





Guidance for High THC Cannabis Cultivation Application and Licensing

Version (2.2)

## **Table of Contents**

Ve	ersion Control	3
Te	erms & Abbreviations	3
1	Introduction	4
	1.1 About This Document	4
	1.2 Licence Types	5
	1.3 About the GSC	6
	1.4 The GSC's Mission	6
	1.5 Which Cannabinoids the GSC Controls	6
	1.6 The Status of CBD, THCA and Synthesised Products	7
	1.6.1 CBD	7
	1.6.2 THCA	7
	1.6.3 Synthetic Cannabinoids and Cannabinoids Derived Otherwise than from Cannabis	7
	1.7 Permissions Relating to High-THC Cultivation	7
	1.7.1 Case Studies	8
	1.7.2 Cultivation Licence Types	8
	1.7.3 Glazing and the Nature of the Facility for Indoor Growing	9
	1.7.4 Permitted Cultivars	9
	1.8 Product Use and Route to Market	9
	1.9 Testing and Labelling Requirements for Export	9
	1.9.1 Labelling	9
	1.9.2 Testing	
2	The Approval and Licensing Process in Summary	10
3	Application	12
	3.1 Requirements	12
	3.1.1 Application Acceptance	12
	3.1.2 Applications That Do Not Meet Acceptance Criteria	12
	3.1.3 Application Requirements	12
	3.1.4 Integrity and Competence Checks	14
	3.1.5 Business Checks	15
	3.1.6 Site Checks	15
	3.1.7 Security and Record Keeping	16
4	Multiple Licences	16
5	Licensing	16
	5.1 Licensing Process	16
	5.2 Licence Conditions	16
	5.2.1 Generic Conditions	17
	5.2.2 Class Specific Conditions	17
	5.2.3 Licence Specific Conditions	17
6	General Supervision, Enforcement Pathway	17
7	Subsequent Licenses	
	7.1 Renewals and Compliance History	
	7.2 Licence Surrender	
	ppendix A – Fees	
Αŗ	ppendix B - Overview of High THC Licensing	19



## Version Control

Version	Date published	Comments / Changes
V1.0	Not published	-
V1.1	8 April 2021	Amendments
V1.2	12 April 2021	Amendments
V1.3	13 April 2021	Amendments
V1.4	15 April 2021	Version for informal consultation with key stakeholders
V1.5	13 May 2021	Post consultation, all feedback incorporated
V1.6	18 May 2021	Internal sign off
V2.1	6 June 2021	Approved for publication/RMR
V2.2	5 August 2021	Licence Types Amended

## **Terms & Abbreviations**

2020 Regulations	Misuse of Drugs (Cannabis) Regulations 2020				
Active Part/ Product	Any part of the cannabis plant or cannabis derived product that contains more than trace amounts of controlled cannabinoids				
Biomass	Harvested cannabis plant material (excluding fibres and hemp hurds)				
Cannabis	Any plant of the genus <i>Cannabis</i>				
Cannabinoids	Chemicals, whether psychoactive or not, obtained through the cultivation of cannabis. Cannabinoids include THC and CBD				
Cannabis Derived Products	Cannabis products that are created using a manufacturing licence				
CBD	Cannabidiol, a cannabinoid – not a controlled cannabinoid				
CBN	Cannabinol				
Commission	The decision-making board of the GSC				
Controlled Cannabinoids	Cannabinol (CBN)  • Tetrahydro derivatives of cannabinol  • 3-alkyl homologues of tetrahydro derivatives of CBN				
Cultivation	The activity of raising plants. Cultivation includes the planting of seed or seedlings as well as the pruning of plants				
DfE	Isle of Man Department for Enterprise				
Extraction	Process that removes cannabinoids from biomass e.g. by means of a solvent. The result of extraction is known in Isle of Man regulation as a preparation				
GSC	Isle of Man GSC				
Inspectorate	The staff of the GSC managed by the Chief Executive				
Key Personnel	Anyone accountable for the operation of the business, e.g. the responsible person, directors of the licensee				
Manufacture	The creation of a cannabis derived product using substances other than cannabis biomass				
POCA	Proceeds of Crime Act 2008				
Psychoactive	Also psychotropic, affecting mental processes				



Responsible Person (RP)	The person having overall accountability for licensing and compliance
Source of Funds	The vehicle used to fund a licensee's operation.
Source of Wealth	The activity used to generate the funds used to fund a licensee's operation
THCA	Tetrahydrocannabinolic Acid
THC	Tetrahydrocannabinol
UN Single Convention	United Nations Single Convention on Narcotic Drugs 1961, an international treaty that requires signatory countries to control narcotics in their territory.

#### Introduction

#### 1.1 About this document

This document has been produced by the GSC to provide guidance on the application process for -

## Cultivation - Indoor Cultivation of Female Plants Only Research - Indoor Cultivation of Male and Female Plants

Separate guidance is available for related licences see: 1.2 Licence Types

The content of this guidance does not constitute legal advice.

Please contact <u>canna@gov.im</u> if you cannot find guidance that matches your proposed business model, or if you have any questions about the guidance itself.

#### Please note a licence is not required for -

- Possession, import and export of cannabis seeds
- Postal services, couriers, airlines and shipping moving controlled cannabinoids to and from the Isle of Man in the course of their business to and from a licensed recipient<sup>1</sup>.

The application form to begin a licence application can be downloaded on the GSC website www.isleofmangsc.com.

GSC

<sup>&</sup>lt;sup>1</sup> There is an obligation to ensure safe custody, transit and receipt of any such goods.

## 1.2 Licence Types

I want to grow Low THC cannabis

Industrial Hemp Licence



I want to grow High THC female cannabis plants

High THC Licence



This document

I want to grow male or female cannabis plants for research use only, or analyse cannabinoids on behalf of others

Analysis & Research Licence



I want to transport and store cannabis independent of cultivation

Transport & Storage



I want to process or extract cannabinoids from biomass cannabis, or manufacture cannabis derived products

Manufacture & Extraction Licence



I want to import or export cannabis to / from the Isle of Man

Import / Export Licence



I want to posess seeds for use other than cultivation

No Licence





## 1.3 About the GSC

The GSC is an independent statutory board of Tynwald, the parliament of the Isle of Man, and comprises the Inspectorate and the Commission. The Inspectorate is managed by the Chief Executive of the GSC and is responsible for processing applications and conducting supervision.

The Commission consists of various independent members drawn from relevant professions and backgrounds. Monthly hearings are held by the Commission to review and make licensing and supervision decisions, supported by recommendations from the Inspectorate. More information on the board members and meeting dates can be found on the GSC website.

The mandate to licence and supervise specific controlled substances, namely cannabis, has been given to the GSC by the Transfer of Functions (Cannabis) Order 2020. The types of licences that can be issued and the relevant fees are set out in the Misuse of Drugs (Cannabis) Regulations 2020 (2020 Regulations). Licensing and oversight of the activity described in this guidance sits solely with the GSC.

The GSC is available 9:00am to 5:00pm Monday to Thursday and 9.00am to 4.30pm on Friday and can be contacted via phone on \*44 (0)1624 694331 by e-mail at canna@gov.im or at the address below -

#### **Cannabis Licensing & Supervision Team**

Isle of Man GSC Ground Floor St. George's Court Myrtle Street Douglas IM1 1ED

## 1.4 The GSC's Mission

The GSC's mission is to ensure that -

- · Controlled cannabinoids remain within legitimate markets
- Products that contain cannabinoids originating from the Isle of Man are properly labelled for consumers so that the products may be used safely.

# 1.5 Which Cannabinoids the GSC controls

The regulations define controlled cannabinoids as -

- Cannabinol (CBN)
- Tetrahydro derivatives of cannabinol
- 3-alkyl homologues of cannabinol
- 3-alkyl homologues of tetrahydro CBN derivatives.

**Cannabinol** means cannabinol-type phytocannabinoids CBN-C5, CBNM-C5, CBN-C4, CBN-C3, CBN-C2 and CBN-C1.

Cannabinol Derivative means any cannabinoid that shares the dibenzo-pyran scaffold of cannabinol, irrespective of substituent at position 1 or the arrangement of bonds, where that derivative has been reliably assessed as having a psychoactive property, or where such a property has not been ruled out. At the time of writing, this means cis and trans- $\Delta$ 9-THC-C5,  $\Delta$ 9-THC-C4,  $\Delta$ 9-THC-C3,  $\Delta$ 9-THC-C1 as well as  $\Delta$ 8-THC-C5. This definition may capture synthetic cannabinoids. The GSC does not issue licences for synthetic cannabinoids.

Cannabinoids with this basic structure **and** which are either known to be psychoactive or whose psychoactive properties have not been excluded fall under GSC control.

The sidechain may contain any number of carbon atoms and any number of substituents.



**Homologues** are interpreted to mean molecules with variable counts of repeating identical sub-structures. In the case of 3-alkyl homologues, this is interpreted to include any number of carbon atoms on the sidechain, i.e. not just  $\Delta 9$ -THC-C3 or Cannabinol-C3.

**Cannabis** means plant material, whether live or harvested. See 1.6 below for the status of THCA present in the plant.

**Cannabis Resin** means any substance derived from the harvested trichomes of cannabis, whether processed or not, and which has the potential for psychoactive properties.

## 1.6 The Status of CBD, THCA and Synthesised Products

#### 1.6.1 CBD

CBD has no recorded psychoactive effect and is therefore not considered to be a controlled drug. The extraction of CBD from biomass is controlled by regulations under a class 6 extraction licence and a class 9 manufacturing licence (see separate guidance) and these licences do not require the cannabinoid to be a controlled cannabinoid in order for the GSC's licensing powers to apply.

In consequence, if a licensee intended to export a CBD product then the export licence (see separate guidance) will require the product to be accurately labelled so that the customer can see what the product contains. In addition to describing the ingredients, the label or attached documentation will need to advise the consumer of any harmful substances detected in the product (see 1.9 for testing and labelling requirements).

#### 1.6.2 THCA

Tetrahydrocannabinolic acid (THCA), whether in a live or harvested plant part, or extracted in another form, is not a controlled cannabinoid, but it is easily converted into THC. For this reason, the GSC will also control THCA as if it were a controlled substance.

## 1.6.3 Synthetic Cannabinoids and Cannabinoids Derived Otherwise than from Cannabis

Any process which does not use cannabis plants but nonetheless produces controlled cannabinoids requires licensing where a controlled cannabinoid is processed.

Synthetic cannabinoids that are cannabinol derivatives (see 1.5) cannot be produced without a licence. If a model intends to synthesise cannabinoids rather than harvest them from plants, potential applicants are advised to discuss the matter with the GSC prior to applying for a licence. A simplified overview of licensing in the High-THC Sector can be found at Appendix B.

#### 1.7 Permissions relating to High-THC cultivation

Licensing is available for analysis of cannabis based products. Such licensing provides the following permissions -

The law allows two types of cultivation licence where high-THC cannabis is grown. They differ in their permissions, specifically as to -

- Whether male plants may be cultivated or not
- Which end products can be sold.

Class 3 licences are designed to produce -

- Biomass for cannabinoid extraction
- · Plant parts for sale.

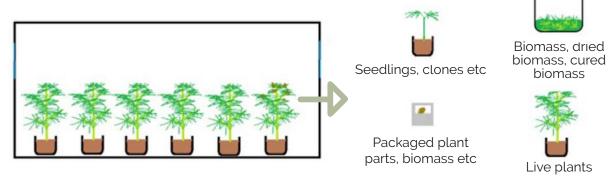
Class 3 licences may also be used to sell seedlings and other propagated plant parts. Only female plants may be used.

**Class 4 licences** are designed for cultivators who are breeding plants with the intention of selling the seed, seedlings or other propagated plant parts. The wholesale supply of biomass or plant parts is not permitted under this licence alone.

Both licences may be held at the same time and the permissions are cumulative, meaning for example, that all biomass can be sold under dual licensing.



## 1.7.1 Case Studies



**ABOVE: Figure 1.7.1 CLASS 3 CULTIVATION LICENCE.** Under a cultivation licence, only female plants may be grown. All live and harvested parts of the plant may be sold. The cultivation licence permits the packaging of plant parts.



**ABOVE: Figure 1.7.2 CLASS 4 RESEARCH LICENCE.** Under a research licence, female and male plants may be grown. The sale of products is restricted to live plants and seeds, however, on a samples-to-prospective-customers basis (i.e. not bulk retail), plant parts may be packaged and supplied.



ABOVE: Figure 1.7.3 CLASS 3 and CLASS 4 DUAL LICENSING. If both a class 3 and class 4 licence are held, then there is no restriction on the sale of any product arising from the facility, including any usable material from the class 4 licence that is surplus to requirements.

#### 1.7.2 Cultivation Licence Types

17/12 Catalvation Licenses Types						
Licence Type	Cultivation	Harvest	Posession	Supply/offer to supply active part/ product		
Class 3	Yes – indoor cultivation of female only plants	f Yes storage,		This licence permits the following to be sold— Cannabis biomass (including flowers, leaves, buds)  Cannabis seedlings and other propagated plant parts		
Class 4 High THC Cannabis	Yes – indoor cultivation of male and female plants	Yes	Yes including storage	This licence permits the following to be sold— Cannabis seeds, Cannabis seedlings and other propagated plant parts.  The licence also permits the supply		
				of limited samples of biomass (including flowers, leaves and buds) for the purposes of testing or establishing a cultivar's credentials.		



#### 1.7.3 Glazing and the Nature of the Facility for Indoor Growing

By default, a high THC cultivation facility may have no more than twenty percent glazing. It is possible under the regulations to operate facilities with alternative arrangements.

If an applicant wishes to operate a regime with a different level of glazing, then the Commission's permission must be secured for the variation. The permission will only be granted if the applicant can demonstrate that the alternative facility is as secure as a building with the twenty percent restriction in place.

#### 1.7.4 Permitted Cultivars

Cultivators of indoor cannabis may use any strain of cannabis that suits their business model. Licensees should expect that the GSC will seek to test all products destined for non-industrial consumers for harmful substances.

#### 1.8 Product use and Route-to-Market

Not all licensees will cultivate or create products for sale (e.g. test labs and transport licensees). If an applicant hopes to export a product they have made or cultivated, then the proposed route-to-market must be described when they apply for a licence.

The route to market element of the application needs to demonstrate an understanding of the supply chain and the target market. Specifically what permissions are needed to transport products through territories in the supply chain and what permissions are needed to sell product to the class of customer that is being targeted.

# 1.9 Testing and Labelling Requirements for Export 1.9.1 Labelling

The labelling regime in the Isle of Man requires the seller of a product to accurately describe the ingredients of a product, including levels of harmful substances. In seeking to establish the ingredients of a product, licensees may resort to third-party or in-house test labs. This section is included in order that test lab applicants can come to understand the obligations the GSC places on its other lciensees.

The GSC may obtain samples of material from any part of any process, including at the point of proposed export. Broadly, those samples will be made available to a test lab of the GSC's choice, and at the GSC's expense, with a view to identifying the presence of the following:

- · Metals (cadmium, lead, arsenic and mercury)
- Mycotoxins
- · Harmful, chemical residues, including residues from pesticides and solvents.

The obligation for accurate labelling sits with the holder of the export licence, even if the products are supplied by another licensee.

#### 1.9.2 Testing

The testing regime in the Isle of Man depends on the nature of the product's customer and the requirements apply to the export licence, not the cultivation licence.

If the customer is industrial or commercial in nature, and tests the quality of products as part of its goods-inwards process, then the testing of product is not mandatory, although labelling must nonetheless be accurate.

If the customer is not industrial or commercial in nature, and is unlikely to have the ability to test the product for harmful substances, then the product must be tested against the standards in **1.9.1.** 

The testing facility must possess ISO17025 accreditation.



## 2 The Approval and Licensing Process in Summary

When an applicant applies for licensing, the application pack (see 3.1.3) is assembled by the applicant and supplied to the GSC.

Following processing, the Inspectorate will lay the application before the Commission for a decision at hearing. The Inspectorate will typically only recommend an application for hearing when it believes the application will gain approval, but an applicant has the right to insist that an application be heard by the Commission.

Approval may contain conditions that need to be fulfilled before the licence can be granted. If approval has been given, there are no conditions left to fulfil and the applicant is ready to commence business, then the licence can be purchased immediately.

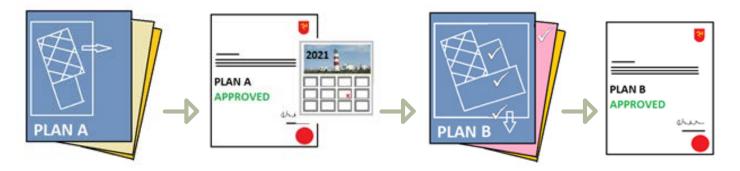
If the business is not yet ready to operate then a letter of approval will be issued. At the same time, the GSC will agree an approval period during which the approval letter may be used to move the venture forward. When the approval period lapses, the GSC will issue an invoice for the licence.

If the business is still not ready to commence operations, the GSC will determine if the approval period is to be extended or if the invoice for the licence must be issued. If it is issued, the licensee will have the status of 'paid, not live' until operations commence.

Before the licence is granted, the GSC will check that the facilities and arrangements that have been created match the proposals in the application. If at any time after approval the details of the application required to be flexed, then the applicant must confer with the GSC on the revised arrangements so that the approval can be reconfirmed.

As part of the approval, the applicant is asked to agree to any interim checks the GSC requires. The GSC may use this agreement to request information and updates, inspect works in progress and so forth to ensure that the venture is progressing as agreed in the current approval letter.



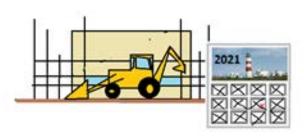


1. The GSC process the application

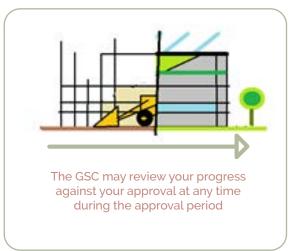
2. Successful applications receive an approval letter which specifies the approval period

3. Any changes to the approved proposal must be notified to the GSC in order that the approval letter can be updated





6. If the approval period has lapsed and it is evident that more time is required, the GSC will make the decision on whether to invoice for the licence or defer invoicing



## 3 Application

#### 3.1 Requirements

The elements that are required for a licence application are listed below along with a description of the checks carried out by the GSC to ensure the safety and reputation of the Island. Additional checks may be carried out at the GSC's discretion, including checks that refer applicant information to trusted third parties places on its other lciensees.

#### 3.1.1 Application Acceptance

For an application to be accepted and processed, the following criteria must be met—

- · The application must be complete
- All required supporting information must be included

"Credible" means that even if the permissions and customers have not yet been secured (for example, the applicant is a new market entrant), participation in the market is still theoretically possible within existing frameworks of law and policy.

Where applications are not complete or the supporting information is not included, applications may be rejected. Rejected applications may be resubmitted once their deficiencies have been corrected.

#### 3.1.2 Applications That Do Not Meet Acceptance Criteria

If an application fails to be accepted, for example because it is obviously incomplete or missing key information, then the GSC will explain the reasons for not processing the application at that time. An applicant can always resubmit an updated application once deficiencies have been addressed. Having an application declined is an informal process and does not form part of the GSC's record of an applicant.

There is no fee for an application. To ensure fair treatment to all applicants, the GSC will only progress applications that are complete and clearly evidence the acceptance criteria.

#### 3.1.3 Application Requirements

Applicants must be an Isle of Man registered company with a minimum of two on-Island directors and a nominated on-Island Responsible Person (RP). One of the on-Island directors may be appointed as the RP or another individual who lives in the Isle of Man may be appointed.

Applications can be submitted by the registered business or with the assistance of a legal or corporate advisor. The GSC accepts applications from all three channels and has no preference in the submission channel used.

The application form is split into the following sections -

#### **Application Details**

The application needs to indicate:

- · What class of licence is being applied for
- Whether it is a first year licence or a renewal of a previously held licence (different fees apply for the first year's application see **Appendix A** for fee structure).



#### Responsible Person Details.

The Responsible Person (RP) is the on-Island business representative to whom the licence will be supplied and who is accountable for supplying the GSC with any information it requires as well as disclosing significant events to the GSC as they occur. The RP can nominate others to conduct day to day business with the GSC but cannot delegate responsibility.

The RP will be required to fill in a Personal Declaration and will be subject to diligence checks by the GSC.

#### Other Key Persons

The application needs to indicate who the senior figures are for controlling:

- Security
- Regulatory Compliance
- Finance.

These individuals will be required to fill in Personal Declaration Forms of the Application Form and will be subject to diligence checks by the GSC.

#### **Business/Organisation Details**

The business must be an Isle of Man registered company.

For the applicant business the following documentation is required—

- A copy of the Certificate of Incorporation
- Group structure chart highlighting shareholding percentages
- Register of Shareholders
- Details of how the business will be funded i.e. start-up and running costs.
- Details of the vehicle funding the Isle of Man company and details about how that wealth was generated, that can be corroborated by the GSC
- 3 year financial projection and a sensitivity analysis that tests the variables in the business plan. Note that the GSC allows a grace period to run before the licence is purchased. The model should assume that the licence fee will be payable within 3 months of approval even if the GSC has discretion to extend that period.
- Details of individuals other than the RP who may exercise control over a business including—
  - Beneficial owners
  - Shareholders
  - Directors (minimum of two on-Island directors required)
  - Trustees.

Each of the individuals named in this section will be required to fill in a Personal Declaration Form.

#### Other Licences

If the application is being made by an existing business, then the application must declare any existing licensing arrangements (cannabis licenses held elsewhere) and licensing history (previous licenses declined, held, revoked or surrendered).

People who are required to complete a Personal Declaration Form are invited on that form to disclose separately any involvement with an entity that has a licensing history.



#### **Business Plan**

A business plan is required in the application process, he business plan should include—

- An outline of planned activity under the licence—
  - Planting/harvesting schedules
  - Cultivars to be used
  - Known third parties or third party roles involved in the operation including contractors e.g. transport, security, machinery operators etc.
- Details of the end use of the product, route to market and intended customers for that product
- Proposed area for cultivation, details of proposed size and location and—
  - A site plan clearly showing the area(s) or premises to be used for cultivation highlighting storage facilities and any nearby features
  - Details of site owners for all proposed sites.
- Security and Record Keeping, details relating to the following and copies of standard operating procedures (SOP) for—
  - How the site will be contained and protected from theft (by external or internal agents)
  - For operations with no Class 4 licence, how the applicant will ensure that no male (or intersex) plants are allowed to be cultivated, and how they will be removed and destroyed
  - For operators with a Class 4 licence, how the applicant will ensure that pollen cannot escape into the external environment
  - How the cultivation and any subsequent processes will be tracked in order that (a) batches may be traced back to problematic processing, (b) problematic batches may be recalled and (c) illicit diversion of product can be detected
  - Pest management plans
  - How waste materials will be safely disposed of; including—
    - How waste containing controlled cannabinoids or THCA will be put beyond use
       (i.e. in a way that prevents the recovery of controlled cannabinoids)
    - How waste products arising from agricultural or industrial processes will be safely disposed of
  - Incident management procedures to record actual or attempted theft;
     accidental damage or loss; or other adverse incidents
  - Procedures for tracking deliveries, stock checks, site access, etc.
  - Record keeping in relation to incoming stock and outgoing produce.

The GSC recognises that new market entrants may yet require to procure facilities. If an applicant does not currently have facilities then the application should still contain as much detail as available. This should include estimates on facilities and arrangements where concrete detail is not yet available.

The GSC may seek to validate the information provided through other agencies, third party providers and by requesting further information. The GSC always reserves the right to conduct additional checks, even if those checks are not part of the standard application process.

#### 3.1.4 Integrity and Competence Checks

The GSC carries out checks on individuals to ensure the sectors it regulates are run by people of integrity and that those in charge of the business understand their legal and regulatory obligations, including those of good business and compliance.

Applicants for GSC licensing are exempted from the Rehabilitation of Offenders Act 2001, which means that convictions that may appear to be spent are still visible to the GSC.



The GSC takes a common-sense approach to sanctions and convictions that a person may have. Any declared convictions and sanctions falling outside of those mentioned will be assessed

on an individual basis and factors such as length of time passed, type of offence, relevance of offence to the sector will be considered.

It is critical that all sanctions and convictions are declared. The Identification of undeclared convictions or sanctions will always cause delay and can cause an application to stall or be discontinued.

#### **Integrity and Competence Information**

Information is required in order to allow the GSC to check the backgrounds of owners and controllers. Owners must be people of integrity (i.e. they respect the law) and controllers must be people of integrity and competence (i.e. they respect the law and can be relied upon to act in the licence's best interests).

If a person is identified as an owner (shareholder, trustees, etc) or a controller (RP, head of security/compliance or finance) then their Personal Declaration Form should be accompanied by -

- Identification documents and proof of address to allow the GSC to carry out verification of identity
- A brief outline of experience that relates to the application to show that the applicant understands the nature of the proposed business
- Declarations of any sanctions or convictions or ongoing cases in order to assess individual integrity (including sanctions from other regulatory bodies)
- Information about any other licences held that may be relevant to the application and demonstrate experience of compliance requirements.

#### 3.1.5 Business Checks

Applicants are required to be aware of, and comply with, any policies or regulations that are applicable in the proposed business activity, specifically—

- Health and safety requirements
- Company law
- Data protection
- Environmental protection.

These areas of law belong to other enforcement bodies in the Isle of Man. While the GSC does not oversee compliance in these areas, any failure to comply with any Isle of Man legislation may cause the GSC to review a licence.

The following documents are required from applicants to satisfy business checks—

- A shareholder register this provides a list of shareholders and helps the GSC to ascertain any beneficial owners and controllers of a business;
- Source of funds checks the applicant/licensee may be required to provide evidence that funds are available for the immediate liabilities incurred by the business in order to prove sustainability
- Financial projections to evidence how much funding is required and assist with demonstrating that the business model is sustainable.

#### 3.1.6 Site Checks

Once a site has been established, an applicant or an approved entity can expect the site to be visited by the GSC. The GSC may invite additional specialists to such a visit to offer opinions on technical matters. If the acquisition of a site follows approval, the GSC may choose to visit that site at any time to inspect its suitability.



#### 3.1.7 Security and Record Keeping

Licensees will be required to present a plan of site security including any arrangements for storage, access controls and movement of goods on and off site. A business risk assessment should outline any relevant controls relating to site security and access.

Access records should be kept to identify visitor and staff access and controls should be in place to ensure that visitors are identified and not left unattended in areas where cultivation or controlled substances are present.

## 4. Multiple Licences

The Isle of Man's licensing framework splits the various roles in the regulated cannabis sector so that businesses may specialise.

It is permitted to acquire any number of licenses provided competence can be demonstrated to discharge the licensed functions.

The licensing framework predicts the acquisition of multiple licenses by companies and use a maximum fee cap to control costs to the licensee. The fee cap is automatically applied every time a licence fee is paid, whether a new licence or a renewal. It operates over a rolling 12 month period which means that the decision to add a new class of licence retains the benefit of the fee cap, no matter when it is added.

The fee cap is £62,500. This means that the maximum amount of licence fees that will have been paid in any twelve month window is £62,500, even if the cumulative costs of the same licenses is higher.

If an applicant knows that it requires multiple licences, then it may make a single application for the licenses it requires. If this is the case, each guidance note for each licence class must be read and details included in the application that meet the guidance's requirements.

Discrete licenses within a multi-licensing application can be released as operations come on stream.

Applicants are however discouraged from selecting multi-licensing on a "just-in-case" basis, with a view to dropping approvals in the future. For this reason, the business model that is submitted must demonstrate the requirement for the multi-licence approach.

Details of the cap and the method of calculation are available separately on the GSC website.

## 5. Licensing

#### 5.1 Licensing Process

When the approval grace period lapses, the licence fee becomes due and the GSC will issue a 28-day-payable invoice for the approved licences.

The GSC will also check that the facilities and arrangements that sit under the licence are the same as those on the approval letter, notwithstanding that letter may have been modified any number of times prior to the issue of the licence.

#### **5.2 Licence Conditions**

When a licence is issued it will refer to applicable parts of the Cannabis Licensing Conditions, a central document which outlines licence conditions applicable to each type of licence.

For example, a licence permission may include a condition requiring the reporting of male plants or a condition obliging licensees to implement the GSC's policy on specific subjects with the policy being available on the GSC's website.



#### 5.2.1 Generic Conditions

Generic conditions apply to all licence classes. If multiple licences are held, these conditions apply for each licence.

Examples of generic conditions are—

- Licensees must not act, or by omission of action bring the Isle of Man' regulated cannabis sector into disrepute
- Any theft or losses (including mistaken or accidental destruction) must be reported to the GSC as soon as they are discovered, detailing the quantity lost and the strength (estimated if necessary) of any psychoactive compounds.

#### 5.2.2 Class Specific Conditions

Specific conditions may apply to the class of licence that is held. If multiple licences are held then conditions may overlap or may not. If they do not overlap then the conditions in a given licence are to be read as only applying to the activities cited in the licence in which they are found.

An example of a class-specific condition is the requirement to report the use of a pesticide or plant growth regulator to the GSC.

#### 5.2.3 Licence Specific Conditions

A licence may become restricted by the GSC, that is to say the licence remains in force to allow continued possession of controlled substances while some defect is corrected or steps are taken to wind down the licence.

If a licence is being managed as part of a wind-down process, then specific conditions will outline what the licensee is required to do as part of that process in order to remain under the protection of the licence.

## 6. General Supervision, Enforcement Pathway

A programme of supervision will be conducted by the GSC. The GSC's supervision of licensees includes -

- Visits and site inspections, including visits to check security arrangements
- Regular reguests for financial data
- · Checking that reportable events are being notified or pre-approved
- Auditing of record keeping
- Technical checks relevant to the licence.

Correspondence between the GSC and the licensee that relates to supervision will be addressed to the responsible person, or their delegates.

If supervision suggests that a licensee is not in compliance with its licence conditions or the regulations, then the GSC will consider the risk to security and/or customer safety. The GSC's aim is to guide licensees to compliance and then help them maintain compliance.

If the conduct of a licensee remains unsatisfactory after notification, then the GSC has three remedies that it can impose.

The first remedy is a partial restriction of the licence. The restriction is achieved through licence conditions. In such an arrangement, some aspect of the licensed activity might be stopped or limited until an issue has been addressed. This will typically be imposed where a licensee has already been asked to resolve an issue and has failed to do so.

The second remedy is full restriction. All licensable activity ceases and the continued power of the licence is simply a concession to avoid exposing those under its protection to a Misuse of Drugs Act prosecution. This action means that the GSC believes there is a significant risk of the misuse of drugs arising from the licensee's continued activity.



Finally, the GSC can revoke a licence. The protection of the licence falls away and it becomes unlawful for people previously associated with the licence to possess controlled drugs. This action indicates that the GSC has identified a material failure in the aims of licensing i.e. that the continued operation of the licensee means that drugs are being diverted or that customers' welfare will be harmed. This action can also be predicted if it becomes clear that the licensee holds the GSC's requests for compliance in contempt.

## 7. Subsequent Licenses

Licences last for one year from the date of purchase. If an applicant wishes to renew a licence, then the GSC should be told in good time. At present the notification period is 12 weeks.

#### 7.1 Renewals and Compliance History

Once a licence has been issued, the licensee will come under the GSC's supervision. If deficiencies are discovered during supervision then remediation will begin in order to reestablish compliance.

If a licensee is -

- in compliance when the licence expires; or
- · not in compliance, but the GSC is satisfied with ongoing remediation efforts

then any second or subsequent licence will not require a repetition of the initial application process. A short review will check that all reportable events have been declared as they occurred and if they have been, then the second or subsequent licence will be issued as a formality.

If a licensee is not in compliance and the GSC becomes dissatisfied with the remediation effort then regulatory action, including action that affects the licence, will occur at that time. Put another way, the GSC will not postpone an intervention until the expiry of a licence, but rather will control the risk as soon as it arises.

Similarly, if the short review of reportable events discovers unreported events then licence renewal may require additional information to be submitted, which will necessarily include the reasons behind the failure to report the event when it occurred.

This policy means that a licensee who is in compliance and approaching the expiry of their licence can be confident of renewal.

#### 7.2 Licence Surrender

It is the obligation of the licensee to ensure all licence conditions are met at all times. The protection against Misuse of Drugs Act offences afforded by the licence depends upon compliance with the licence conditions.

A licensee that no longer believes it can adhere to licence conditions may indicate its intention to surrender the licence. The GSC will coordinate the orderly wind-down of the licence until all stocks of controlled cannabinoids have been disposed of and the protection of the licence may be removed.



## Appendix A - Fees

Licence Type	Year 1 Fee	Standard Fee
Industrial Hemp Licence Without Use	£500	£250
Industrial Hemp Licence With Use	£10,000	£5,000
Cannabis Licence (high THC cultivation)	£45,000	£35,000
Research Licence (male & female plants)	£20,000	£12,000
Transportation and Storage Licence	£5,000	£2,500
Extraction Licence	£22,500	£17,500
Import Licence	£10,000	£7,500
Export Licence	£10,000	£7,500
Manufacture Licence	£22,500	£15,000
Analysis Licence	£12,500	£8,000
Possession Licence (for a purpose specified by the Commission)	£o	£o

Fees are capped at £62,500 in a preceding period of 364 days for licensees with multiple licence types.

## Appendix B – Overview of High THC Licensing

The GSC's view of the sector: **Seeds and cultivation** 

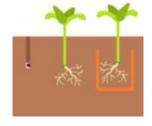
The import of seed for sale to others, and the export of seed for sale to others does not require a licence. It is not an offence to possess cannabis seed.

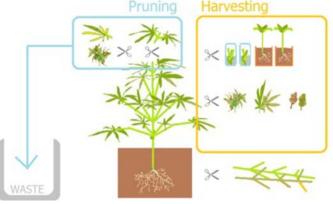




However, an IMPORT licence is required to bring propagated cannabis plants (clones, micropropagation material) into the Isle of Man; likewise if the intention is to export the same, then an EXPORT licence is required.

To plant cannabis seeds, or seedlings into a growing medium (soil, water, etc.) a CULTIVATION licence is required. The cultivation licence permits the growing of female cannabis plants, pruning and harvesting of plant material (e.g. flowers, leaves and buds) for sale or for onward propagation as future plants (e.g. clones).





Under a cultivation licence pruning permanently removes plant material from the supply chain. e.g. diseased or infested leaves, pollen bearing organs, pruned tops for creating optimal light absorption, etc.

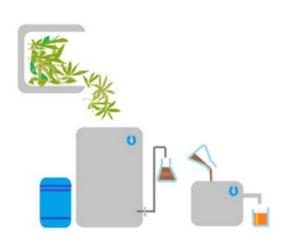
Harvested material can be packaged and sold where there is a legitimate, receiving market, or be used to make future plants e.g. clones from a mother plant



To cultivate male cannabis plants, a RESEARCH licence is required. This will permit cultivation of female plants as well as male plants. Research licence conditions allow the sale of seed and live plants. However harvested biomass can only be supplied in the form of small samples of plant parts in order to permit potential customers to evaluate results. Research licences require tighter bio-security measures than other cultivation licences to prevent the unwanted pollination of neighbouring indoor or outdoor facilities. Inspections will also be conducted differently so that inspectors do not become pollinators as they move from one facility to another.



#### The GSC's view of the sector: **Extraction and manufacturing**



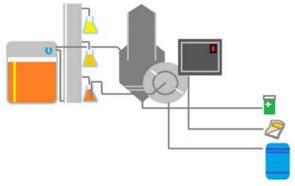
Packaging raw plant material is permitted under a cultivation licence (it is considered a function of harvesting). However, using plant material in a process to create an extracted preparation would require an EXTRACTION licence.

Where an extraction process contains multiple steps, the GSC permits the process to continue under an extraction licence until extract is no longer being "cleaned-up" (e.g. winterisation to remove waxes, etc.) but rather is now being separated into independently saleable products.

If a process starts with an extracted preparation, or a combination of substances that include cannabinoids, then it will likely fall under a MANUFACTURING licence.

Activities under a manufacturing licence never begin with untreated plant material, and will typically go beyond simple uses of refrigeration, solvents or filtration.

Once correctly labelled, the end products arising from a manufacturing are only restricted by target markets and transit permissions.

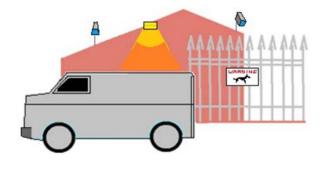


Distillation, crystallisation, the use of ovens and centrifuges that operate on non-plant material are indications that a manufacturing licence is required.

The law allows the use of very small quantities of plant material in the manufacturing process if its use can be justified.

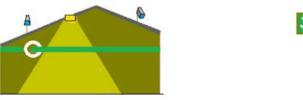
#### The GSC's view of the sector: **Transport & Storage**

A TRANSPORT and STORAGE licence permits participation in the regulated cannabis sector, allowing licensees to possess controlled cannabinoids in the discharge of their service. One licence covers both activities but competence must be shown for each function in turn (storage and/or transportation).





**Transport & Storage – organic mode:** A licensee will need a transport and storage licence if it intends to transport its own products containing controlled cannabinoids between two or more facilities, or to and from ports or the airport.





**Transport & Storage – third party mode:** A third party can use the transport & storage licence to move controlled cannabinoids between facilities that are licensed to unconnected parties or between facilities owned by the same licensee, or between those facilities and ports and the airport.





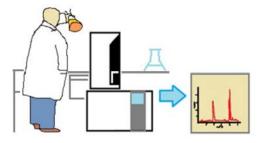
**Partial use of transport and storage licence:** A third party may choose to simply operate either a secure storage facility for other licensees to use, or may choose to operate only a transportation service that does not store controlled cannabinoids between legs of the journey.

#### The GSC's view of the sector: **Import & Export**

IMPORT and EXPORT licences are available separately and are needed whenever controlled cannabinoids, including plants and products that contain them, are moved into the Isle of Man or out of the Isle of Man. If a licensee intends to perform both functions then they require both licences. These licences do not confer special privileges with respect to export from the UK to other (non-Isle of Man) countries or import into the UK from those countries, where UK rules on cannabinoids prevail.

#### The GSC's view of the sector: Research

To establish a testing laboratory in the Isle of Man that will temporarily take possession of samples that may contain controlled cannabinoids then a RESEARCH licence will be required.



The research licence permits controlled cannabinoids in any form to be held and tested, including raw plant material, industrial chemical preparations and final products derived from cannabis. However the total amount of samples that may be held is restricted.



Ground Floor | St George's Court | Myrtle Street | Douglas | Isle of Man | IM1 1ED