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GUIDANCE DOCUMENT

Building and Production Security Requirements for Marihuana for Medical Purposes



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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance 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 provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in the document, to allow the Department to adequately mitigate the risk of diversion of controlled substances to an illicit market or use.

This document should be read in conjunction with the relevant sections of other applicable guidance documents and the *Directive on Physical Security Requirements for Controlled Substances*.

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1. Purpose

The document is intended to help Licensed Producers (LPs) comply with Division 3 security measure requirements of the *Marihuana for Medical Purposes Regulations* (MMPR) which include general security measures, and security measures for the perimeter of site and areas within a site where cannabis is present.

LP's should note that this guidance document **does not** apply to the storage of dried marihuana, marihuana seeds and cannabis used solely for the purpose of testing in order to determine the percentages of cannabinoids in dried marihuana. The security measures for the storage of these substances can be found in Health Canada's *Directive on Physical Security Requirements for Controlled Substances* (Security Directive). The Security Directive establishes realistic minimum security standards for the **storage** of controlled substances and applies to dried marihuana, marihuana seeds, and to cannabis used solely for the purpose of conducting in-vitro testing in order to determine the percentages of cannabinoids in dried marihuana (both packaged and unpackaged). In addition to the requirements included in the Security Directive, there are specific outcome based requirements set out in Division 3 of the MMPR. These requirements aim to prevent unauthorized access to your site and to restrict and monitor access to areas within your site where cannabis is present.

It is the LP's responsibility to ensure that provincial, municipal and federal legislation including building and fire codes are complied with. Health Canada's Office of Controlled Substances is the authority responsible for licensing and compliance monitoring under the *Controlled Drugs and Substances Act* (CDSA) and MMPR.

2. Background

The safeguarding of controlled substances is an issue that confronts all manufacturers, distributors, practitioners, pharmacists, law enforcement and government. Health Canada limits the handling of these substances through policies, guidelines and legislation such as the CDSA, the *Narcotic Control Regulations* (NCR) and the MMPR. Cannabis, its preparations, derivatives, and similar synthetic preparations as listed under Schedule II of the CDSA are included in the definition of a controlled substance. Those wishing to engage in lawful activities must, therefore, be properly licensed and ensure that the controlled substances are adequately secured and safeguarded at all times for public safety and to minimize risks of diversion.

3. Scope

This guidance document is applicable if you are interested in producing marijuana for medical purposes or want to engage in any other regulated activity set out in the MMPR. These guidelines outline regulatory requirements and include examples of security measures that you can put in place for both building construction and electronic systems. The Procedures section of this document will assist you on how to meet these requirements. Furthermore, it is the LP's responsibility to ensure that provincial, municipal and federal legislation including building and fire codes are complied with.

This guidance document does not apply to licensed dealers under the *Narcotic Control Regulations*, the *Benzodiazepines and Other Targeted Substances Regulations*, and Part G or Part J of the *Food and Drug Regulations*.

Please note that all waste cannabis material from cultivation or production is considered to be a controlled substance 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 as per Schedule II of the CDSA. Waste cannabis material that is a controlled substance must be secured in accordance with the CDSA and as outlined in Health Canada's *Directive on Physical Security Requirements for Controlled Substances* (Security Directive) until destroyed.

4. Procedures

As part of the application to become a LP, you must provide a detailed description of the security measures at the proposed site, in accordance with Division 3 of the MMPR and the Security Directive, published by Health Canada, as amended from time to time. It is up to you to determine potential security risks at your site and to design and implement appropriate security systems and protocols to meet the regulatory requirements outlined above. Health Canada officials will review your security proposal as part of their consideration of your application. It is important that you seek appropriate professional advice before undertaking any construction work.

The security of your site and of the areas within your site where cannabis is present does not end with the design and construction. Security requirements detailed in the regulations require your attention on a continual basis. It is the ongoing responsibility of the LP to ensure that all requirements for securing their site, areas within their site where cannabis is present and the storage of cannabis and any activities relating to the production of marijuana for medical purposes (as per their licence) are met.

In addition, it is the responsibility of the LP to ensure that provincial, municipal and federal legislation including building and fire codes are complied with.

5. Specific Regulatory Provisions in Division 3 of the MMPR

In this section, specific regulatory provisions from the MMPR are reproduced in bold and italicized text, followed by guidance on how these regulatory provisions can be met.

5.1 Regulatory Provisions Relating to Securing Your Site

MMPR s41 ***A licensed producer must ensure that the security measures set out in Division 3 are carried out.***

MMPR s42 ***The licensed producer's site must be designed in a manner that prevents unauthorized access.***

MMPR s47 ***Those areas [within a site where cannabis is present] must include physical barriers that prevent unauthorized access.***

Guidance: Signage and Physical Barriers

If your site is a stand-alone building, or a space within a building that shares walls, then physical barriers and signage posted at the perimeter and entrance to your building/space can assist in ensuring that your site is secure. The main purpose is to prevent unauthorized access and to act as a definite demarcation. Physical barriers are required for securing all areas within a site where cannabis is present. Physical barriers should provide sufficient resistance to impede unauthorized access to the premises where cannabis is present.

For example, a physical barrier of some kind (e.g. a fence surrounding the site) and a sign stating that it is private property or a restricted area and that unauthorized access is prohibited are appropriate.

Guidance: Entrances, Doors and Frames

Minimizing the number of entranceways to the site and areas within a site where cannabis is present will assist in securing and monitoring the space; however, it should remain consistent with fire and building safety codes. Securing all entrances to the building, site or areas within a site where cannabis is present would prevent unauthorized access.

For example, entranceways to areas within a site where cannabis is present could be equipped with commercial steel doors and frames. Doors may be specified as fire rated where required. The doors could also be equipped with the appropriate locking hardware, door closers, contact switches, and electronic access control mechanisms, to assist in providing appropriate security against unauthorized access.

Keeping your entranceways closed and locked to the extent possible given your business operations can assist in ensuring that your site and areas within a site where cannabis is present are secure.

Keeping doors and entrances to the areas within your site where cannabis is present closed at all times with an operational intrusion detection system on (alarm system that operates at all times) would further prevent unauthorized access.

Guidance: Openings, Ducts and Mechanical/Electrical Pass-Throughs

Minimizing the number of openings, ducts and pass-throughs in your site and areas within your site where cannabis is present will assist in preventing unauthorized access.

Protecting all other openings with security screens, steel bars or equivalent material, welded to steel frames will assist in preventing unauthorized access to your site. The screens and bars are most effective in preventing unauthorized access including quick entry, grab and exit type intrusions.

Where appropriate to accommodate pipe or conduit movement or expansion, pipes and conduits can be enclosed in a close-fitting sheet metal sleeve and fastened to a frame to provide appropriate security.

Guidance: Wall Construction

The walls of your site should be constructed to assist in ensuring that unauthorized access to your site and areas within your site where cannabis is present is prevented.

For example, slab-to-slab construction and steel mesh sheets attached to the underside of structural joists can assist in ensuring wall security.

Guidance: Glazing Panel Security

Appropriate use of glazing panels can assist in ensuring that unauthorized access to your site is prevented.

For example, any glazing panels used in roofing (in a greenhouse for example) should be attached directly to the roof structure in such a manner as to preventing removal from the outside.

Building security can be further ensured by using appropriate electronic equipment to monitor glazing elements, including sensors that can detect breakage of glazing panels.

Mechanisms that can provide secure monitoring of glazing elements include at least one of the following:

- Glass-break sensors of sufficient number may be appropriately installed to provide 100% coverage of the glazing area.
- Electrically conductive foil or wire can be incorporated in the glazing elements to provide detection of breaks.
- Volumetric or beam-break detection systems can be employed to provide 100% coverage of the interior surface area of the glazing.

5.2 Regulatory Provisions Relating to Monitoring and Detection

Perimeter of the Site

MMPR s43. (1) The perimeter of the licensed producer's site must be visually monitored at all times by visual recording devices to detect any attempted or actual unauthorized access.

MMPR s43. (2) The [visual recording] devices must, in the conditions under which they are used, be capable of recording in a visible manner any attempted or actual unauthorized access.

MMPR s44. The perimeter of the licenced producer's site must be secured by an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in the site or tampering with the system.

MMPR s45.(1) The system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to the detection of any occurrence [of attempted or actual unauthorized access].

MMPR s45.(2) If any such occurrence is detected, the personnel must make a record of: the date, time of the occurrence; and the

measures taken in response to it and the date and time when they were taken.

Areas Within a Site Where Cannabis is Present

MMPR s48.(1) Those areas [within a site where cannabis is present] must be visually monitored at all times by visual recording devices to detect illicit conduct.

MMPR s48.(2) The devices must, in the conditions under which they are used, be capable of recording in a visible manner illicit conduct.

MMPR s51.(1) The intrusion detection system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to the detection of any occurrence [of illicit conduct, any attempted or actual unauthorized access to or movement in those areas or tampering with the system].

MMPR s51.(2) If any such occurrence is detected, the personnel must make a record of: the date, time of the occurrence; and the measures taken in response to it and the date and time when they were taken.

Guidance: Video Coverage

Visual monitoring of the perimeter of your site, as well as the areas areas within your site where cannabis is present can be achieved using closed circuit video equipment (CCVE). Appropriate lighting equipment in conjunction with CCVE can assist in the detection, classification, assessment, and recognition of the images recorded.

Camera should be in sufficient number and appropriately located to cover the area to be monitored.

Guidance: Redundancy and Back-Ups

Keeping all cameras recording 24/7, and having appropriate back-up mechanisms in place can achieve the appropriate coverage to detect illegal activity, unauthorized access and any attempts to breach the security of your site and of the areas within your site where cannabis is present.

Back-up mechanisms must ensure that all visual recordings and records of a detected occurrence be retained for two years. These back-up mechanisms may include storing the visual recordings on multiple media devices.

5.3 Regulatory Provisions Relating to Access Control

MMPR s42. The licensed producer's site must be designed in a manner that prevents unauthorized access.

MMPR s46. (1) Access to each area within a site where cannabis is present must be restricted to persons whose presence in the area is required by their work responsibilities.

MMPRP s46.(2) The responsible person in charge or, if applicable, the alternate responsible person in charge must be physically present while other persons are in those areas.

MMPR s46.(3) A record must be made of the identity of every person entering or exiting those areas.

Guidance: Securing access to the site perimeter and areas within a site where cannabis is present

There is a wide range of appropriate electronic access control systems, including intrusion detection mechanisms and CCVE that may be employed to ensure that access to the site, and areas within the site where cannabis is present, is restricted to the appropriate personnel and that a record is kept of each person entering or exiting those areas.

The system that you install must be capable of identifying each individual who enters or leaves restricted areas to comply with regulatory requirements. A personal identification number (PIN) credential system alone is not sufficient for access control because PINs can be purposefully or inadvertently disclosed.

For example, a security system that requires a PIN and an identification card, or biometrics and visual monitoring are examples of ways to prevent both unauthorized access to those areas within a site where cannabis is present, and keep track of the movements of personnel that enter and leave those areas.

Guidance: Security System Control Mechanisms

Steps should be taken to ensure the appropriate control of codes, keys, combinations and other elements of your security system.

For example, to ensure appropriate security, only senior personnel including the senior person in charge, the responsible person in charge and any alternate responsible persons in charge should have access to alarm codes, vault combinations and other security elements for the site. Changing combinations and codes on a regular basis and when there are any changes with any senior personnel will assist in ensuring appropriate control of the security system.

5.4 Regulatory Provisions Relating to Intrusion Detection

Perimeter of the Site

MMPR s44. *The perimeter of the licenced producer's site must be secured by an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in the site or tampering with the system.*

MMPR s45.(1) *The system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to any occurrence of an attempted or actual unauthorized access to or movement in the site or tampering with the system.*

MMPR s45.(2) *If any such occurrence is detected, the personnel must make a record of: the date, time of the occurrence as well as all measures taken in response to it and the date and time when they were taken.*

Areas within a site where cannabis is present

MMPR s49. *Those areas [within a site where cannabis is present] must be secured by an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in those areas or tampering with the system.*

MMPR s51. *The intrusion detection system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to the detection of any occurrence [of illicit conduct, any attempted or actual unauthorized access to or movement in those areas or tampering with the system].*

A robust intrusion detection system can assist in securing both your site and areas within your site where cannabis is present.

Guidance: Monitoring

Monitoring your site's perimeter and areas within your site where cannabis is present via an intrusion detection system with personnel in a central location will

allow your personnel to detect any unauthorized attempts to enter those areas; or to tamper with security equipment. Appropriately trained personnel will assist in responding to any incident involving detected unauthorized activity.

When there are no responsible personnel present, a link to a monitoring station will enable notification to the appropriate personnel and law enforcement.

A response plan should be designed to ensure quick action when detection has occurred.

Guidance: Records of Detected Matters

Keeping all cameras recording 24/7, and having appropriate back-up mechanisms in place can achieve the appropriate coverage to detect illegal activity, unauthorized access and any attempts to breach the security of your site and areas within your site where cannabis is present.

Back-up mechanisms must ensure that all visual recordings and records of a detected occurrence be retained for two years. These back-up mechanisms may include storing the visual recordings on multiple media devices.

Guidance: Tampering

The effectiveness of any system is dependent on the signal reaching the individuals responsible for the monitoring of the signal and the response to its warning. Depending on how the signal is carried, tampering with the line carrying the signal may result in the signal not reaching its intended destination. An acceptable system should be able to identify, record, and notify if the lines are tampered with or if an attempt has been made.

A response plan should be designed to ensure quick action when tampering occurs.

Guidance: Power Supply

In order to comply with regulations, your security system must include visual recording devices, access control and an intrusion detection system which must operate on a continuous basis.

For example, supporting your security system and all components (e.g., sensors, control units and communicators/enunciators, volumetric sensors, glass-break detectors, beam-break sensors) with an uninterruptible power supply sufficient for 24/7 continuous operation would effectively maintain the integrity of your security system.

5.5 Regulatory Provision Relating to Air Filtration

MMPR s50. Those areas [within a site where cannabis is present] must be equipped with a system that filters air to prevent the escape of odours and, if present, pollen.

Guidance: Air Filtration

To assist in the prevention of the escape of pollen, odours, and other particles, all exhaust air from your cultivation area and other areas within your site where cannabis is present can be filtered through appropriate air filtration systems.

For example, a high-efficiency particle air filter such as a H13 HEPA filter can ensure appropriate ventilation and filtration of exhaust air.