

AGENDA

- Introduction
- Cannabis Regulatory Models
- Federal Licence Classes and Permissions
- Federal and Municipal Considerations



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WHO IS CCI?

CCI is a global consulting firm with subject matter expertise in the regulated consumer products industry

- A legacy of success based on knowledge of safety and compliance best practice
- Fifteen years of licencing and regulatory expertise
- Successful completion of over 66,000 licences
- The original consulting company in Canada to offer a breadth of cannabis services
- A proud Canadian company with a global presence in more than 25 countries around the world





Regulatory Models

THE FUTURE

Now (Post -October 17 th, 2018)

- Recreational and medicinal
- Craft cannabis

October 2019

- Edible cannabis
- Cannabis extracts
- Cannabis topicals

Post -October 2019

- Cannabis Health Products
- Veterinary Health Products
- Cosmetics and Household Use Products





THE PLAYERS NEW ACTS & REGS



Federal – HC, CFIA, PMRA The Cannabis Act & Regulations Safe Food for Canadians Act & Regulations **Tobacco and Vaping Act** Pest Management and Regulatory Agency

Provincial – AGCO, OMAFRA Cannabis Control Act & Regulations Land Use Act & Regulations

> Municipal Local By -Laws



REGULATORY MODELS

Federal:

- Cultivation and production of safe quality products
- Prevention diversion and protection of young persons
- Establishment of provincial distribution model
- Continuity of access for medicinal use

Provincial:

- Establishment of recreational sale and distribution
- Land use protection guidelines

Municipal:

- Urban planning and development for federally licensed and provincial retail licensed sites
- Local law enforcement





Federal Licences

TYPES OF CANNABIS LICENCES

The Cannabis Act and Regulations, introduced new facility licensing classes to cultivate, manufacture, research, test and sell cannabis and cannabis products.

- Cultivation Standard
- Cultivation Micro
- Cultivation Nursery
- Processor Standard
- Processor Micro
- R&D
- Sale for Medical Purposes
- Analytical Testing
- Cannabis Drug
- Industrial Hemp





CULTIVATION LICENCES

The Standard Cultivation Licence allows for the following activities:

- Cultivation, harvesting and drying of cannabis.
- Outdoor cultivation
- Sale of cannabis to licence holders: Cultivation, Processor, R&D, Testing Laboratory, and Cannabis Drug Licence.

The Micro Cultivation Licence allows for the same activities as Standard with the restriction:

• A holder may cultivate a total of 200 m 2 of cannabis canopy.

The Nursery Licence allows for the same activities as Standard with the following restrictions:

- Unlimited cannabis canopy.
- Up to 50 m² of flower canopy for breeding and testing.
- Obligated to destroy flowers within 30 days.
- Sale of only seeds and plants to other licence holders.



PROCESSOR LICENCES

The Standard Processor Licence allows for the following activities:

- Processing unlimited quantities of cannabis.
- Formulation development, manufacturing, packaging and labelling.
- Sale of Cannabis to licence holders: Cultivation, Processor, R&D, Testing Laboratory, and Cannabis Drug Licence.
- Sale of Cannabis Products to Provinces for recreational distribution and to Federal Medical Sales Licence holders for medical distribution.

The Micro Processor Licence allows for the same activities as Standard with the restriction:

• A holder may process a total of 600 kg of dried cannabis (or equivalent) annually.



IOTHER LICENCES TYPES

End -user recreational sale is provincially licensed

Federal Medical Sales Licence:

- Patient registration and prescription processing.
- Direct or indirect sale to patients

R&D Licence:

- Limited cultivation, processing and clinical testing based on protocol.
- Development, manufacturing, packaging and labelling.

Cannabis Drug Licence:

- Cannabis drug development, manufacturing, distribution and sale.
- Traditional pharm acy sale via prescription

Analytical Testing Licence:

- Mandatory third-party analysis
- Product stability trials

Industrial Hemp Licence:

- Cultivation and harvest of select cannabis cultivars
- Distribution and sale of seeds, fiber, leaves and flowers







FACILTY LAYOUT

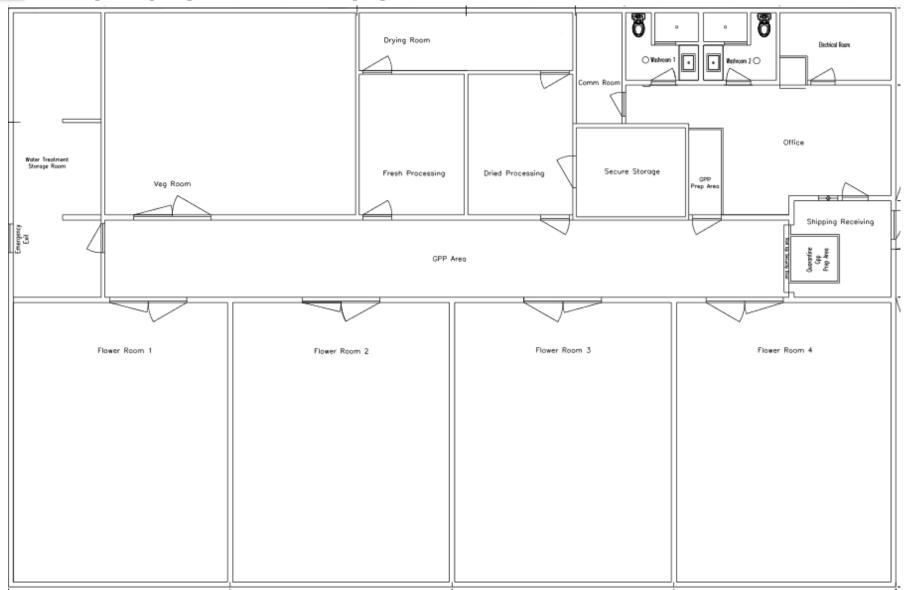
Layout of facility depends on licence type, operations and business scale

Standard List of Rooms:

Administrative Areas	Cultivator Areas	Processor Areas	Transition and Warehouse Areas	Support Areas
Reception/Security Office	Genetics/Mother Room	Extraction Rooms	Changerooms/ Gowning Areas	Maintenance/ Machine Shop
Offices/Meeting Rooms	Propagation Room	Dispensing/ Mixing Rooms	Transition Corridors	Mechanical/ Utilities Room
Call Center	Vegetative Rooms	Production Rooms	Shipping/ Receiving Areas	Chemical/Hazmat Storage
Washrooms	Flowering Rooms	Packaging/ Labelling Rooms	General Warehouse	Laneways/ Parking Lot
Lunchroom	Outdoor Cultivation Areas	Sanitation Room	Secure Storage Room	
Server Rooms	Trimming Room	Equipment Storage	Destruction Room	
Document Storage	Drying Room	Laboratories		
Corridors	Curing Room			

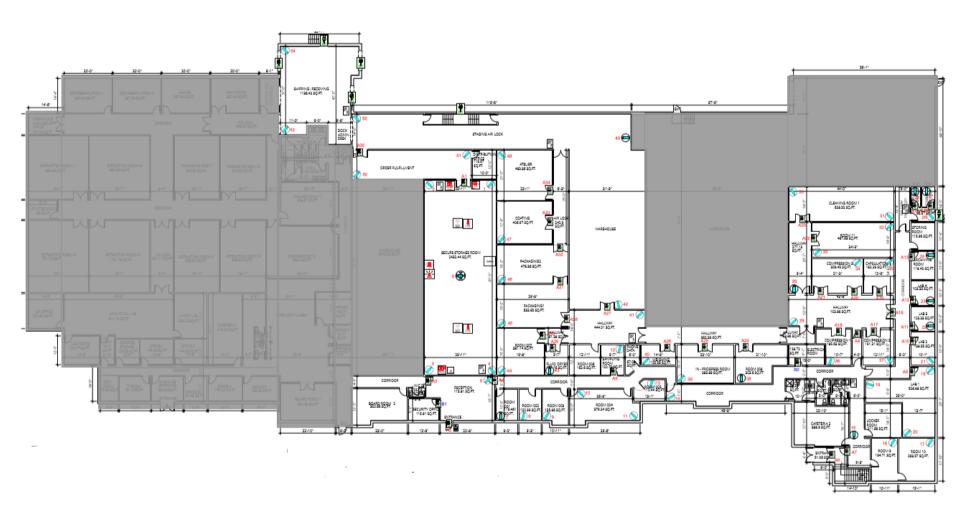


MICRO SITE LAYOUT





STANDARD SITE LAYOUT





Federal, Provincial & Municipal Considerations

| FEDERAL CONSIDERATIONS

Health Canada ensures public health and safety are paramount.

Licensing

- Corporation, personnel and business model
- Physical security
- Good Production Practices (GPP)(Sanitation, air, odour control, quality assurance)
- Mandatory testing for pesticides
- Packaging and labelling

Physical Site Amendments and New Products

- Adding/removing operational areas
- Packaging and labelling
- Product Notices

Promotion

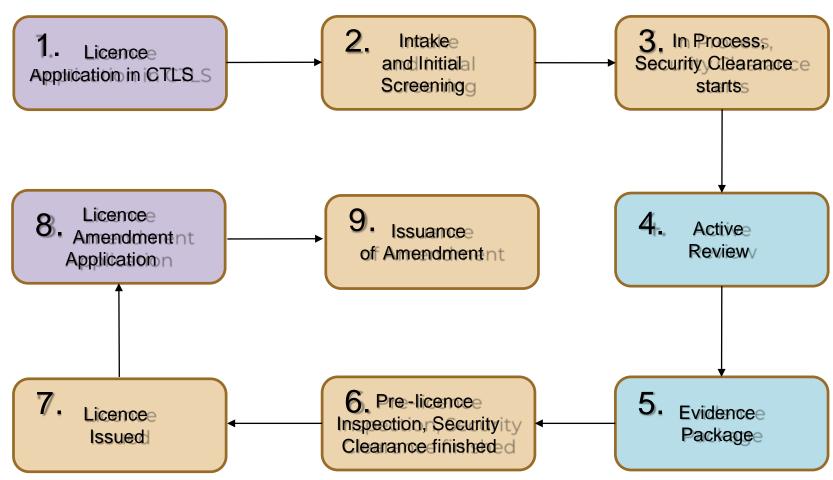
- Advertising and promotional prohibitions
- CRA Excise Tax licence and stamps





HEALTH CANADA LICENSING APPROACH

Application Eligibility: Applicants must have a fully constructed building in place, including evidence that they building meets physical security and Good Production Practices (GPP) requirements





| FEDERAL CONSIDERATIONS

For licence holders, compliance is key.

Regulatory Inspections

- o Inspection Types: Pre -licence, Initial, Targeted, Regular
- Assess compliance to Cannabis Act and Regulations
- Regional Cannabis Inspectorates issue minor/major/critical observations and compliance rating
- https://www.canada.ca/en/health -canada/services/drugs -medication/cannabis/compliance enforcement/medical -cannabis -quarterly -compliance -enforcement -report -inspection data -summary.html

Suspension and Revocation

- o Four licence suspensions to date
- One licence revocation

Administrative Monetary Penalties (AMPs)

- New Notice of Violation and Monetary Penalty Process
- https://www.canada.ca/en/health -canada/services/cannabis -regulations -licensed producers/administrative -monetary -penalties.html



| FEDERAL CONSIDERATIONS

Health Canada ensures public health and safety are paramount.

For licence holders, compliance is key.

Recent HC Guidance Publications:

- CTLS User Guide
- Licensing Application Guides
- Physical Security Requirements
- Licence Management Guide
- Excise Tax Licence and Fees Management
- Good Production Practices
- Packaging and Labelling
- Product Notices
- Promotional Prohibitions
- Regulatory Reporting
- Mandatory Testing Requirements
- Voluntary Recall Guide
- Mandatory Testing Requirements





PROVINCI AL CONSIDERATIONS

Health Canada defers urban planning considerations to provincial and municipal governments.

- Provincially Regulated:
 - Alcohol and Gaming Commission of Ontario:
 - Sale and Distributionhttps://www.agco.ca/cannabis -municipalities
- OMAFRA:
 - Guidelines on Permitted Uses in Ontario's Prime Agricultural Land
 - Agricultural Impact Assessments
 - General Environmental Issues
 - Water resources and conservation
- Email concerns to:

ag.info.omafra@ontario.ca





Cannabis Regulations S. 40: A holder of a licence must not conduct any activity that is authorized by the licence at a dwelling -house.

Municipally Regulated:

- Development and building permits
- Zoning, survey, and land use compatibility
- Neighbouring lots/businesses, communities impact assessment:
 - o Noise, traffic, visual disturbance
- Lot size, partitioning/am algam ation and dwelling assessment
- Hazards and obstructions assessment
- Municipal services assessment:
 - o Road access and snow removal
 - o Utilities: Hydro, gas, water
 - o Water and sewage removal





Health Canada defers urban planning considerations to municipal governments.

- Municipalities can support compliance for federally regulated concerns:
 - Physical security
 - o Product diversion
 - o Advertising and promotion
 - Public health and sanitation
 - Local disturbances (e.g. odour control)
- Email concerns to:

cannabis@canada.ca

Or contact:

Benoit P. Seguin
Associate Director
Compliance Issues and Response
Cannabis Legalization and Regulation Branch,
Health Canada

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Exterior Building – North Side

North Side Exterior Cameras Overview





Exterior Building – East Side

East Side Exterior Cameras







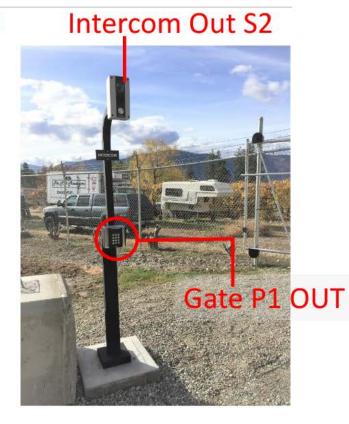




Exterior – Main Perimeter Gate Entrances

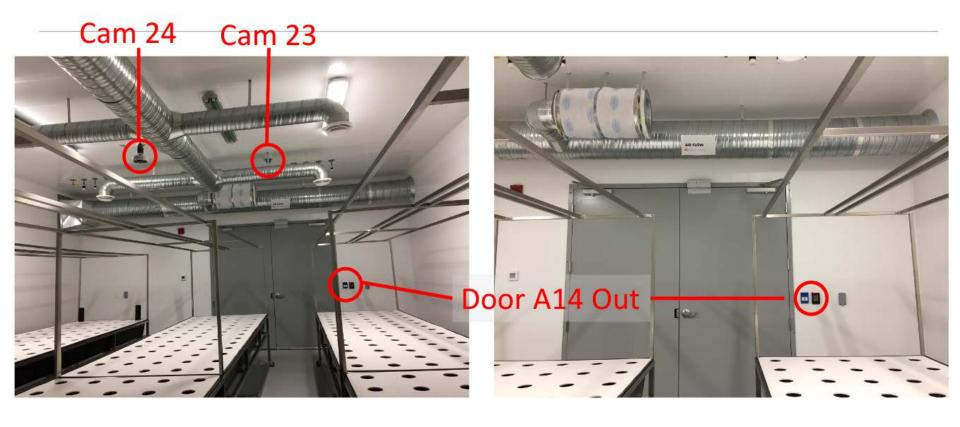








Interior – Flower Room 1 (continued)





Questions?

