orders and determine if an order should be refused to be filled.
- Verify the process and/or system in place to notify the person placing the order in writing that the licensed producer is refusing to fill an order.

6.3.10 Shipping

- Verify how the licensed producer ensures the safe keeping of cannabis (including dried marihuana) during its shipping, delivery, or transportation.
- Verify that each shipment of dried marihuana to a client or an individual who is responsible for that client contains Health Canada's Information on the Use of Marihuana for Medical Purposes document in English and French, as well as a separate document containing the information contained in the client label.
- Verify that the licensed producer has a process and/or system in place that ensures that dried marihuana is shipped in only one shipment per order.

- Verify that shipping packages:
  - Will not open or permit the escape of its contents during handling and transportation.
  - Is sealed so that it cannot be opened without the seal being broken.
  - Prevents the escape of marihuana odour.
  - Prevents the contents from being identified without it being opened.
- Verify that the licensed producer uses a shipping method that will allow the packages of cannabis including dried marihuana to be tracked during transit and ensures their safekeeping during transit.

6.3.10.1 Offsite Laboratory Analysis

- If applicable, review the shipping process and/or system the licensed producer uses to send samples to an external laboratory for analysis.
- Verify that the external laboratory holds a licence to conduct activities with cannabis.

6.3.10.2 Destruction Offsite

If applicable, review the shipping process and/or system the licensed producer uses for destruction at a location other than the licensed site.

6.3.11 Returns

- Verify whether the licensed producer accepts returns.
- If the licensed producer accepts returns:
  - verify that they will have a process or system to ensure returned marihuana is not resold;
  - verify that the licensed producer keeps appropriate records for returned marihuana;
  - review the shipping process and/or system the licensed producer uses for returns from their clientele.

6.3.12 Receiving

- Verify the licensed producer keeps appropriate records for any receipt of cannabis.

6.3.13 Loss and Theft

6.3.13.1 At the Site

- Review with the licensed producer the process or verification steps that are in place to indicate/identify a theft of cannabis (including dried marihuana) or an unusual waste or disappearance of cannabis that cannot be explained on the basis of normal accepted business activities.
- Verify with the licensed producer the quantity of material they consider an unusual waste or disappearance.

6.3.13.2 In Transit

- Review the process that is used to address a loss or theft of cannabis (including dried marihuana) during transit.

6.3.14 Destruction

- Verify that the licensed producer has a process and/or system to witness and record the destruction of cannabis.
- Assess records of destruction.

6.3.15 Adverse Reactions

- Verify the licensed producer has a process and/or system in place to record a case report for each serious adverse reaction to the dried marihuana they sell or provide. If applicable, verify that OCS has been appropriately notified of adverse reactions.

6.3.16 Recall

- Verify that the licensed producer has a process and/or system to address the recall of every lot or batch of dried marihuana that has been made available for sale (i.e. determining extent of the recall, methods of notifying affected parties).
- Verify that the process and/or system includes a step to notify the Minister with the information required under section 62 of the MMPR within three days after the day on which the recall is commenced.
- Verify the individual(s) responsible for initiating and coordinating recalls.
- Verify that the recall procedure can be put into operation at any time, during and outside of normal working hours.

- Verify that the process and/or system the licensed producer uses to identify and store recalled products separately in a secure area until further action is determined.
- Verify that the licensed producer assesses and records at intervals the progress and efficacy of the recall, and issues a final report, including a final reconciliation.
- Verify who is responsible for notifying all Canadian and foreign clients involved in the distribution and import of the recalled product.
- If a recall has been conducted, assess the record of the recall.
- Verify that the licensed producer maintains distribution records so that each lot can be traced.

6.3.17 Information Sharing

- Verify that the licensed producer has a process and/or system in place to verify that the individual requesting information on a possible client is a member of a Canadian police force.
- Verify how the licensed producer ensures that they respond within 72 hours after receiving the request from a member of a Canadian police force.

6.4 Exit interview

A brief exit interview will be conducted at the LP's site at the end of the on-site portion of the inspection. Record the name and title of all individuals in attendance. CS-FRM-0220 *Inspection Attendance Record* may be used to record attendance.

Preliminary inspection findings including any draft observations, required changes, and improvements to meet the requirements of the MMPR should be discussed with the designated personnel.

The LP should be advised that a written response to each observation must be submitted to the Inspector within ten (10) days from the date the inspection report is issued.

Encourage the LP to seek clarification and respond to questions. If unable to provide a response, make note of the question and provide a response in follow up. Offer the opportunity for the LP to provide additional information, records or documents.

The Lead Inspector should provide compliance promotion material to the LP if applicable.

Inform the designated personnel of the date that a copy of the inspection report will be issued to the company.

Advise the designated personnel that the results of the inspection will be shared with the OCS.

No documents will be left at the site.

6.5 Reporting

6.5.1 Writing of Report

Using the approved template (CS-FRM-0221 *MMPR Initial Inspection Report)*, the Lead Inspector will prepare the inspection report.

In the report, the Lead Inspector will document the discrepancies which exist in terms of what has been observed versus the requirements of the MMPR. The inspection report is intended to describe the situation noted at the time of the inspection and to identify practices in place up until the time of the inspection.

Observations must be factual and must not include personal opinions, qualifiers or subjective comments. Observations must be formulated clearly, concisely and precisely aligned to the applicable regulatory requirement. Specific examples may be added for additional clarification.

Observations will be identified as 'critical' or 'non-critical' and listed according to importance. Classification of observations may require consultation with the RM.

The inspection report and related documents must not include any information pertaining to clients, individuals applying to become client applicants, or health care professionals, or any information that could potentially identify these individuals without prior discussion between the Lead Inspector and the RM. The RM will confirm if this information is required.

The Lead Inspector will make a general conclusion of the LP's ability to comply with the MMPR.

The Lead Inspector will assign a risk rating to the LP.

The Lead Inspector will sign and date the inspection report and submit it to the RM within five days.

The RM will review the inspection report and sign it. The RM will issue the inspection report to the LP.

The RM will scan and upload the signed inspection report to the Controlled Drugs and Substances Database and send the report to the Manager of the LPD and to the Section Head of the National Compliance Section for administrative purposes. This information will be used to help determine future inspection cycles.

6.5.2 *Reviewing the Corrective Action Plan*

The Lead Inspector will review the corrective action plan submitted by the LP in response to each observation cited in the Inspection Report and determine if the proposed actions are sufficient.

If all actions are determined to be sufficient, the RM will issue a final monitoring letter to the LP noting that no further action is required at this time and the results of the corrective actions will be evaluated during the next inspection. The RM may wish to use CS-FRM-0200 as a template.

If any actions are determined to be insufficient, the RM will issue a monitoring letter to the LP requesting additional information. The RM may wish to use CS-FRM-0200 as a template. Once all corrective actions are deemed sufficient the lead Inspector will issue a final monitoring letter to the LP noting that no further action is required and results of the corrective actions will be evaluated during the next inspection. The RM may wish to use CS-FRM-0200 as a template.

6.5.3 *Closing the Inspection*

The RM will scan the letters issued to the LP and upload the scan to the Controlled Drugs and Substances Database. The RM will send the report to the Manager of the LPD and to the Section Head of the National Compliance Section for administrative purposes. This information will be used to help determine future inspection cycles.

The OCS will close the inspection.

7. APPENDICES

CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*
CS-POL-001 *CDSA Compliance and Enforcement Policy*

CS-GD-010 *MMPR Compliance Management and Endpoints*
MMPR Inspection Questionnaire
CS-FRM-0231 MMPR Initial Inspection Report Template

8. REFERENCE DOCUMENTS

You may find it useful to refer to the following documents:

- CDSA
- MMPR
- Inspections reports and follow-up for other sites of the same company or group, if applicable
- Guidance Document on Sanitation Requirements of Dried Marihuana

9. AUTHORS

The author of this document is:
The editors of this document are:

10. DOCUMENT REVISION HISTORY

Version	Change Made	Effective Date

This is **Exhibit "J"** referred to in
the Affidavit of **TODD CAIN**
Affirmed before me at the City of
Ottawa, in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Sherri Laureen Szabados, a Commissioner, etc.,
Province of Ontario, for the Government of Canada,
Department of Health.
Expires December 2, 2015

Controlled Substances Program

STANDARD OPERATING PROCEDURE	
Conducting Targeted Inspections under the *Marihuana for Medical Purposes Regulations*	**Doc. Number: CS-SOP-023** **Version: 1.**

Bureau/Office/Area: RAPB & OCS	**Status:** DRAFT	**Effective Date:** TBD

Approved by:	

The Office of Controlled Substances ensures that precursors and controlled substances are handled effectively and remain in legal distribution channels. This involves developing legislation, regulations, policies and operations that support the control of illicit drugs and other substances.

The regional Controlled Substances Program is the compliance and enforcement arm of the Office of Controlled Substances, who conducts compliance and monitoring activities to enforce the *Controlled Drugs and Substances Act* and its associated regulations including but not limited to the Precursor Control Regulations, the Narcotic Control Regulations, and the Marihuana for Medical Purposes Regulations (MMPR).

Inspectors conduct on-site inspections of regulated parties who perform regulated activities such as the importation, production and distribution of narcotics, targeted substances, restricted drugs, marihuana for medical purposes, industrial hemp, controlled drugs and precursors.

Health Canada staff work closely with both our internal partners within Health Canada and external partners including the RCMP, local law enforcement, the Canada Border Services Agency and provincial licensing bodies through joint training initiatives and other collaborative efforts.

FOREWORD

Standard Operating Procedure (SOP) documents are meant to provide guidance to Health Canada employees on how to perform specific tasks to ensure that the requirements of all governing legislation and regulations are met. They also serve to familiarize employees with the applicable tools and record keeping methods and requirements for a specific task. SOP documents provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

SOP documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may* be acceptable if they are supported by adequate justification and applicable legislative or regulatory requirements have been met. Alternate approaches should be discussed in advance with the relevant program area.

This document is dynamic in nature, and is offered without prejudice to future measures, which Health Canada might take in this area.

TABLE OF CONTENTS

1. PURPOSE

The purpose of this SOP is to establish a pre-defined procedure. SOPs are written instructions that are necessary to achieve and maintain a consistent approach to a process. This SOP also provides a platform for training and assessing quality.

Inspections are conducted to monitor and verify compliance with the requirements of the *Controlled Drugs and Substances Act* (CDSA) and the MMPR. The procedures described herein are intended to ensure uniformity of action within the CSP.

This document has been developed to:

- Outline the steps followed during an MMPR Targeted Inspection;
- Provide direction to Regional Managers (RM), Section Heads (SH), and Inspectors regarding targeted inspections of a licensed producer (LP) under the *Marihuana for Medical Purposes Regulations* (MMPR); and
- Assist in ensuring a consistent approach and uniformity to the targeted inspection program.

This document will evolve, guided by information collected through compliance and enforcement activities conducted under the new MMPR.

2. SCOPE

This procedure applies to targeted inspections of a Licensed Producers. Targeted inspections are conducted under Section 31 of the CDSA to assess compliance with the MMPR.

PLEASE NOTE:
In addition to the collection of information and verifications that reflect regulatory requirements of the MMPR, this SOP also includes related questions, considered to be best practices by Health Canada, which Inspectors may use during an inspection.

Any observation or recommendation (i.e. refusal or that a condition be included on the licence) made by the Inspector, must be clearly linked to a deficiency in a regulatory requirement and must reference the applicable section of the MMPR.

3. DEFINITIONS

3.1 Acronyms

A/RPIC	Alternate Responsible Person in Charge
CDSA	*Controlled Drugs and Substances Act*
CSP	Controlled Substances Program
FDA	*Food and Drugs Act*
FDR	*Food and Drug Regulations*
IUMMP	Information on the Use of Marihuana for Medical Purposes: Consumer Information Sheet
LPD	Licences and Permits Division
MMPR	*Marihuana for Medical Purposes Regulations*
NCED	National Compliance and Exemption Division
NCPR	*New Classes of Practitioners Regulations*
NCR	*Narcotic Control Regulations*
PCPA	*Pest Control Products Act*
PPE	Personal Protective Equipment
RPIC	Responsible Person in Charge
RM	Regional Manager
SOP	Standard Operating Procedure
Senior PIC	Senior Person in Charge
THC	Delta-9-tetrahydrocannabinol

3.2 Definitions

AUTHORIZED PARTY	Individuals authorized under subsection 12.(4) of the MMPR to purchase or receive dried marihuana from a licensed producer
DESIGNATED PERSONNEL	Includes any of the following individuals: the Senior Person in Charge, the Responsible Person in Charge, or the Alternate Responsible Person(s) in Charge
IMMEDIATE CONTAINER	The container in direct contact with the dried marihuana
INSPECTOR	Any person designated as an Inspector under section 30 of the CDSA
LICENSED PRODUCER	The holder of a licence issued under the MMPR

LOW COMPLIANCE RISK LP	A licensed producer who has demonstrated, through inspection results and previous compliance history with the CDSA and the MMPR, a pattern of compliance which is less likely to result in health risks or diversion of product to illicit markets.
NON-LOW COMPLIANCE RISK LP	A licensed producer who has demonstrated, through inspection results or previous compliance history with the CDSA and the MMPR, a pattern of non-compliance which is more likely to result in health risks or diversion of product to illicit markets.
REGULATED PARTY	Individuals authorized under subsection 12.[2] of the MMPR to purchase or receive marihuana; and cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting in vitro testing that is necessary to determine the percentage of cannabinoids in dried marihuana from a licensed producer
SECURITY DIRECTIVE	Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the storage of Controlled Substances)
SECURITY GUIDE	Guidance Document: *Building and Production Security Requirements for Marihuana for Medical Purposes*
TARGETTED INSPECTION	an in-depth inspection which is not intended to assess the compliance with all of the requirements of the MMPR but focuses on identified criteria
TECHNICAL GUIDE	Guidance Document: *Technical Specifications for Testing Dried Marihuana for Medical Purposes*

4. ROLES AND RESPONSIBILTIES

The planning of the inspection is a shared responsibility between the Inspector(s) and the RM. The Licences and Permits Division (LPD) and the National Compliance and Exemption Division (NCED) may also provide input on the scheduling of the inspection.

The RM is responsible for assigning an inspection team to conduct the targeted inspection and will identify a Lead Inspector. To the extent possible, Inspectors will be rotated through the inspection schedule and inspect a variety of companies. Regional Managers (RM) are responsible for ensuring Inspectors follow these procedures.

Inspectors are responsible for observing and applying procedures. The Lead Inspector is responsible for ensuring that all aspects of the inspection are addressed.

The Lead Inspector is responsible for the overall inspection, including:

- contacting the Compliance Section Head and requesting any reports or correspondence related to the LP and ensuring that all information with regards to the file has been received and are available for the inspection;
- developing an inspection plan;
- coordinating all aspects of the inspection;
- assigning tasks and responsibilities amongst the team, as required;
- ensuring that inspection notes are taken by each team member according to shared responsibilities;
- acting as the spokesperson for the team;
- coordinating the writing of the report;
- organizing the exit interview;
- recommending follow-up actions; and
- signing the inspection report and submitting it to the RM.

Within the context of an administrative inspection and the normal execution of their duties, Inspectors may review files that contain personal information. For example, inspections of licensed producer applicants and licensed producers will require Inspectors to access to records to verify that client registration and other record keeping systems meet the requirements of the MMPR. There may be circumstances where in order to perform their duties (i.e., to document potential diversion of controlled substances, suspected fraudulent activities) the Inspector may need to reproduce or make note of client information, of an individual applying to be a client,

or a health care professional. Under these circumstances, Inspectors should contact their Section Head or Regional Manager to discuss, taking into consideration an individual's right to privacy and the appropriate approach to collecting this information for compliance management purposes.

Inspectors will only collect information as required when exercising their duties as an Inspector. Inspectors must ensure that all information is safeguarded and protected in accordance with the *Privacy Act*. Generally, Inspectors should not reproduce or make note of client information including the client's unique identifier, of an individual applying to be a client, or a health care professional. An inspection report, with the exception of an inspection report related to suspected diversion of controlled substances, fraudulent activities, or serious contraventions of the regulations must not include any information pertaining to clients, individuals applying to become clients or health care professionals or any information that could potentially identify these individuals.

5. BACKGROUND

The MMPR provides a regulatory framework whereby Canadians who are deemed to benefit from access to marihuana for medical purposes can have access to it. The MMPR replaces the *Marihuana Medical Access Regulations* which will be repealed on March 31, 2014.

Health Canada plays a role in protecting the health of Canadians who are prescribed marihuana for medical purposes, by ensuring they receive the medication deemed necessary. A second objective is to ensure the supply of marihuana for these Canadians meets their prescribed requirements. Health Canada is a regulatory department, and C&E activities are essential to the success of regulatory activities.

The operational framework and strategic direction for C&E activities to be conducted under the MMPR is set out in CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*, CS-POL-001 *CDSA Compliance and Enforcement Policy*, and CS-GD-010 *MMPR Compliance Management and Endpoints.*

The role of Inspectors includes performing site inspections, providing compliance promotion, communicating with LPs and LP applicants, and conducting monitoring and enforcement activities.

Section 30 of the CDSA covers the designation of Inspectors and their duty to identify themselves when entering a place under the authority of this Act.

Section 31 of the CDSA describes the places an Inspector may enter, the powers granted to them, and the use of computers and copying equipment in carrying out an inspection.

Section 9 of the MMPR authorizes inspections to be conducted to confirm information submitted in support of an application, amendment or renewal of a licence.

5.1 Resources and Equipment

During an inspection, each Inspector must carry their badge and inspector identification card, and must use PPE as required. In addition the following materials may be useful:

- Inspection plan
- Notebook and pens
- Cellular phone
- Measuring tape
- Business cards
- CSP/ OCS telephone contact list
- MMPR PLI Questionnaire
- Sample Medical Document for the MMPR
- MMPR
- IUMMP
- NCR and NCPR
- CDSA and FDA Schedule B
- Security Directive
- Security Guide
- Technical Guide
- Industrial Hemp Technical Manual – Standard Operating Procedures for Sampling, Testing and Processing Methodology

6. PROCEDURE

Regulatory requirements assessed during a regular inspection should also be applied to targeted inspections. Procedures on the performance of various components of an MMPR inspection can be found in the standard operating procedure CS-SOP-024 *Conducting a Regular Inspection.*

All LPs will undergo a full inspection once products is ready for sale, referred to as the initial inspection within 3-6 months of being issued their licence in accordance with CS-SOP-022 *Conducting an Initial Inspection under the MMPR.*

The results of the pre-licence inspection contribute to the risk assessment of the LP. The LPs are categorized as low, medium, or high risk. Medium or high risk LPs are grouped together as non-low risk and are referred to the RM for additional targeted inspections.

The low risk group of LPs will undergo a full inspection within 12 months of their last inspection as per CS-SOP-224 *Conducting a Regular Inspection under the MMPR.*

A targeted inspection is an in-depth inspection, which is not intended to assess the compliance with the entire breadth of the MMPR requirements, but focuses on identified criteria.

The on-site portion of a targeted inspection should be unannounced and is completed within one (1) day.

The number of Inspectors assigned to complete at targeted inspection will be determined by the RM.

Every targeted inspection will include:

- a re-inspection of any observation classified as critical from the previous inspection;
- follow up on complaints from industry, registered clients, etc.;
- areas of high risk, such as verification of subsets of inventory, record keeping, good production practices and client registration procedures, etc.; and
- at the discretion of the Inspector and if time permits, a re-inspection of any non-critical observations from previous inspections.

Four critical areas of risk have been identified in relation to marihuana production. The risk categories can be summarized as:

- Risk of diversion,
- Risk to the health or safety of Canadians who require marihuana for medical use,
- Security of the site (risk of serious loss or theft),
- Risk to the confidence of Canadians in the marihuana product produced by LPs and the confidence in the MMPR program.

An observation is defined as a deficiency or deviation from the requirements of the law (i.e. CDSA, NCR, and MMPR) found during the inspection of a regulated party (i.e., licensed producer). Inspectors will categorize individual observations as critical

(more likely to result in diversion or risk to health of patients) or non-critical (less likely to result in diversion or risk to health of patients).

Inspectors must document all observations and, in particular, critical observations in a manner that conveys how the LP's action or inaction impacts the critical risk area. Inspectors shall discuss all critical observations with the RM.

Non-critical observations are those that are deemed by the Inspector in consultation with the regional manager, less likely to have a serious impact on critical risks for marihuana production.

All observations will be recorded in the inspection report.

A reference list of examples of critical observations can be found in Appendix A.

Inspectors should refer to this list when assessing a site's observations.

Although the list in Appendix A is narrowly focused with respect to critical observations, the Inspectors in conjunction with the RM are encouraged to apply a flexible approach to categorizing each observation found during an inspection. Most importantly critical observations should be justified based on the risk.

6.1 Preparation and Planning

This phase of the inspection consists of three main tasks: gathering information, reviewing documentation, and creating the inspection plan.

The Lead Inspector should contact the National Compliance Section (NCS) three weeks in advance of the inspection to request the LP file for their review. The NCS should provide the LP file including information regarding adverse reactions reports, compliance verifications, and recalls involving the LP, to the Lead Inspector within one week of their request.

The Lead Inspector should review the previous inspection reports and estimate the number of plants expected to be on site at the time of the targeted inspection.

The Lead Inspector should review the previous inspection reports and determine the types of PPE the Inspectors may require at the site. It is the responsibility of each Inspector to have the appropriate PPE with them prior to arriving at the site.

6.1.1 Pre-Inspection Information Gathering

The RM will assign a team of Inspectors to conduct a targeted inspection and identify the Lead Inspector. The RM will also determine whether a detailed assessment of risks to personal safety is required. This determination will include the following factors:

- the compliance history of the LP, if applicable; and
- information previously received from law enforcement regarding the LP.

It is the RM's responsibility to conduct and document a risk assessment where one is required. If deemed necessary, the RM may contact the appropriate RCMP regional coordinator, to ask whether they believe there would be an occupational health and safety risk to the inspection team upon attending the site. The information that the RM may share with the RCMP, or any local police or local enforcement, is limited to the site address and the name of the Senior PIC. The RM will allow at least 48 hours for a response.

If concerns relating to personnel safety are identified in the course of the risk assessment, the RM will determine, in consultation with the Departmental Security Officer and the inspection team, what measures should be taken to mitigate the risks.

6.1.2 Pre-inspection Document Review

The Inspectors will examine the company file and any other pertinent information, including the following information:

- licence;
- organization chart and list of designated personnel;
- floor plans;
- description of the security measures and internal controls;
- reports related to loss and theft, compliance verifications, adverse event reports, and any other pertinent information; and
- all previous inspection reports, responses to observations and corrective action plans.

After reviewing the file, the Inspectors will identify any safety concerns. If serious concerns are noted, police accompaniment should be discussed with the RM.

6.1.3 Preparing the Inspection Plan

The Lead Inspector will create an inspection plan that identifies the following:

- the scope of the inspection;
- the objectives of the inspection
- review corrective actions implemented for each of the critical observations from the previous inspection(s),
- review corrective actions implemented for each of the non-critical observations from the previous inspection(s), (at the discretion of Inspectors)
- visually inspect inventory
- review records related to client registrations, sales, complaints, adverse events, recalls, loss and theft,
- the role of each inspector; and
- PPE required;

Modification to the inspection plan may be required once the Inspectors are on the premises.

6.2 Introductory Meeting

Upon arriving at the site, the Inspectors will introduce themselves and present their identification cards. The Inspectors will not allow anyone to handle their identification cards.

The Inspectors will then present their business cards and request to speak with one of the designated personnel (i.e., Senior PIC, RPIC).

The Inspectors will identify themselves to the designated personnel as above.

The Inspectors will hold a brief meeting with the available designated personnel to explain the purpose of the inspection and under what statute and regulations it is being conducted. The names and titles of all individuals attending the meeting will be documented. CS-FRM-0220 *Inspection Attendance Record* may be used to document attendance.

The following should be accomplished during the introductory meeting:

- General information on how the inspection will be conducted should be provided to company personnel.

- The list of the designated personnel and other personnel should be verified including their names, titles, contact information, and hours of work.
- The civic address of the site should be verified. Confirm the site is not a dwelling-place and if there is more than one building at the site. If the site is a dwelling-place the Inspector should contact the RM immediately.
- Confirm if there are any co-existing entities that operate within the site.
- The overall hours of operation of the facility (including office area, production area, storage area, shipping/receiving area, etc.) should be verified.
- The information regarding the proposed activities and substances identified on the producer's licence should be confirmed.
- The geographical area that the LP services should be confirmed.
- The expected clientele should be confirmed.
- An updated site/floor plan should be requested.
- Re-confirm whether plants are present on the site and identify their storage location(s) on the site/floor plan.
- If the LP is in apparent violation of their Marihuana Medical Access Regulations licence(s), the Inspector should note all compliance related issues in their note book and advise the RM when convenient.
- An inventory report should be requested.
- Discuss potential personal health and safety concerns found at the site and re-confirm with the LP the PPE required at the site and, if applicable, any health and safety procedures that must be followed.
- Confirm the last time that pesticides were applied or when a treatment was applied to deal with any pests at the facility (pest control within the facility and/or for the plants).

6.3 Inspection

The Controlled Substances Programme (CSP) currently carries out compliance and enforcement activities for regulations under the *Controlled Drugs and Substances Act* (CDSA). In the interest of treating marihuana for medical purposes like any other narcotic used for therapeutic purposes, the procedures and tools which exist for other controlled substances form the basis of the compliance and enforcement program for licensed producers under the MMPR.

Details on performance of specific activities such as inventory reconciliation, quality assessment, security verification, establishment inspection, etc. are addressed in other CSP SOP documents. CSP personnel are referred to the following documents which provide information on performing the specific activities:

1) Conducting a Regular Inspection of a Licensed Producer, CS-SOP-224
2) Conducting an Inspection of a Controlled Substance Licensed Dealer, CS-SOP-XXX

Inspection notes will be recorded in the Inspectors' notebooks.

The inspection can generally be divided into three parts – inventory, physical inspection, and a document review or audit.

6.4 Exit interview

A brief exit interview will be conducted at the LP's site at the end of the targeted inspection. Record the name and title of all individuals in attendance. CS-FRM-0220 *Inspection Attendance Record* may be used to document attendance.

Preliminary inspection findings, the adequacy of the correct actions, required changes, and improvements to the met the requirements of the MMPR should be discussed with the designated personnel.

If the Inspectors determine that the corrective action progress and timeline(s) are on track, and there are no new observations, the LP should be advised that they will not be required to provide a written response.

If the Inspectors determine that the corrective action progress and timeline(s) are not on track, or if there are new observations, the LP should be advised that they will be required to provide a written response. The date of the response is expected in 5 days from the date the inspection report is issued.

Encourage the LP to seek clarification and respond to questions. If unable to provide a response, make note of the question and provide a response in follow up. Offer the opportunity for the LP to provide additional information, records or documents.

The Lead Inspector should provide compliance promotion material to the LP if applicable.

Inform the designated personnel of the date that a copy of the inspection report will be issued to the company.

The designated personnel will also be informed that the results of the inspection will be shared with the OCS.

No written documents will be left at the site.

6.5 Writing of Report

Using the approved template (CS-FRM-0231 *MMPR Targeted Inspection Report*), The Lead Inspector will complete and submit the inspection report to the RM.

In the report, the Inspector will document the discrepancies which exist in terms of what has been observed versus the requirements of the MMPR and what was submitted as corrective actions.

Observations must be factual and must not include personal opinions, qualifiers or subjective comments. Observations must be formulated clearly, concisely and precisely aligned to the applicable regulatory requirement. Specific examples may be added for additional clarification.

Observations will be identified as 'critical' or 'non-critical' as well as 'repeat observations' or 'new observations' and listed according to importance. Classification of observations may require consultation with the RM.

Items not selected for inspection by the team are not required to be mentioned in the Targeted Inspection Report (IR).

The inspection report and related documents must not include any information pertaining to clients, individuals applying to become client applicants, or health care professionals, or any information that could potentially identify these individuals without prior discussion between the Lead Inspector and the RM. The RM will confirm if this information is required.

The Lead Inspector will make a general conclusion of the applicant's ability to comply with the MMPR.

The Lead Inspector will sign and date the targeted inspection report and submit it to the RM within three days. The RM will review the inspection report and sign it.

The RM will scan and upload the signed inspection report to the Controlled Drugs and Substances Database and send the report to the Manager of the LPD and to the Section Head of the National Compliance Section for administrative purposes. This information will be used to help determine future inspection cycles.

Once the Targeted Inspection report is finalized and signed, the original along with any other inspection material is sent to the CSP Regional Headquarters.

7. APPENDICES

Appendix A
CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*
CS-POL-001 *CDSA Compliance and Enforcement Policy*
CS-GD-010 *MMPR Compliance Management and Endpoints.*
CS-SOP-224 *Conducting a Regular Inspection under the MMPR*
MMPR Inspection Questionnaire

8. REFERENCE DOCUMENTS

You may find it useful to refer to the following documents:

- CDSA
- MMPR
- Inspections reports and follow-up for other sites of the same company or group, if applicable
- Guidance Document on Sanitation Requirements of Dried Marihuana

9. AUTHORS

The author of this document is:
The editors of this document are:

10. DOCUMENT REVISION HISTORY

Version	Change Made	Effective Date
1	Initial issuance of document for internal consultation	
1.1	Revisions after internal consultation.	
1.2	Revision after DMC discussion. Issuance for external consultation	
2.0	Final version posted	

Appendix-A

The following set of observations are examples of critical and non-critical observations for comparison purposes only. The scope and severity of the deviations should be assessed by the Inspector in context of the current inspection.

Critical	Non-critical
148.(2) Inventory and production records were not maintained for the appropriate period of time	Failure to notify the Minister prior to changing designated personnel
17. Performing regulated activities without designated personnel; Insufficient supervision by the Person-in-Charge; Insufficient designated personnel to supervise all shifts;	
##Incomplete or inaccurate record keeping	Annual report not signed
148. (1)(a) Inability to report in a manner that permits an audit of cannabis activities	A few original documents not available (e.g. Chain of signatures)
148. (1)(b) Inventory records stored off site; unavailable at licensed site	Some information missing from records such as telephone number of supplier
NCR 20(6) MMPR 19. Unexplained losses of small amounts of Cannabis without informing the police and the Minister	Records: Information recorded is different from information found on other corresponding documents (may be considered critical under certain circumstances)
Internal controls and security measures only partially implemented with activity occurring	Destruction related issues. i.e. excessive stockpiling, uncontrolled waste storage
Incomplete documents pertaining to destruction	20.(2) Unqualified witnesses to the destruction as per the regulations
Loss of a licence, permit, registration or authorization certificate	20. Unsuitable method of destruction
Failure to notify Minister prior to making changes in security measures	46.(1) Access to cannabis not restricted to persons whose presence is required by their work responsibilities (may be considered critical depending on the situation)
46.(3) Access log not available	66. Labels do not have the required information 70.(2) Label is not bilingual (EN & FR)
Failure to document suspicious transactions	73.(1)(a) LP is filling back orders
Insufficient control measures in the receiving/shipping area (may be considered critical under certain circumstances)	78. Import declaration not sent to the Minister within 15 days of release 86. Export declaration not sent to the Minister within 15 days of release
Records: - Supporting documents missing, original	96. LP did not inform the Minister within 5 days that a security clearance is no longer required

documents not available - Adjustments made with no explanation - Discrepancies found: no explanations, not investigated or reported - Unusual and/or large quantities ordered without verification by LD - Documents pertaining to imports or exports missing or not available	
18. Does not take appropriate measure to ensure the safekeeping of the cannabis during transportation	54.(1) Marihuana has been treated before, during or after the drying process with a pest control product that has not been registered under the *Pest Control Products Act* for use on marihuana for medical purposes.
19. An unexplained loss of a substantial quantity or a series of unexplained losses of cannabis (potential security, internal control or access issues)	55. Premises not maintained under sanitary conditions
Physical security measures identified on the licence application have not been implemented [23.(1)(h)]	57. Insufficient sanitation program
No Inventory records available	58. Lack of appropriate standard operating procedures for Good Production Practices (Division 4)
12.(6) Import without a permit 12.(7) Export without a permit	
25.(k) Failure to comply with a licence condition	
False or misleading documents, including record keeping	
Unauthorized sale to a non-licensed producer or other	
73.(2)(b) Ship only to the shipping address indicated in the order	
54.(2) Dried marihuana contains residue of a pest control product in excess of any maximum residue limit specified for the product under section 9 of the *Pest Control Products Act*.	
53.(1) The microbial and chemical contaminants of dried marihuana are not within generally accepted tolerance limits for herbal medicines for human consumption.	

This is **Exhibit "K"** referred to in
the Affidavit of **TODD CAIN**
Affirmed before me at the City of
Ottawa, in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Sherri Laureen Szabados, a Commissioner, etc.,
Province of Ontario, for the Government of Canada.
Department of Health.
Expires December 2, 2015

Controlled Substances Program

STANDARD OPERATING PROCEDURE

Conducting a Regular Inspection under the *Marihuana for Medical Purposes Regulations*	**Doc. Number: CS-SOP-024** **Version:** 1

Bureau/Office/Area: OCS & RAPB	**Status:** DRAFT	**Effective Date:**

Approved by:	**Date:** XX, 2014

The Office of Controlled Substances ensures that precursors and controlled substances are handled effectively and remain in legal distribution channels. This involves developing legislation, regulations, policies and operations that support the control of illicit drugs and other substances.

The regional Controlled Substances Program is the compliance and enforcement arm of the Office of Controlled Substances, who conducts compliance and monitoring activities to enforce the *Controlled Drugs and Substances Act* and its associated regulations including but not limited to the Precursor Control Regulations, the Narcotic Control Regulations, and the Marihuana for Medical Purposes Regulations (MMPR).

Inspectors conduct on-site inspections of regulated parties who perform regulated activities such as the importation, production and distribution of narcotics, targeted substances, restricted drugs, marihuana for medical purposes, industrial hemp, controlled drugs, and precursors.

Health Canada staff work closely with both our internal partners within Health Canada and external partners including the RCMP, local law enforcement, the Canada Border Services Agency and provincial licensing bodies through joint training initiatives and other collaborative efforts.

FOREWORD

Standard Operating Procedure (SOP) documents are meant to provide guidance to Health Canada employees on how to perform specific tasks to ensure that the requirements of all governing legislation and regulations are met. They also serve to familiarize employees with the applicable tools and record keeping methods and requirements for a specific task. SOP documents provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

SOP documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may* be acceptable if they are supported by adequate justification and applicable legislative or regulatory requirements have been met. Alternate approaches should be discussed in advance with the relevant program area.

This document is dynamic in nature, and is offered without prejudice to future measures, which Health Canada might take in this area.

TABLE OF CONTENTS

1. PURPOSE

The purpose of this SOP is to establish a pre-defined procedure. SOPs are written instructions that are necessary to achieve and maintain a consistent approach to a process. This SOP also provides a platform for training and assessing quality.

Inspections are conducted to monitor and verify compliance with the requirements of the *Controlled Drugs and Substances Act* (CDSA) and the MMPR. The procedures described herein are intended to ensure uniformity of action within the CSP.

This document has been developed to:

- Outline the steps followed during a regular inspection of a Licensed Producer;
- Provide direction to Regional Managers (RM), Section Heads (SH), and Inspectors regarding full inspections of a licensed producer (LP) under the *Marihuana for Medical Purposes Regulations* (MMPR); and
- Assist in ensuring a consistent approach and uniformity to the full inspection program.

This document will evolve guided by information collected through compliance and enforcement activities conducted under the new MMPR.

2. SCOPE

This procedure applies to the first full inspection, the regular inspection, of licensed producers under the MMPR. These inspections are conducted under Section 9 of the MMPR and Section 31 of the CDSA.

PLEASE NOTE:
In addition to the collection of information and verifications that reflect regulatory requirements of the MMPR, this SOP also includes related questions, considered to be best practices by Health Canada that Inspectors may use during an inspection.

Any observation or recommendation (i.e. refusal or that a condition be included on the licence) made by the Inspector, must be clearly linked to a deficiency in a regulatory requirement and must reference the applicable section of the MMPR.

3. DEFINITIONS

3.1 Acronyms

A/RPIC	Alternate Responsible Person in Charge
CDSA	*Controlled Drugs and Substances Act*
CSP	Controlled Substances Program
FDA	*Food and Drugs Act*
FDR	*Food and Drug Regulations*
IUMMP	Information on the Use of Marihuana for Medical Purposes: Consumer Information Sheet
LPD	Licences and Permits Division
MMPR	*Marihuana for Medical Purposes Regulations*
NCED	National Compliance and Exemption Division
NCPR	*New Classes of Practitioners Regulations*
NCR	*Narcotic Control Regulations*
PCPA	*Pest Control Products Act*
PPE	Personal Protective Equipment
RPIC	Responsible Person in Charge
RM	Regional Manager
SOP	Standard Operating Procedure
Senior PIC	Senior Person in Charge
THC	Delta-9-tetrahydrocannabinol

3.2 Definitions

AUTHORIZED PARTY	Individuals authorized under subsection 12.(4) of the MMPR to purchase or receive dried marihuana from a licensed producer
DESIGNATED PERSONNEL	Includes any of the following individuals: the Senior Person in Charge, the Responsible Person in Charge, or the Alternate Responsible Person(s) in Charge
IMMEDIATE CONTAINER	The container in direct contact with the dried marihuana
INSPECTOR	Any person designated as an Inspector under section 30 of the CDSA

LICENSED PRODUCER	The holder of a licence issued under the MMPR
REGULAR INSPECTION	A regular inspection is a full inspection similar to the initial inspection and includes an assessment of all of the requirements of the MMPR.
REGULATED PARTY	Individuals authorized under subsection 12.[2] of the MMPR to purchase or receive marihuana; and cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting in vitro testing that is necessary to determine the percentage of cannabinoids in dried marihuana from a licensed producer
SECURITY DIRECTIVE	Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the storage of Controlled Substances)
SECURITY GUIDE	Guidance Document: *Building and Production Security Requirements for Marihuana for Medical Purposes*
TECHNICAL GUIDE	Guidance Document: *Technical Specifications for Testing Dried Marihuana for Medical Purposes*

4. ROLES AND RESPONSIBILITIES

The planning of the inspection is a shared responsibility between the Inspector(s) and the RM. The Licences and Permits Division (LPD) and the National Compliance and Exemption Division (NCED) may also provide input on the scheduling of the inspection.

The RM is responsible for assigning an inspection team to conduct inspections and will identify a Lead Inspector. To the extent possible, Inspectors will be rotated through the inspection schedule and inspect a variety of companies. RM's are responsible for ensuring Inspectors follow these procedures.

Inspectors are responsible for observing and applying them.

The Lead Inspector is responsible for ensuring that all aspects of the inspection are addressed, including:

- confirming that all information with regards to the file has been received; and is available for the inspection;
- reviewing all of the file history of the licensed producer;
- developing an inspection plan;
- coordinating all aspects of the inspection;
- assigning tasks and responsibilities amongst the team, as required;
- ensuring that inspection notes are taken by each team member according to shared responsibilities;
- acting as the spokesperson for the team;
- organizing the exit interview;
- coordinating the writing of the report;
- recommending follow-up actions;
- assigning a site risk assessment level; and
- signing the inspection report, and submitting it to the RM.

Within the context of an administrative inspection and the normal execution of their duties, Inspectors may review files that contain personal information. For example, inspections of licensed producer applicants and licensed producers will require Inspectors to access to records to verify that client registration and record keeping systems meet the requirements of the MMPR. There may be circumstances where in order to perform their duties (i.e., to document potential diversion of controlled substances, suspected fraudulent activities) the Inspector may need to reproduce or make note of client information, of an individual applying to be a client, or a health

care professional. Under these circumstances, Inspectors should contact their Section Head or Regional Manager to discuss, taking into consideration an individual's right to privacy, the appropriate approach to collecting this information for compliance management purposes.

Inspectors will only collect information as required when exercising their duties as an Inspector. Inspectors must ensure that all information is safeguarded and protected in accordance with the *Privacy Act*. Generally, Inspectors should not reproduce or make note of client information including the client's unique identifier, of an individual applying to be a client, or a health care professional. An inspection report, with the exception of an inspection report related to suspected diversion of controlled substances, fraudulent activities, serious contraventions of the regulations, must not include any information pertaining to clients, client applicants, health care professionals or any information that could potentially identify these individuals.

5. BACKGROUND

The MMPR provides a regulatory framework whereby Canadians who are deemed to benefit from access to marihuana for medical purposes can have access to it. The MMPR replace the *Marihuana Medical Access Regulations* which will be repealed on March 31, 2014.

Health Canada plays a role in protecting the health of Canadians who are prescribed marihuana for medical purposes, by ensuring they receive the medication deemed necessary. A second objective is to ensure the supply of marihuana for these Canadians meets their prescribed requirements. Health Canada is a regulatory department, and C&E activities are essential to the success of regulatory activities. The operational framework and strategic direction for C&E activities to be conducted under the MMPR is set out in CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*, CS-POL-001 *CDSA Compliance and Enforcement Policy*, and CS-GD-010 *MMPR Compliance Management and Endpoints.*

The role of Inspectors includes site inspections, compliance promotion, communications to and from LPs and LP applicants, monitoring and enforcement activities.

Section 30 of the CDSA covers the designation of Inspectors and their duty to identify themselves when entering a place under the authority of this Act.

Section 31 of the CDSA describes the places an Inspector may enter, the powers granted to them, and the use of computers and copying equipment in carrying out an inspection. Subsection 31.(2) of the CDSA covers the entry into a dwelling-place and the conditions attached to that activity.

Section 9 of the MMPR authorizes inspections to be conducted to confirm information submitted in support of an application, amendment or renewal of a licence.

5.1 Resources and Equipment

During an inspection, each Inspector must carry their badge and Inspector identification card, and must use PPE as required. In addition the following materials may be useful:

- Inspection plan
- Notebook and pens
- Cellular phone
- Measuring tape
- Business cards
- CSP/ OCS telephone contact list
- MMPR PLI Questionnaire
- Sample Medical Document for the MMP
- MMPR
- IUMMP
- NCR and NCPR
- CDSA and FDA Schedule B
- Security Directive
- Security Guide
- Technical Guide
- Industrial Hemp Technical Manual – Standard Operating Procedures for Sampling, Testing and Processing Methodology

6. PROCEDURE

Regular inspections, similar to initial inspections, are full MMPR inspections. The Licensed Producer (LP) will be assessed against all applicable requirements of the MMPR.

Low risk LPs will undergo a regular inspection within twelve (12) months of the inspection that identified them as a low risk LP. All other LPs will be inspected through targeted inspections on a monthly basis.

Regular inspections are unannounced.

The result of the regular inspection will contribute to the frequency and scope of subsequent inspections as well as provide information for the renewal of licence, when applicable.. The Inspector will use CS-FRM-0224 *Licensed Producer Regular Inspection Report Template* to report the results of all regular inspections.

6.1 Preparation and Planning

The regular inspection will be unannounced. However, if it is deemed necessary to announce the inspection date in advance, approval must first be obtained from RM. If approval is obtained, the Senior PIC will be notified the day before the inspection. If the Senior PIC cannot be reached, the RPIC or, if not available, the A/RPIC will be informed.

Except under extraordinary circumstances, the regular inspection shall not be postponed. If such a condition appears to exist, prior approval from RM must be obtained. The inspection should then be planned for the next business day or as soon as possible.

This phase of the inspection consists of three main tasks: gathering information, reviewing documentation, and preparing the inspection plan.

6.1.1 Pre-Inspection Information Gathering

The RM will also determine whether measures to mitigate risks to personal safety are required in accordance with the SOP entitled Safety and Security of Regional Compliance Officers.

The on-site portion of a regular inspection should be completed within five (5) days depending upon the activities conducted by the LP. The number of Inspectors assigned to complete a regular inspection will be determined by the RM.

6.1.2 Pre-inspection document review

The Inspectors will examine the company file and any other pertinent information, including the following information:

- the producer's licence;
- floor plans, organizational chart and list of designated personnel;
- description of the security measures and internal controls including record keeping, good production practices, quality assurance, etc.;

- any pertinent correspondence;
- loss and theft reports, compliance verifications, recall reports, adverse event reports and other pertinent information;
- import/export permits and applications; and,
- all previous inspection reports, follow-up letters, and responses.

After reviewing the file, the Inspector will identify any safety concerns. If serious concerns are noted, police accompaniment should be discussed with the RM.

6.1.3 Preparing the Inspection Plan

The Lead Inspector will create an inspection plan that identifies the following:

- the scope of the regular inspection;
- the objectives of the inspection
    - to assess whether or not the LP is meeting the applicable requirements of the MMPR (see section 6.6 of this document for detailed information);
    - to verify that all corrective actions taken in response to previous observations have been implemented;
    - visually inspect inventory;
    - review records related to client registrations, sales, complaints, adverse events, recalls, loss and theft;
    - compliance promotion;
- the role of each Inspector (the Inspector who will conduct the inventory reconciliation must be identified); and
- PPE required.

Modification to the inspection plan may be required once the Inspectors are on the premises.

6.2 Introductory Meeting

Upon arriving at the site, the Inspectors will introduce themselves and present their identification cards. The Inspectors will not allow anyone to handle their identification cards.

Confirm site is not a dwelling-place and whether there is more than one building at the site. If the site is a dwelling-place the Inspector(s) should contact the RM immediately.

The Inspectors will then present their business cards and request to speak with the Senior PIC.

The Inspectors will identify themselves to the designated personnel as above.

If the Senior PIC is not present, the Inspector will ask one of the designated persons present to advise the Senior PIC of the inspection.

If the RPIC is also absent and there is no A/RPIC, the Inspector must:
1) ensure that no transactions are allowed to take place until either the RPIC or A/RPIC is on the premises; and 2) contact the RM immediately.

The RPIC may be contacted by phone, and may designate an individual to assist with the inspection until he or she arrives at the site.

The Inspectors will hold a brief meeting with the available designated personnel to explain the purpose of the inspection and under what statute and regulations it is being conducted. The names and titles of all individuals attending the meeting will be documented. CS-FRM-0220 *Inspection Attendance Record* may be used to document attendance.

The following should be accomplished during the introductory meeting:

- General information on how the inspection will be conducted should be provided to company personnel.
- Advise the company that if observations of a critical nature (more likely to cause a risk to health or pose a risk of diversion) the Senior/ PIC will be notified as soon as possible.
- Compliance promotion material (FAQs, information sheets), not previously distributed, should also be provided to company personnel;
- Identification of any potential personal health and safety concerns found at the site and, if applicable, any health and safety procedures that must be followed.
- The Inspector assigned to inventory reconciliation should request an up to date inventory report that includes the inventory of all stages of production, It is critical that the Inspector receives the inventory report prior to commencing the inspection. If possible this Inspector should leave the meeting in order to start the inventory reconciliation (see Section 6.6.1 of this document).

- Verification of the following information:
    - List of all designated personnel and other personnel including names, titles, contact information and hours of work. Any changes to designated personnel should be noted;
    - Civic address(es) of all sites where any aspects of licensed activities are located;
    - The licensed producer's clientele;
    - Whether any other entities are operating on the site;
    - Overall hours of operation including office area, production area, storage area, shipping /receiving area, etc.;
    - All activities and substances on site are permitted according to licence;
    - Any changes to existing floor plan and if so, a new floor plan should be requested;
    - If or when pesticides were applied and the names of applied pesticides; and
    - Production of CO_2 and whether CO_2 and CO levels are monitored.
- Verification that all corrective actions planned in response to previous observations have been implemented.

In order to facilitate the inspection, the Inspector should request documentation at the beginning of the inspection to give the LP time to obtain the information.

6.3 Inspection

The inspection can generally be divided into three parts – inventory, physical inspection, and a document review or audit.

Inspectors will note any observed non-compliance with the MMPR as well as discrepancies between observed practices and records and those on file with OCS. In addition, the Inspectors will document any opportunities for diversion and assess the security measures for effectiveness and sufficiency.

The Inspector, at their discretion, may review any written SOPs the company has developed. The SOPs related to concerns identified during 6.2 (pre-inspection document review) and through discussions with designated personnel during the introductory meeting should be reviewed.

6.3.1 Inventory

With the up-to-date inventory in hand, the Inspector will proceed with a physical inventory reconciliation of a representative sample of the inventory. The inventory must be verified as soon as possible after commencing the inspection.

The sample selected must be proportional to the total inventory and products handled by the LP and must reflect all activities the LP conducts. As a guiding principle, $\sqrt{n}+1$ can be used to determine representative sample amounts for each form of cannabis to be verified during the inspection.

For the selected sample, the Inspector will proceed with a complete review of all phases of operations, including all production phases packaging, retained samples, waste material, distribution, returns and destruction.

The Inspector will verify inventory of various forms of cannabis, i.e., plants, bulk dried marihuana, dried marihuana packaged for sale for medical purposes, samples, reference standards and unservicable product/waste, as well as a representative sample of dried marihuana products, based on the activities conducted by the licensed producer.

The Inspector must reconcile the information collected at different steps of the process. In order to reconcile transactions and inventory of a particular product, the Inspector will establish a starting date for the verification. This starting date must be the date a physical inventory was taken. The Inspector will check the receipts and disbursements from that date onwards up to the day the inventory was taken which should be the first day of inspection.

Expired or damaged products to be destroyed should already have been removed from the saleable inventory and listed in a separate record. Returned products should be listed in a separate record as well. Final disposition of the returned product should be identified (e.g., sale to another LD or LP, or destruction). The theoretical yield and loss of weight from drying will be determined based on the grower's inventory system (i.e., their predicted, documented and historical yield).

The Inspector will note any discrepancy between the theoretical inventory and the physical count and will ask for explanations. If significant discrepancies are found for which no satisfactory explanations can be provided by the designated representatives, the Inspector shall contact the RM to discuss how to proceed.

6.3.2 Diversion Indicators

The following lists possible signs that may indicate a diversion issue at the licensed producer. Inspectors should be aware that any sign may also have a legitimate

explanation. The list is intented to cover circumstanaces where additional questions should be asked:

- Missing product
- Sales to patients that do not correspond to the registered client list.
- Sales above the 150 grams inidacted in the MMPR
- Havest records that are greatly different from typical production.
- Culling "male" plants close to the harvest time.
- Unusual loss of material
- Evidence of production of derivatives of marihuana (hasish, etc.)
- Lack of production records

6.3.3 Security

Verify the accuracy of the floor plan on file or provided at the time of the inspection and record the location of the areas within the site where cannabis is present.

Review the ventilation, and the flow of material through the site.

6.3.3.1 Site Perimeter

- Verify that a system is in place to control the distribution of the codes, keys, and other elements of the security system.
- Review personnel that have access to keys and codes and how this information is tracked.
- Verify whether the perimeter of the site prevents unauthorized access.
- Assess the perimeter of the site to ensure that there are sufficient visual recording devices to visually monitor it at all times in order to detect attempted or actual unauthorized access.
- Assess whether the visual recording devices, in the conditions under which they are used, are capable of recording in a visible manner any attempted or actual unauthorized access.
- Test the intrusion detection system that is used to detect:
  - attempted or actual unauthorized access to, or
  - movement around the perimeter, or
  - tampering with the system.
- Verify that the intrusion detection system operates and is monitored at all times.
- Verify that records of breaches of the intrusion detection system are kept and contain all required information.

6.3.3.2 Area(s) within the Site where Cannabis is Present

- Verify that the area(s) within the site where cannabis is present (referred to in section 6.2.2 as "those area(s)") is restricted to persons whose presence in those area(s) is required by their work responsibilities.
- Verify that the RPIC or A/RPIC, if applicable, is physically present while other persons are in those area(s).
- Verify that a system is in place to control the distribution of the codes, keys, and other elements of the security system.
- Verify if those area(s) have any physical barriers or signage posted to prevent unauthorized access.
- Verify if there are sufficient visual recording devices to visually monitor the area(s) at all times to detect illicit conduct.
- Assess whether the visual recording devices, in the conditions under which they are used, are capable of recording in a visible manner illicit conduct.
- Assess/test the intrusion detection system that is used to detect:
  - attempted or actual unauthorized access to, or
  - movement in the area(s), or
  - tampering with the system.
- Verify that the intrusion detection system operates and is monitored at all times.
- Verify that records of breaches of the intrusion detection system are kept and contain all required information.
- Assess the systems in place that filter air to prevent the escape of odour and, if present, pollen in these areas. Verify whether odour is detectable outdoors.

6.3.3.2.1 Storage

PLEASE NOTE:
These additional requirements apply to the storage of controlled substances which includes dried marihuana, marihuana seeds and cannabis used solely for the purpose of testing in order to determine the percentage of cannabinoids in dried marihuana (both packaged and unpackaged). These requirements also apply to all waste cannabis material from cultivation or production with the exception of mature cannabis stalks that do not include leaves, flowers, branches or seeds; and fibers derived from the stalks, as well as, any non-viable cannabis seeds. Additionally, these requirements do not apply to plants or cannabis material undergoing the drying process.

- Verify that only the RPIC, A/RPIC(s) and persons whose presence is required by their work responsibilities have access to the vault/safe or cage.
- Verify that an appropriate system is in place to control the distribution of the codes, keys, combinations, etc.

- Verify that the street value of stored cannabis does not exceed the approved security level as indicated on their license.
- Verify that only cannabis is kept in these areas.
- Verify the in-house laboratory, if applicable, stores reference standards and samples as required by the Security Directive.
- Verify that the RPIC or A/RPIC, if applicable, are physically present while other persons are handling controlled substances.
- Verify that only the RPIC and/or A/RPIC(s) have the authorization to disarm a vault/safe or cage.
- Verify that only the RPIC and A/RPIC(s) have the key to the cage and the combination for the safe/vault.
- Verify the storage conditions (vault or safe and cage, if applicable) against the measures submitted and the Security Directive.
- Verify that the combination is changed at regular intervals (at least once a year) and/or when a person having the combination is no longer a designated RPIC or A/RPIC. (This requirement only applies to Security Level 8 and higher.)
- Conduct an alarm test of the intrusion detection devices and system required by the Security Directive. Request an incident report from the monitoring firm to ensure that the firm is able to report all incidents related to the safety devices

6.3.4 Good Production Practices

- Verify that SOPs have been implemented at the site regarding the production, packaging, labelling, and storage of the dried marihuana.
- Verify that any changes to SOPs have been implemented have been documented appropriately.
- Review records of THC and cannabidiol content from various batches to verify uniformity.
- Verify that the licensed producer has developed a sampling plan to verify uniformity of THC and cannabidiol content of the finished products. Review records of this sampling plan.

6.3.4.1 Premises for Production, Packaging, Labelling, and Storing of Dried Marihuana

- Verify that the areas permit activities to be conducted under sanitary conditions.

- Verify that the storage conditions of the dried marihuana maintain its quality.

6.3.4.2 Equipment to Produce, Package, Label, and Store Dried Marihuana

- Verify that equipment the designed, constructed, maintained, operated and arranged in a manner that:
  - Permits the effective cleaning of its surfaces.
  - Permits it to function in accordance with its use.
  - Prevents it from contaminating the dried marihuana.
  - Prevents it from adding extraneous substance to the dried marihuana.

6.3.4.3 Sanitation Program (Areas where the Dried Marihuana is Produced)

- Verify that a written sanitation program is implemented for the areas used to produce, package, label and store the dried marihuana.
- Observe and note any areas of sanitation concern. If any concerns are noted, review the sanitation plan to ensure they are being implemented as written and note any possible deficiencies in written plan.

6.3.4.4 Material Control

- Verify that the licensed producer has written procedures for the transportation, receipt, identification, examination, handling, sampling, testing and approval or rejection of marihuana.
- Verify each lot of marihuana is assigned a distinctive lot number.
- Verify that containers of marihuana are inspected upon receipt for closure and physical integrity.
- Verify that dried marihuana is retested after any exposure to conditions likely to adversely affect their purity, quality or composition.
- Verify each lot of dried marihuana is identified and treated according to its quality status (i.e. quarantined, approved or rejected).
- Verify that marihuana is stored in appropriate conditions, including appropriate temperature and humidity, to protect against quality deterioration and contamination.
- Verify that appropriate systems and controls are established to ensure water used to produce products is of potable quality and meets the Guidelines for Canadian Drinking Water Quality [see http://www.hc-sc.gc.ca/ewh-semt/water-eau/drink-potab/guide/index_e.html], WHO guidelines for Drinking Water Quality or other standards.
- Verify that outdated or obsolete printed packaging materials are destroyed.

6.3.4.5 Process Control

- Verify that a master production document has been prepared for the production of each product, and that the quality assurance person has reviewed and approved the document.
- Verify that complete batch records are prepared and retained.
- Verify that each batch of product produced is allocated an individual batch number that can be tracked.
- Verify that deviations from written and approved production processes, standards and test methods, are recorded and evaluated with the final approval given by the quality assurance person.
- Verify that all materials, products, samples, containers, processing areas and major equipment are identified at all times to indicate their contents and/or status.
- Verify that procedures are in place to prevent extraneous materials from being included in the "in process" materials and the final package.
- Verify procedures are in place to identify, store and dispose of rejected or contaminated/adulterated products.
- Verify that approved written procedures are established for reprocessing batches that do not conform to finished product specifications.
- Verify labels are securely stored to prevent mix-ups (i.e. stored and withdrawn against a packaging order).
- Verify that written procedures exist and are followed to ensure the correct labels and packaging materials are issued and used.
- Verify that each package bears a lot number and expiry date, if applicable.
- Verify that written procedures are set up and followed for preparing samples, including the conditions of their storage and the duration of such storage.
- Verify that on completion of each stage of processing, the equipment and containers used during critical in-process stages are appropriately labelled.

6.3.4.6 Records

- Verify that current versions of SOP(s) are maintained on site.
- Verify records of each batch of dried marihuana produced, packaged or labelled have been done accordingly to a master production document.
- Verify that the licensed producer maintains a list of all brand names of the dried marihuana they produce, package, or label.

6.3.5 Quality Assurance

PLEASE NOTE:
This section applies to dried marihuana for sale for medical purposes, as well as to any imported marihuana when it is to be sold or provided in Canada, and to any Canadian-produced marihuana which is to be exported.

- Verify the identity of the quality assurance (QA) person, the date of appointment, qualifications, and any changes to QA staff.
- Verify that written specifications are set up and approved by the QA.
- Verify that the specifications for dried marihuana correspond with an appropriate Schedule B pharmacopoeial standard.
- Verify that every lot or batch of dried marihuana is tested for microbial and chemical contaminants as required by the Pharmacopeia selected from Schedule B to the FDA, as well as, for the THC and cannabidiol levels, and any pesticide residues, if applicable.
- Verify that a visual inspection of the dried marihuana take place to verify the absence of pests or extraneous substances (i.e. any material or substance other than dried marihuana).
- Verify that written analytical methods to perform all chemical and microbiological tests enumerated in the specification of the finished product are in place.
- Verify that the licensed producer and any external laboratory will have a technical agreement and that the QA ensures that laboratories (in-house and/or contract) are capable of performing all of the tasks and responsibilities assigned to them.
- Verify written procedures are established and followed for sampling, inspecting, and testing dried marihuana.
- Verify that the QA approves or rejects all procedures, specifications, test methods, controls and results that affect the purity, quality and composition of the product.
- Verify that every lot or batch of dried marihuana is approved by the QA prior to its sale based on its completed batch records and test results.
- Review various testing results for dried marihuana for the following information
- Testing has been established according to section 53 of the regulations
- Methodology for the testing has been established
- Note whether an outside laboratory is conducting testing and verify the lab is appropriate for conducting testing (i.e. licensed facility)

- Test result reviewed were within established limits for microbial and chemical contamination
- Verify a validated methodology has been established to determine the THC and cannabidiol content of the cannabis (including dried marihuana).
- Verify that the licensed producer has established specifications and tolerance limits for THC and cannabidiol for each brand of dried marihuana that they produce.
- Verify whether pest control products are used on marihuana.
- If applicable, verify that the licensed producer has determined its maximum residue limit(s) specified for its pesticide control product(s). http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php
- Verify a validated methodology is established to determine the pesticide control product residues.
- Verify a process is developed to record every complaint received regarding the quality of the dried marihuana and whether any further investigations and/or corrective action required.
- Review records of complaints and written actions taken in response.
- Verify that written procedures are reviewed regularly and kept up-to-date.
- Verify that there is a system for revising the procedures and the reason for any revisions is documented.
- Verify the system will ensure that only current procedures are in use.

6.3.5.1 Retention Sample

- Verify that retention samples are maintained for at least one year after the date of the last sale or provision of any portion of the lot or batch of dried marihuana.
- Verify that the retention samples are in sufficient quantities that would enable the Minister to make a determination of whether the lot or batch of dried marihuana meets the requirements of the laboratory tests.
- Verify the retained samples are maintained in their immediate containers or in containers of the same material and construction
- Verify the retention samples are stored in the environmental conditions listed on the label.
- Request review of various retention samples to ensure the above criteria is being met.

6.3.5.2 Records

- Review the documentation, used to capture the approval of the dried marihuana by the quality assurance person prior to its sale.

- Verify that the quality assurance person maintains all laboratory records of tests and investigations.
- Verify that the quality assurance person maintains all records of complaints with the following information: the name and description of the product, the lot number, the source and nature of the complaint, and any response. When an investigation is conducted, verify that the quality assurance person will include in the written record the findings and any follow-up action taken.
- Verify that the licensed producer keeps records of retention samples maintained at the site.
- Verify authorized written procedures for all sections of these requirements are retained for reference and inspection.
- Verify that all written procedures have evidence of their approval for use by the quality assurance person.

6.3.6 Registration

6.3.6.1 New Applications/Amendment Applications

- Verify that all of the required registration information is being collected.
- Verify the process and/or system in place to ensure that the medical document contains all required information and was signed by an authorized healthcare practitioner.
- Verify the process and/or system in place to notify clients in writing when they have been registered. Ensure that all of the information required under subsection 111.(2) and section 116 of the MMPR is captured.
- Verify that each client will receive a unique identifier.
- Verify that registrations are assigned an appropriate expiry date.
- Verify the means of preventing a client from placing an order and receiving an order of dried marihuana after their registration has expired.
- Review samples of registration records.

6.3.6.2 Refusals

- Verify the process and/or system in place to assess applications and determine if they should refuse to amend a registration of an existing client or to register the potential client.
- Verify the process and/or system in place to notify clients or potential clients in writing that the LP is proposing to refuse or to register them as a client.

- Verify the process and/or system in place to assess the response provided by the client or potential client and the reason(s) why the LP's decision to refuse to register them is unfounded.
- Verify the process and/or system in place to return the medical document without delay to the clients or potential clients they refuse to register.
- Review samples of applications that have been refused.

6.3.6.3 Cancellation

- Verify the process and/or system in place to assess the situation and determine if a registration should be cancelled.
- Verify the process and/or system in place to notify clients in writing that their registration has been cancelled.
- Verify the process and/or system in place to assess the response provided by the client and the reason(s) why the licensed producer's decision to cancel their registration is unfounded.
- Verify that medical documents are not returned to a client whose registration has been cancelled.

6.3.7 Packaging

- Verify whether the immediate container has a security feature that satisfactorily indicates whether a package has been opened.
- Verify that the immediate container is a child resistant package that meets the requirements of subsections C.01.001.(2) to (4) of the FDR.
- Verify the package sizes offered by the licence producer and/or the process used to ensure that no more than 30g of dried marihuana is in the immediate container.
- Verify the process and/or system the licensed producer uses to ensure that the immediate container does not contain less than 95% and not more than 101% of the net weight as specified on the label.
- Verify that the package keeps dried marihuana dry and free from contamination.

6.3.8 Labelling

- Perform a review of client and product labels.

6.3.9 Ordering

6.3.9.1 Clients

- Verify that client orders contain all of the required information.
- Verify that a record is made of the information required under subsection 138.(1) of the MMPR for each order received.
- Verify the process and/or system in place to assess orders and determine if an order should be refused to be filled.
- Verify the process and/or system in place to notify clients in writing that the licensed producer is refusing to fill an order.
- Verify the process and/or system in place to prevent a client or the individual responsible for that client from being sold or provided with a total quantity of dried marihuana that exceeds 30 times their daily quantity in any 30-day period.

6.3.9.2 A Person other than a Client

PLEASE NOTE: This applies to authorized parties (specifically hospital employees and section 56 exemption holders) and regulated parties

- Verify that before filling any written order the licensed producer verifies that it contains all of the required information as per subsection 131.(3) of the MMPR.
- Verify the licensed producer has a process and/or system in place to assess the orders and determine if an order should be refused to be filled.
- Verify the process and/or system in place to notify the person placing the order in writing that the licensed producer is refusing to fill an order.

6.3.10 Shipping

- Verify how the licensed producer ensures the safe keeping of cannabis (including dried marihuana) during its shipping, delivery, or transportation.
- Verify that each shipment of dried marihuana to a client or an individual who is responsible for that client contains Health Canada's *Information on the Use of Marihuana for Medical Purposes* document in English and French, as well as a separate document containing the information contained in the client label.
- Verify that the licensed producer has a process and/or system in place that ensures that dried marihuana is shipped in only one shipment per order.
- Verify that shipping packages:
  - Will not open or permit the escape of its contents during handling and transportation.
  - Is sealed so that it cannot be opened without the seal being broken.
  - Prevents the escape of marihuana odour.

- Prevents the contents from being identified without it being opened.
- Verify that the licensed producer uses a shipping method that will allow the package (cannabis including dried marihuana) to be tracked during transit and will ensure its safekeeping during transit.

6.3.10.1 Offsite Laboratory Analysis

- If applicable, review the shipping process and/or system the licensed producer uses to send samples to an external laboratory for analysis.
- Verify that the external laboratory holds a licence to conduct activities with cannabis.

6.3.10.2 Destruction offsite

- If applicable, review the shipping process and/or system the licensed producer uses for destruction at a location other than the licensed site.

6.3.11 Returns

- Verify whether the licensed producer accepts returns.
- If the licensed producer accepts returns:
- verify that they will have a process or system to ensure returned marihuana is not resold;
- verify that the licensed producer keeps appropriate records for returned marihuana;
- review the shipping process and/or system the licensed producer uses for returns from their clientele.

6.3.12 Receiving

- Verify the licensed producer keeps appropriate records for any receipt of cannabis.

6.3.13 Loss and Theft

6.3.13.1 At the Site

- Review with the licensed producer the process or verification steps that are in place to indicate/identify a theft of cannabis (including dried marihuana)

or an unusual waste or disappearance of cannabis that cannot be explained on the basis of normal accepted business activities.

- Verify with the licensed producer the quantity of material they consider an unusual waste or disappearance.

6.3.13.2 In Transit

- Review the process that is used to address a loss or theft of cannabis (including dried marihuana) during transit.

6.3.14 Destruction

- Verify that the licensed producer has a process and/or system to witness and record the destruction of cannabis.
- Assess records of destruction.

6.3.15 Adverse Reactions

- Verify the licensed producer has a process and/or system in place to record a case report for each serious adverse reaction to the dried marihuana they sell or provide.
- If applicable, verify that OCS has been appropriately notified of adverse reactions.

6.3.16 Recall

- Verify that the licensed producer has a process and/or system to address the recall of every lot or batch of dried marihuana that has been made available for sale (i.e. determining extent of the recall, and means of notifying affected parties).
- Verify that the process and/or system include a step to notify the Minister with the information required under section 62 of the MMPR within three days after the day on which the recall is commenced.
- Verify which individual(s) are responsible for initiating and coordinating recall activities.
- Verify that the recall procedure can be put into operation at any time, during and outside normal working hours.
- Verify that the process and/or system the licensed producer uses to identify and store recalled products separately in a secure area until further action is determined.

- Verify that the licensed producer assesses and records at intervals the progress and efficacy of the recall, and issues a final report, including a final reconciliation.
- Verify who is responsible for notifying all Canadian and foreign clients involved in the distribution and import of the recalled product.
- If a recall has been conducted, assess the record of the recall.

6.3.16.1 Records

- Verify that the licensed producer maintains distribution records so each lot can be traced.

6.3.17 Information Sharing

- Verify that the licensed producer has a process and/or system in place to verify that the individual requesting information on a possible client is a member of a Canadian police force.
- Verify how the licensed producer ensures that they respond within 72 hours after receiving the request from a member of a Canadian police force.

6.4 Exit Interview

A brief exit interview will be conducted at the LP's site at the end of the inspection. Record the name and title of all individuals in attendance. CS-FRM-0220 *Inspection Attendance Record* may be used to document attendance.

Preliminary inspection findings including any draft observations, required changes, and improvements to meet the requirements of the MMPR should be discussed with the designated personnel.

The LP should be advised that a written response to each observation must be submitted to the Inspector within ten (10) days from the date the inspection report is issued.

Encourage the LP to seek clarification and respond to questions. If unable to provide a response, make note of the question and provide a response in follow up. Offer the opportunity for the LP to provide additional information, records or documents.

The Lead Inspector should provide compliance promotion material to the LP if applicable.

Inform the designated personnel of the date that a copy of the inspection report will be issued to the company.

Advise the designated personnel that the results of the inspection will be shared with the OCS.

No written documents will be left at the site.

6.5 Writing of Report

Using the approved template (CS-FRM-0241 *MMPR Regular Inspection Report)*, the Inspector will write the inspection report.

In the report, the Inspector will document the discrepancies which exist in terms of what has been observed versus the requirements of the MMPR. The inspection report is intended to describe the situation noted at the time of the inspection and to identify practices in place up until the inspection took place.

Observations must be factual and must not include personal opinions, qualifiers or subjective comments. Observations must be formulated clearly, concisely and precisely aligned to the applicable regulatory requirement. Specific examples may be added for additional clarification.

Observations will be identified as 'critical' or 'non-critical' and listed according to importance. Classification of observations may require consultation with the RM.

The inspection report and related documents must not include any information pertaining to clients, individuals applying to become client applicants, or health care professionals, or any information that could potentially identify these individuals without prior discussion between the Lead Inspector and the RM. The RM will confirm if this information is required.

The Lead Inspector will make a general conclusion of the applicant's ability to comply with the MMPR.

The Lead Inspector will sign and date the inspection report and submit it to the RM within five days. The RM will review the inspection report and sign it.

The RM will scan and upload the signed inspection report to the Controlled Drugs and Substances Database and send the report to the Manager of the LPD and to the Section Head of the National Compliance Section for administrative purposes. This information will be used to help determine future inspection cycles.

7. APPENDICES

CS-OF-001 *Operational Framework for Compliance and Enforcement Activities for the Marihuana for Medical Purposes Regulations (MMPR)*
CS-POL-001 *CDSA Compliance and Enforcement Policy*
CS-GD-010 *MMPR Compliance Management and Endpoints*
CS-FRM-00241 MMPR Regular Inspection Report Template

8. REFERENCE DOCUMENTS

You may find it useful to refer to the following documents:

- CDSA
- MMPR
- Inspections reports and follow-up for other sites of the same company or group, if applicable
- Guidance Document on Sanitation Requirements of Dried Marihuana

9. AUTHORS

The author of this document is:
The editors of this document are:

10. DOCUMENT REVISION HISTORY

Version	Change Made	Effective Date

This is **Exhibit "L"** referred to in
the Affidavit of **TODD CAIN**
Affirmed before me at the City of
Ottawa, in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Sheri Laureen Szabados, a Commissioner, etc.,
Province of Ontario, for the Government of Canada.
Department of Health.
Expires December 2, 2015

Licensed Producer Reporting Requirements
Monthly Report Protected B when completed 320

Licence Name:	
Licence Number:	

NOTE: This report is due at the Office of Controlled Substances on or before the 15th day of each month, for the previous month.

Reporting Period: From: YYYY MM DD To: YYYY MM DD

PART A. Dried marihuana production (kg)

The total amount of dried marihuana (in kilograms) produced in the reporting period.

Amount Produced (kg):	

PART B. Total quantity sold (kg)

The total amount of dried marihuana (in kilograms) sold to the following during the reporting period:

Registered clients (kg):			
Other Licensed Producers (kg):			
Licensed Dealers (kg):		Reason(s) for sale:	
Other Clients (kg):			
If dried marihuana is sold to Other Clients, you must specify the type of client:			
Other Clients details:			

PART C. Number of clients registered

The total number of persons that were registered clients of your organisation at the end of the reporting period. Include only those persons whose registrations were valid on the last day of the reporting period AND the total number of persons that were registered as new clients of your organisation during the reporting period:

Total registered clients:	
Total clients registered during reporting period	

PART D. Number of refused registrations and refusals to fill order

The number of registered clients who tried to register with you, but could not be registered, regardless of the reason AND the number of clients who placed orders or tried to place orders that could not be filled, regardless of the reason:

Total registered clients not registered:	
Total clients whose orders could not be filled:	

PART E. Quantity of dried marihuana held in stock as of the final day of the reporting period

The total amount of dried marihuana (in kilograms) in inventory as of the final day of the reporting period.

Amount in inventory (kg):	

PART F. Import of dried marihuana (kg)

The total amount of dried marihuana (in kilograms) that you imported during the reporting period.

Amount imported (kg):	

PART G. Export of dried marihuana (kg)

The total amount of dried marihuana (in kilograms) that you exported during the reporting period.

Amount exported (kg):	

Licence Name:	
Licence Number:	

Reporting Period: From: YYYY MM DD To: YYYY MM DD

PART H. Quantity lost/stolen (g)

The total amount of dried marihuana (in grams) lost and/or stolen during the reporting period.

Amount lost/stolen (g):	

PART I. Quantity destroyed (g)

The total amount of dried marihuana (in grams) destroyed during the reporting period.

Amount destroyed (g):	

PART J. Number of shipments

The total number of shipments sent to the following during the reporting period:

Registered clients:	
Other Licensed Producers:	
Licensed Dealers:	
Other Clients:	
If dried marihuana is shipped to Other Clients, you must specify the type of client:	
Other Clients details:	

PART K. Number of shipments per province (based on client's location)

The total number of shipments sent to the following in each province and territory in this reporting period:

	AB	BC	MB	NB	NL	NS	NT	NU	ON	PE	QC	SK	YT
Registered clients:													
Other Licensed Producers:													
Licensed Dealers:													
Other Clients:													
If dried marihuana is shipped to Other Clients, you must specify the type of client:													
Other Clients details:													

PART L. Average amount of marihuana for medical purposes authorized (in g)

The average daily amount of dried marihuana (in grams) supported by Health Care Professionals.

Average amount of marihuana (g):	

PART M. Median amount of marihuana for medical purposes authorized (in g)

The median daily amount of dried marihuana (in grams) supported by Health Care Professionals.

Median amount of marihuana (g):	

Licensed Producer Reporting Requirements
Monthly Report

Protected B when completed

Licence Name:	
Licence Number:	

Reporting Period: From: YYYY MM DD To: YYYY MM DD

PART N. Average shipment size (in g)

The average shipment size (in grams) sent to registered clients during the reporting period.

Average shipment size (g):	

PART O. Median shipment size (in g)

The median size (in grams) of the shipments sent to registered clients in the reporting period.

Median shipment size (g):	

PART P. Monthly list of ten highest totals (in g) shipped to a registered client (de-identified)

Report the ten highest amounts of dried marihuana shipped to registered clients in the reporting period. The name or other information of the registered client must not be identified.

1 (g):		6 (g):	
2 (g):		7 (g):	
3 (g):		8 (g):	
4 (g):		9 (g):	
5 (g):		10 (g):	

PART Q. Monthly list of ten lowest totals (in g) shipped to a registered client (de-identified)

Report the ten lowest amounts of dried marihuana shipped to registered clients in the reporting period. The name or other information of the registered client must not be identified.

1 (g):		6 (g):	
2 (g):		7 (g):	
3 (g):		8 (g):	
4 (g):		9 (g):	
5 (g):		10 (g):	

PART R. Number of shipment per 10 g intervals (0-150g)

Report the total number of shipments of dried marihuana to registered clients for each of the following:

0 to 10 grams:		81 to 90 grams:	
11 to 20 grams:		91 to 100 grams:	
21 to 30 grams:		101 to 110 grams:	
31 to 40 grams:		111 to 120 grams:	
41 to 50 grams:		121 to 130 grams:	
51 to 60 grams:		131 to 140 grams:	
61 to 70 grams:		141 to 150 grams:	
71 to 80 grams:			

Licence Name:	
Licence Number:	

Reporting Period: From: YYYY MM DD To: YYYY MM DD

PART S. List of all physicians who have completed medical documents for marihuana for medical purposes for registered clients and their location

A list of all physicians who provided a medical document for a registered client in the reporting period:

	Physician Name	Physician Location	Number of signed medical documents
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

Additional list of physicians attached: ☐

Licence Name:	
Licence Number:	

Reporting Period: From: YYYY MM DD To: YYYY MM DD

PART T. List of all nurse practitioners who have completed medical documents for marihuana for medical purposes for registered clients and their location

A list of all nurse practitioners who provided a medical document for a registered client in the reporting period:

	Nurse Practitioner Name	Nurse Practitioner Location	Number of signed medical documents
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Additional list of nurse practitioners attached: ☐