

# Annex DDD



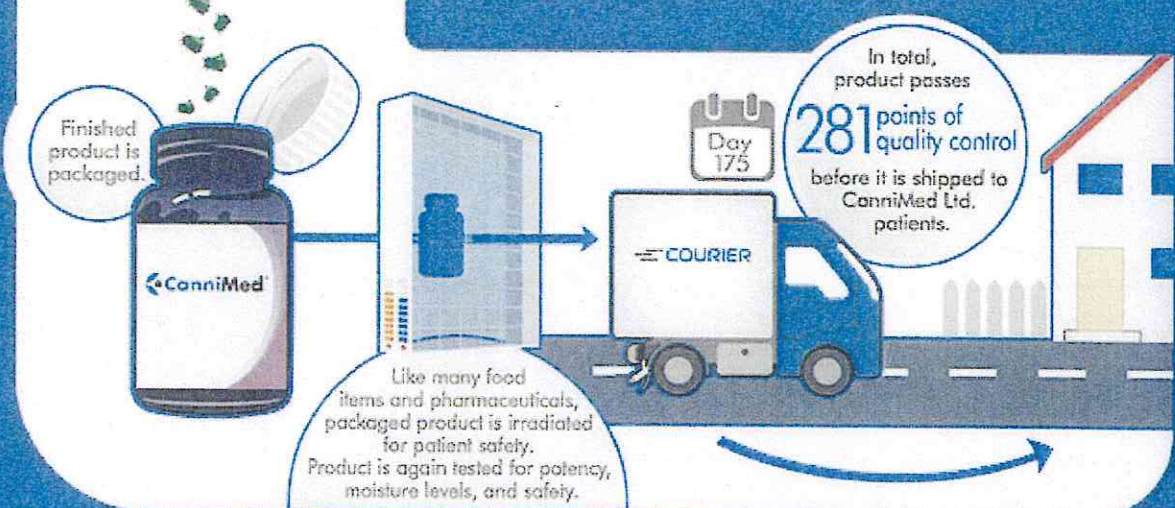
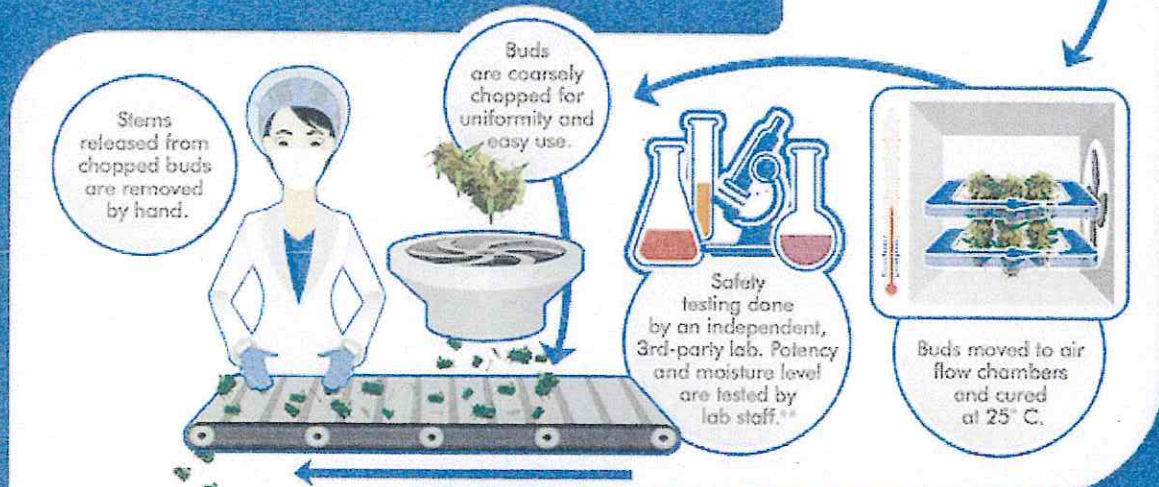
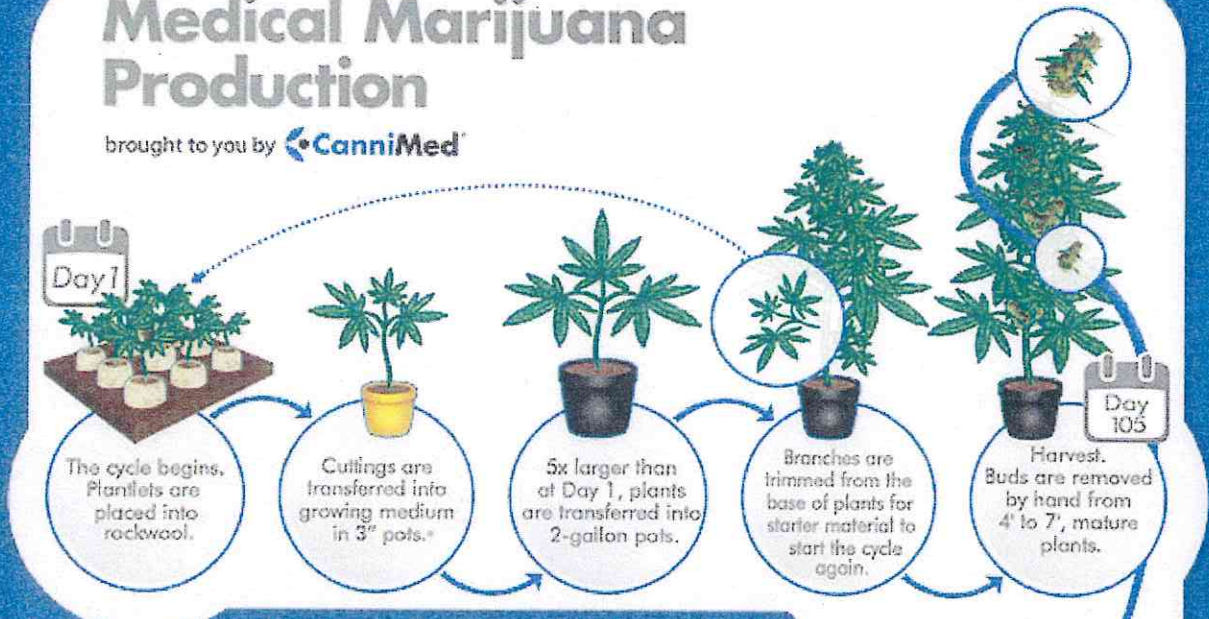
*Photograph of a vault being used at a small MMPR licensed producer facility. Multiple secure doors and areas monitored by video surveillance have to be passed to get to this area.*

# Annex EEE



# Medical Marijuana Production

brought to you by **CanniMed**



\* Growing medium contains coconut coir, peat moss, and limestone.  
 \*\* Safety tests include checks for mold, yeast, bacteria, five varieties of mycotoxin, and metals (mercury, arsenic, cadmium, lead, and others)

**CanniMed**  
 www.cannimed.ca

# Annex FFF





*Photograph of a flowering room at Prairie Plant Systems. Depicts large buds, clean grow environment and very healthy plants.*

# Annex GGG

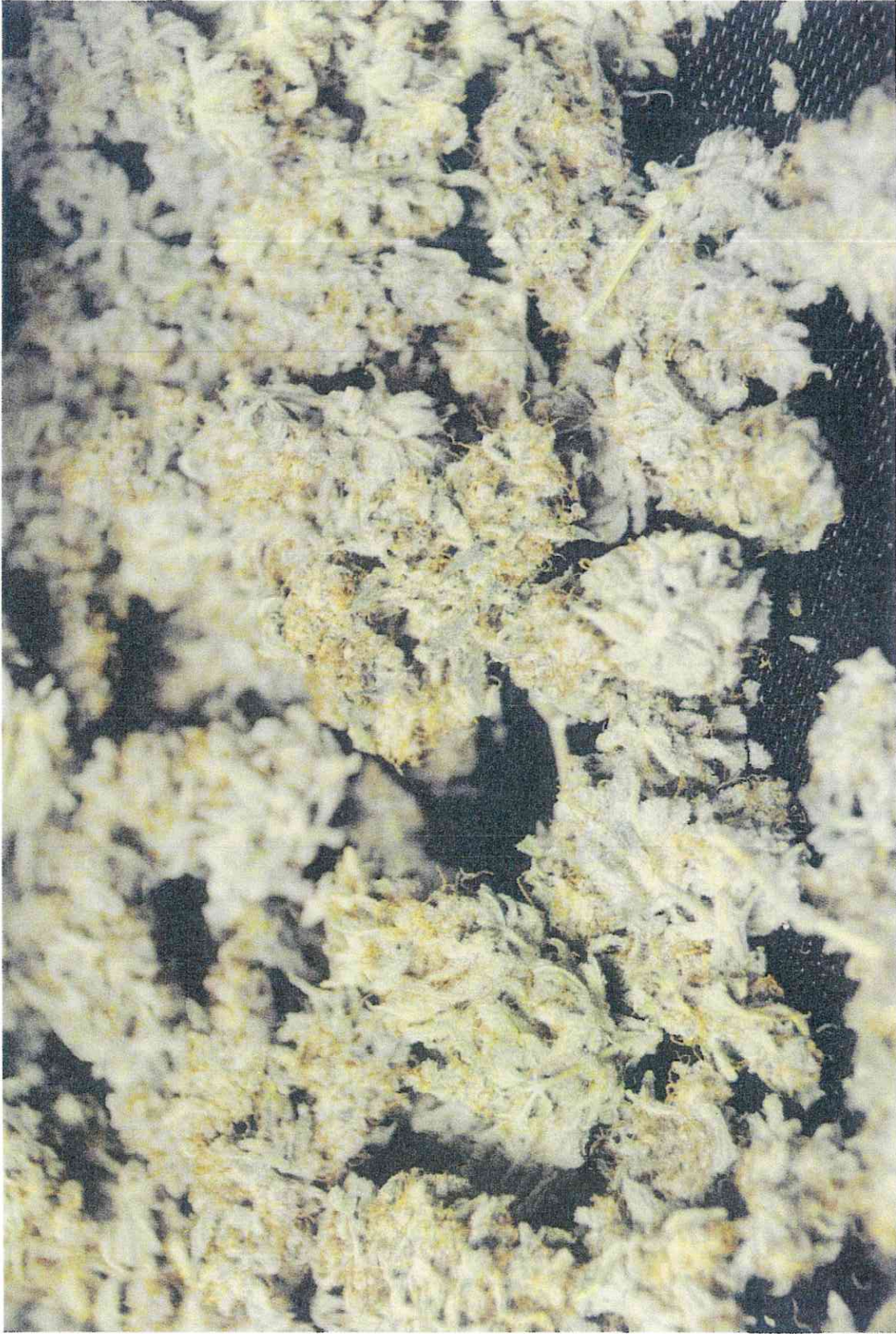




*Photograph of employees at Prairie Plant Systems who are de-stemming the marijuana bud before it is packaged. The clothing attire and cleanliness standards supersede anything I have seen at MMAR production sites.*



# Annex HHH



The above marijuana came from a flowering room at a MMPR production facility that had a bug infestation. Health Canada Inspectors requested all the flowering plants be destroyed and the marijuana bud (above) that was in the process of drying. MMPR licensed producers can't sell potentially contaminated medical marijuana (especially if the consumer has a compromised immune system).



# Annex III



Health Canada Santé Canada

*Canada Gazette, Part II, publication of MMR*

*June 19, 2013*



## **GUIDANCE DOCUMENT**

*Technical Specifications for Testing Dried Marijuana for Medical Purposes*



Published by authority of the  
Minister of Health



Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch

**Canada**

Pub: 130085



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## **1. Purpose**

This document is intended to help Licensed Producers (LPs) comply with certain quality requirements in Division 4 of the *Marihuana for Medical Purposes Regulations* (MMPR). 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**

To date, dried marihuana has not been authorized as a therapeutic product in Canada or in any other country. In addition, no international standards currently exist specifically for the quality of dried marihuana.

Dried marihuana produced by a LP, while exempt from the application of the *Food and Drug Regulations* via the *Marihuana Exemption (Food and Drugs Act) Regulations* other than in the context of marihuana to be used in a clinical trial, is subject to provisions in the *Food and Drugs Act*. This includes a general prohibition (paragraph 8(a) and (b)) against the sale of a drug that was "manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or is adulterated".

Division 4 of the MMPR includes Good Production Practices (GPP) requirements relating to the premises, storage of dried marihuana, equipment, the sanitation program, standard operating procedures, recall of product, and quality assurance personnel. Additionally, the MMPR provide compliance and enforcement measures, allowing for refusal, suspension or revocation of a producer's licence on the basis of risks to public health, safety or security.

## **3. Scope**

The specific regulatory requirements listed in section 5 of this guidance document are applicable to finished dried marihuana which is to be sold or provided by a LP under the MMPR. They do not apply to live plants or to intermediate processing stages. The finished product requirements are also applicable to imported dried marihuana when it is to be sold or provided in Canada, and to Canadian-produced marihuana which is to be exported.



#### 4. Procedures

In order to achieve purity and quality of the finished dried marihuana product, Good Production Practices as outlined in the MMPR must be followed at all stages of production, packaging, labelling and storage of the marihuana.

As specified in the MMPR, each batch or lot of dried marihuana must be approved for release by the LP's Quality Assurance person, who must have the training, experience and technical knowledge relating to the activity conducted and the requirements of Division 4 of the MMPR. This means that the Quality Assurance person must have the ability to evaluate the operations of the LP to ensure compliance with Division 4, and the technical knowledge to be able to assess analytical testing results in order to be able to make the determination of whether the dried marihuana is suitable for sale. The Quality Assurance person is also responsible for investigating quality-related complaints and taking corrective and preventive actions, if necessary.

Visual inspection should confirm the absence of pests or extraneous substances. There is no requirement to mill or irradiate the dried marihuana, although LPs may choose to do so.

#### 5. Specific Regulatory Provisions in Division 4 of the MMPR

***MMPR s53. (1)***      **The microbial and chemical contaminants of dried marihuana must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the *Food and Drugs Act*.**

Guidance: Schedule B of the Food and Drugs Act <sup>1</sup> lists recognized international publications which set technical specifications for pharmaceutical drugs, herbal medicines, and dietary supplements. LPs must maintain consistent specifications for their products according to these publications, and assess each lot or batch of dried marihuana against those specifications before approving the release of a lot or batch for sale. Note that it is the LP's responsibility to decide on the specifications and methods to be used for testing.

As an example, one potential Schedule B publication which could be chosen is the European Pharmacopeia (EP) <sup>2</sup>. All relevant specifications from the EP would then apply. This would include chapter 5.8.1 (current edition 7.5): "Microbial Quality of Herbal Medicinal Products for Oral Use". In this case, testing for total aerobic microbial count, total combined yeast and moulds count, bile-tolerant gram negative bacteria, *Escherichia coli*, and *Salmonella* would have to be conducted, and the results would have to be below the limits listed in Table C of that chapter before the

product could be released for sale. In addition, testing for aflatoxins must also be conducted, with methods and limits as specified in Chapter 2.08.18 (Determination of aflatoxin B1 in herbal drugs) of the EP. These limits are required to demonstrate that the dried marihuana has been produced under sanitary conditions, and that it is appropriate for human consumption. The general monograph on herbal drugs in this same publication would also apply, with the associated limits on heavy metals.

Other microbial and chemical contaminant limits for herbal medicines from a Schedule B publication are acceptable.

***MMPR s53. (2)***      **Analytical testing for those contaminants and for the percentages of delta-9-tetrahydrocannabinol and cannabidiol referred to in these Regulations must be conducted using validated methods.**

Guidance: Testing of dried marihuana can only be performed by the holder of a producer's licence under the MMPR or of a dealer's licence under the *Narcotic Control Regulations*, and must be performed according to validated methods. Validation means establishing documented evidence that will provide a high degree of assurance that the testing methods must consistently and reproducibly lead to the predetermined specifications and quality results in dried marihuana. Appropriate reference standards and controls should be included in each testing protocol, and LPs must maintain records summarizing testing protocols followed and detailed testing results for each batch or lot of finished dried marihuana.

***MMPR s54. (1)***      **Marihuana must not be 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.**

Guidance: Under the *Pest Control Products Act*<sup>3</sup>, pesticides may only be used if assessed and registered by the Pest Management Regulatory Agency (PMRA) for specific uses.

For more information on registration of pesticides, see the PMRA web site<sup>4</sup>.

***MMPR s54. (2)***      **Dried marihuana must not contain any 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*.**

Guidance: During the review of a pest control product by the PMRA, a maximum residue limit (MRL) may be established, depending on the product and the associated risk assessment. If a MRL is established for any pest control product

when registered for use on marihuana for medical purposes, the finished dried marihuana must not contain any pesticide residue exceeding this limit.

## 6. References

- <sup>1</sup> <http://laws.justice.gc.ca/eng/acts/F-27/>
- <sup>2</sup> <http://online6.edqm.eu/ep705/>
- <sup>3</sup> <http://laws-lois.justice.gc.ca/eng/acts/P-9.01/>
- <sup>4</sup> <http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php>



# Annex JJJ

## CANADIAN MEDICAL MARIHUANA TESTING OPTIONS

Pkg	Test	HEALTH CANADA REQUIRED TESTS FOR LICENSED PRODUCERS	Cost/ Sample
1	HC Screen	Safety and stability for final products. Incl: Total & Fecal Coliforms, E.coli, Yeast+Mold, Total Plate Count, P. aeruginosa, S. aureus, Salmonella spp.	\$85.00
2	Metals	Elements and metals naturally occurring or introduced during processing Incl: Al, Sb, As, Ba, Be, B, Cd, Ca, Cr, Co, Cu, Au, Fe, La, Pb, Mg, Mn, Mo, Ni, P, K, Si, Ag, Na, Sr, Ti, W, V, Zn, Hg, Se, Sn	\$70.00
3	Potency	Basic Reporting Criteria –required on all final products Incl: delta 9 THC, delta 9 THC-acid, CBD, CBN, % moisture	\$90.00
4	Aflotoxins	Toxins produced by fungi Incl: Aflatoxin B1, B2, G1, G2, Ochratoxin A	\$150.00
5	Pesticides	Screen incl: organochlorides, carbamates, organophosphates, phenoxy herbicides, organonitrates	\$300.00
6	Foreign Material	Evaluates product for extraneous materials such as metals, wood or plastic pieces, filth, insect parts.	\$40.00

Pkg	Test	ALTERNATE OR OPTIONAL TESTS	Cost/ Sample
1a	Micro Screen	<u>General Screen</u> : used for evaluating internal production processes. Incl: Total & Fecal Coliforms, E.coli, Yeast+Mold, Total Plate Count	\$45.00
3a	Potency	<u>Bragging Rights*</u> : Provides Basic compound concentrations plus additional medically active ingredients. Incl: Δ9 THC, Δ9 THC-acid, Δ8 THC, Δ8 THC-acid, CBD, CBD-acid, CBC, CBC-acid, CBG, CBG-acid, CBN, % moisture * more compounds will be added as standards become available	\$120.00
		<u>OTHER TESTS</u> Terpenes Flavonoid & Phytosterols Food Poisoning Nutrient Tissue Analysis Residual Solvent Testing Plant Pathogens Fertilizer/Feed Analysis	Ask for details

**NOTES:** Sample amounts recommended:

1.	Microbiology	use 2 to 5 grams
1-4	Chemistry	use 4 to 5 grams
5	Pesticides	use ~ 5 grams

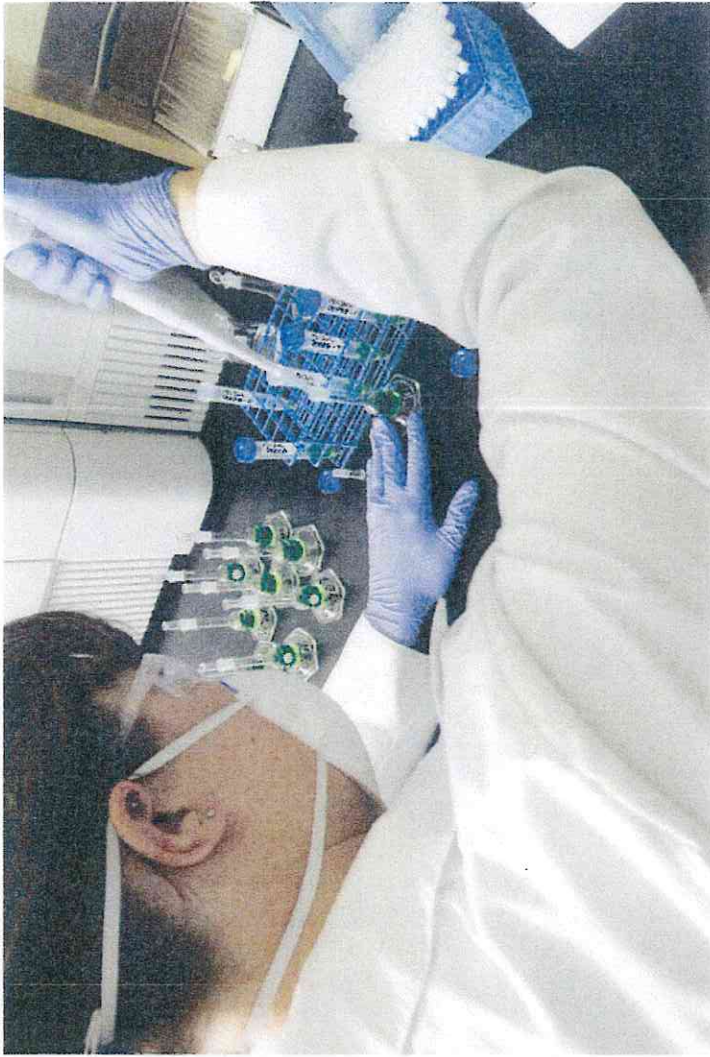
MB Laboratories Ltd holds a Section 9 License for testing Medical Marihuana. We must have a copy of a client's LP or Dealer's License number on file to accept product into the laboratory for testing.

Location/Courier: 2062 W. Henry Ave  
Sidney, BC V8L 5Y1

T: 250 656-1334  
E: [mblabs@pacificcoast.net](mailto:mblabs@pacificcoast.net)  
W: [www.mblabs.com](http://www.mblabs.com)

# Annex KKK

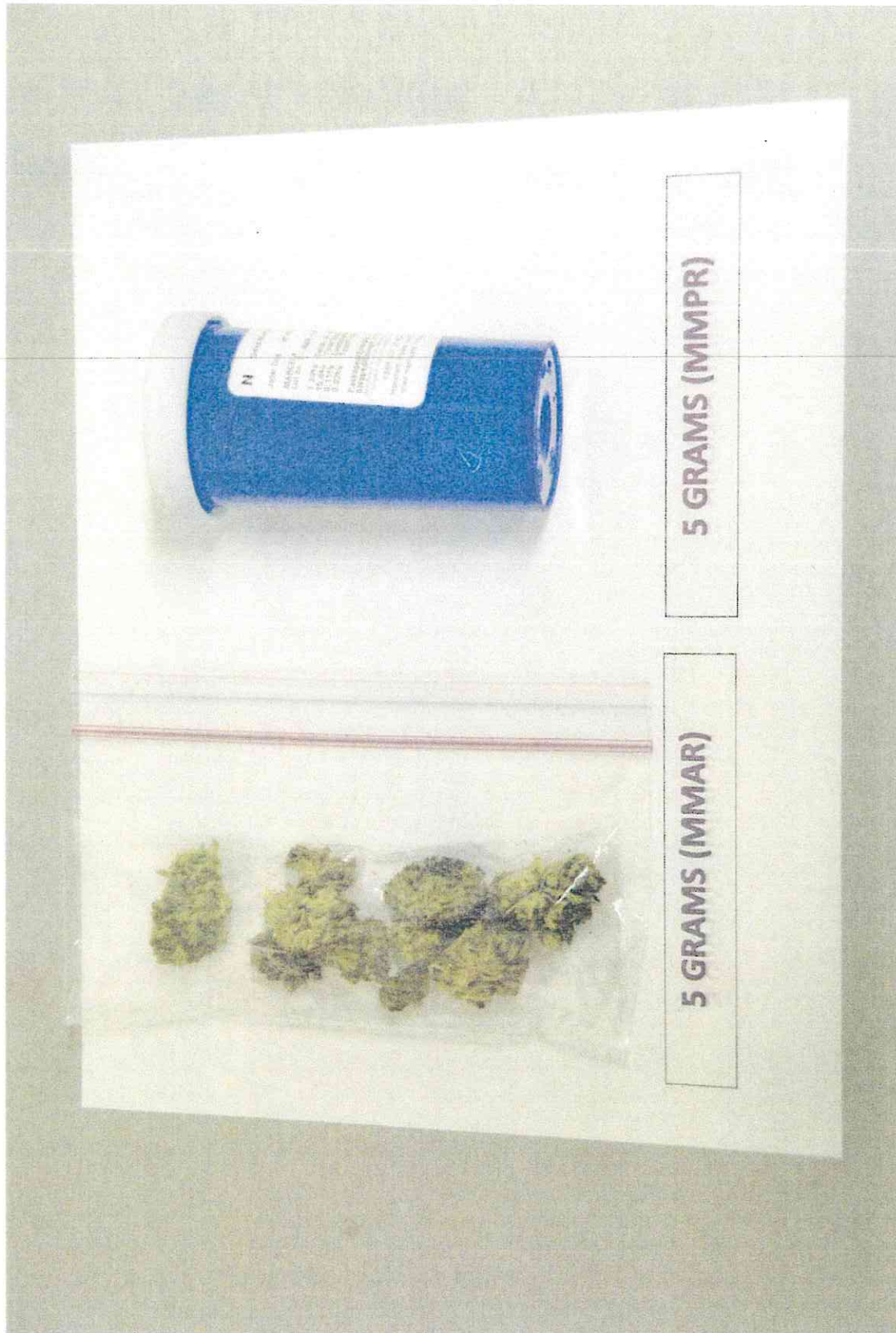




*Photographs of medical marihuana testing conducted at a MIMPR licensed producer facility (Prairie Plant Systems). It appears to me that this method of testing is quantifiable and far better than any testing under the MMAR.*

# Annex LLL

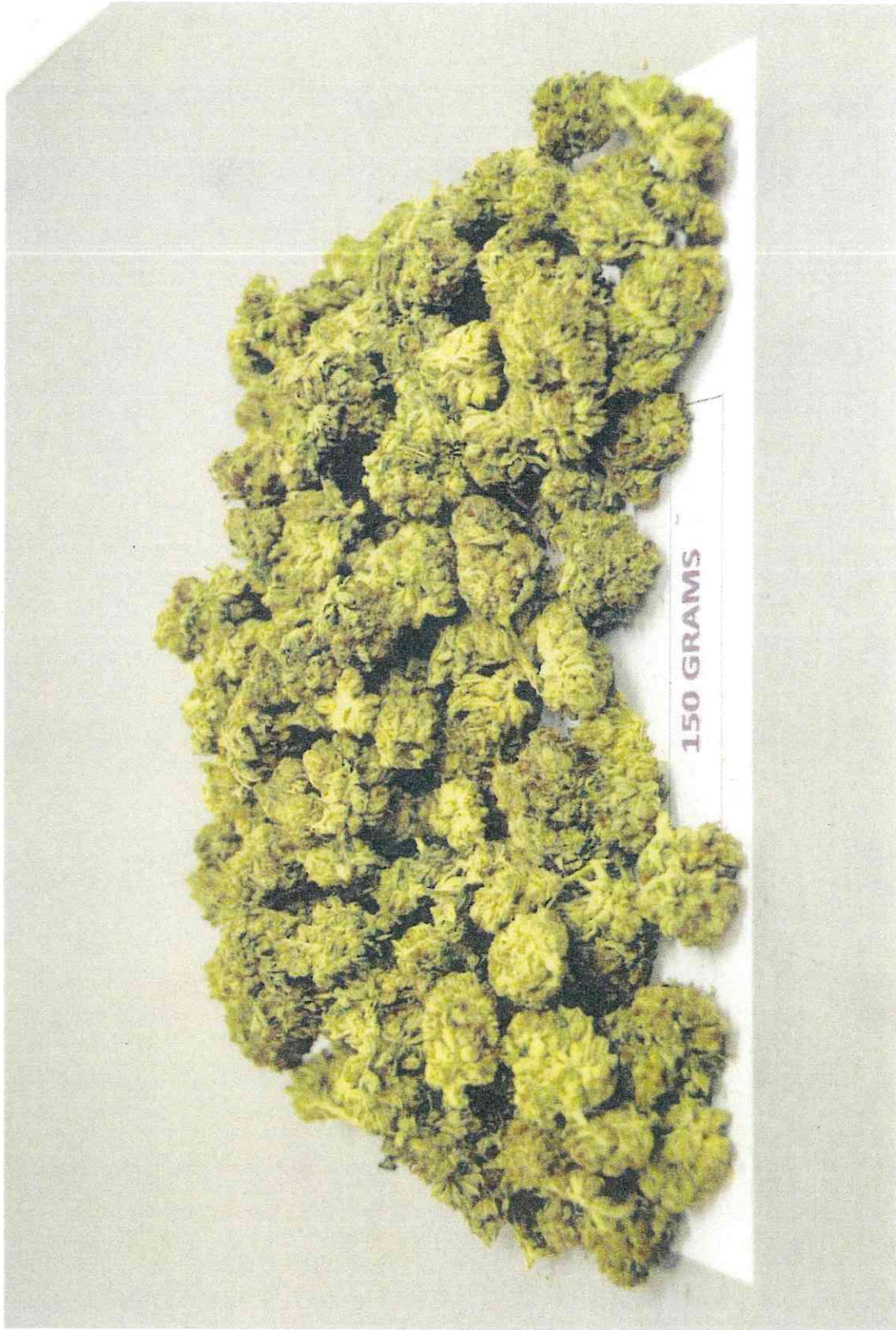




Photograph on the left: represents the typical possession of 5 grams of marijuana under the MMAR.  
Photograph on the right: represents a sample container from a MMAR Licensed Producer. The marijuana would be in a child proof container, and labelled very similar to how other narcotics prescriptions are labelled and dispensed.



# **Annex MMM**



Above photograph depicts 150 grams of marijuana bud on a standard 8.5 x 11 sheet of paper to show the volume associated to this possession amount.

# **Annex NNN**



**CanniMed**

22.1	17.1	15.5	12.0
\$8.78	\$7.80	\$8.13	\$4.88
per gram	per gram	per gram	per gram
9.9	4.10	1.13	
\$7.15	TBA	\$7.48	
per gram		per gram	

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Examples of medical marijuana containers used by a MMAR Licensed Producer (CanniMed).





Further examples of medical marijuana containers being used by a MIMPR Licensed Producer (Bedrocan).



Department of Justice  
Canada

Ministère de la Justice  
Canada

900-840 Howe Street  
Vancouver, British Columbia  
V6Z 2S9

Telephone: 604-666-4304  
Facsimile: 604-775-5942  
Email: bj.wray@justice.gc.ca

June 24, 2014

By Email to shane.holmqvist@rcmp-grc.gc.ca

Cst. Shane Holmqvist  
Federal – Serious Organized Crime  
Coordinated Marihuana Enforcement Team  
Mailstop 304 – 14200 Green Timbers Way  
Surrey, BC V3T 6P3

This is Exhibit " B " referred to in the  
Affidavit of Shane Holmqvist  
Sworn before me at Vancouver, BC  
this 9 day of October, 2014.

**BJ Wray**  
Barrister, Solicitor & Notary Public  
for the Province of British Columbia  
900-840 Howe Street  
Vancouver, BC V6Z 2S9

Dear Cst. Holmqvist

Re: *Allard et al. v. Her Majesty the Queen in Right of Canada*  
**Instruction Letter**

Thank you for agreeing to provide the Attorney General of Canada ("AGC") with an expert report in the matter of *Allard et al. v. Her Majesty the Queen in Right of Canada*. As discussed, this Federal Court litigation involves a constitutional challenge to the *Marihuana for Medical Purposes Regulations* (the "Regulations").

**Background Information**

The plaintiffs in this litigation, all of whom are medical marihuana users, are challenging the constitutionality of the MMPR on the basis that they cause several unjustified violations of their rights to liberty and security of the person under the Canadian *Charter of Rights and Freedoms*.

The plaintiffs' constitutional challenge in *Allard* focuses on four aspects of the MMPR that differ from the old medical marihuana regime: (1) the elimination of personal cultivation of marihuana in favour of requiring approved individuals to purchase from licensed producers; (2) the restriction that licensed producers may not cultivate marihuana in dwelling places or outdoor areas; (3) the limit on possession of marihuana to either 150g or 30 times the amount prescribed for daily consumption by the individual's medical practitioner, whichever is less; and (4) the failure of the MMPR to permit the production and possession of non-dried marihuana such as cannabis oils, salves, tinctures and edibles.

The plaintiffs have obtained an injunction from the Court that permits them to continue personal production of medical marihuana until the constitutionality of the MMPR is decided by the Court.

The AGC is the defendant and it is the AGC's position that the current medical marihuana regime is constitutionally sound, a position that will be defended by legal counsel.



**Facts and Assumptions**

The facts alleged by the plaintiffs are outlined in the Amended Notice of Civil Claim which is enclosed.

**Questions for Your Expert Report**

Please address the following matters in your expert report:

1. The criminal abuses associated with the personal production of medical marihuana including, but not limited to, diversion, organized crime, weapons, "grow rips" and clandestine labs.
2. The safety and health concerns faced by law enforcement officers who investigated and/or inspected personal medical marihuana grow operations under the previous medical marihuana regulations, the *Marihuana Medical Access Regulations*.
3. The RCMP's involvement in the screening of applications to become a Licensed Producer under the new medical marihuana regime, the MMPR.
4. Your inspections of Licensed Producers, including, but not limited to, your observations regarding security measures and quality controls. How do the observations made during your inspections of Licensed Producers compare to the observations made during your inspection or attendance at personal medical marihuana grow locations? How is the compliance of Licensed Producers under the MMPR enforced?

**Format of Your Expert Report**

Your report must be prepared in accordance with the Federal Courts Rules. As such, we ask that you do the following in within the body of your report:

1. Set out the issues to be addressed in the report;
2. Describe your qualifications on the issues to be addressed;
3. Attach your current curriculum vitae as a schedule to the report;
4. Attach this letter of instruction as a schedule to the report;
5. Provide a summary of your opinions on the issues addressed in the report;
6. Set out the reasons for each opinion that is expressed in the report;
7. Attach any literature or other materials specifically relied on in support of the opinions;
8. If applicable, provide a summary of the methodology used in the report;
9. Set out any caveats or qualifications necessary to render the report complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside of your field of expertise; and,
10. Particulars of any aspect of your relationship with a party to the proceeding or the subject matter of your report that might affect your duty to the Court.

Please number each paragraph of your report as this will aid us in referring to your report in Court.

Please sign and date your report.

**Duty to the Court**

As an expert witness, you have a duty to the Court which is set out in the attached Code of Conduct for Expert Witnesses. While you have already reviewed this Code of Conduct in preparing your report for the injunction hearing, please carefully review it again and, after doing so, sign and date the attached Certificate and send it back to us.

**Due Dates and Procedural Matters**

We are required to file our expert reports on or before November 1, 2014. The trial has been set for three weeks commencing February 23, 2015. You may be required to attend the trial for cross-examination and, if so, we will attempt to accommodate your schedule to the extent possible.

Please keep all correspondence pertaining to this assignment in a separate "Expert Witness Report" folder.

We look forward to receiving a draft of your report the **first week of September, 2013.**

Please do not hesitate to contact me by telephone at 604-666-4304 if you require further information or have questions regarding the foregoing.

Yours truly,



BJ Wray  
Counsel

Enclosures: Certificate for Expert Witnesses; Code of Conduct for Expert Witnesses; Amended Notice of Civil Claim