



Guidance for Cannabis Manufacture and Extraction Application and Licensing

Version (2.2)

Table of Contents

Version Control.....	3
Terms & 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 Manufacture and Extraction.....	7
1.8 Product Use, Route to Market.....	9
1.9 Testing and labelling requirements for export.....	9
1.9.1 Labelling.....	9
1.9.2 Testing.....	9
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 Extraction.....	14
3.1.5 Manufacture.....	15
3.1.6 Integrity and Competence checks.....	15
3.1.7 Business Checks.....	16
3.1.8 Site Checks.....	16
3.1.9 Security and Record Keeping.....	16
4 Multiple licences.....	16
5 Licensing.....	17
5.1 Licensing Process.....	17
5.2 Licence Conditions.....	17
5.2.1 Generic Conditions.....	17
5.2.2 Class Specific Conditions.....	17
5.2.3 Licence Specific Conditions.....	17
6 General Supervision, the enforcement pathway.....	18
7 Subsequent licenses.....	18
7.1 Renewals and Compliance History.....	18
7.2 Licence Surrender.....	19
Appendix A – Fees.....	20

These notes are effective from 19 May 2021

Version Control

Version	Date published	Comments / Changes
V1.0	Not published	-
V1.1	15 April 2021	Amendments
V2.1	6 July 2021	Approved for publishing/RMR
V2.2	5 August 2021	Amendments to Licence Types

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 Cannabis
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 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 -

Manufacture of Cannabis derived products

Extraction of Cannabinoids

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

The content of this guidance does not constitute legal advice.

Please contact canna@gov.im 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 recipient¹.

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

¹ 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	IH
I want to grow High THC female cannabis plants	High THC Licence	C
I want to grow male or female cannabis plants for research use only, or analyse cannabinoids on behalf of others	Analysis & Research Licence	AR
I want to transport and store cannabis independent of cultivation	Transport & Storage Licence	TS
I want to process or extract cannabinoids from biomass cannabis, or manufacture cannabis derived products	Manufacture & Extraction Licence	ME
I want to import or export cannabis to / from the Isle of Man	Import / Export Licence	IE
I want to possess seeds for use other than cultivation	No Licence	A

This document

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 -

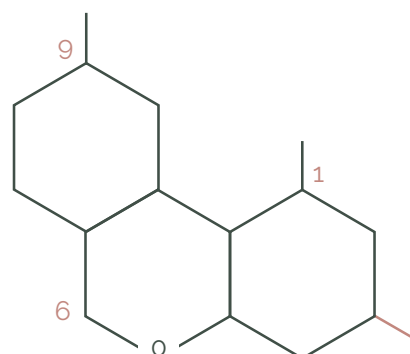
- Cannabinol (CBN)
- Tetrahydro derivatives of cannabinol
- 3-alkyl homologues of cannabinol
- 3-alkyl homologues of tetrahydro CBN derivatives.

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- Δ^9 -THC-C5, Δ^9 -THC-C4, Δ^9 -THC-C3, Δ^9 -THC-C1 as well as Δ^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 Δ^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.

1.7 Permissions relating to High-THC cultivation



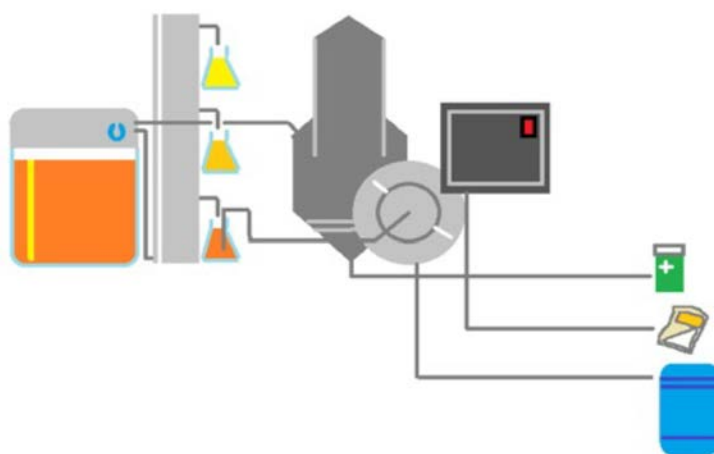
Packaging raw plant material is permitted under a cultivation licence (it is considered a function of harvesting). However, using plant material in a process to create an extracted preparation would require an EXTRACTION licence.

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".

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 following is permissible under each licence type—

Licence Type	Cultivation	Possession	Supply/offer to supply active part/product
Class 6 Extraction	Production of cannabis involving processing cannabis biomass or extracting a preparation from cannabis biomass that contains cannabinoids	Possession of cannabis biomass and preparations extracted from cannabis biomass	Supply and offer to supply of preparations
Class 9 Manufacture	Production of cannabis involving the manufacture of cannabis derived products.	Possession involving storage of a preparation or a cannabis derived product	Supply and offer to supply of cannabis derived products

Additional licences will be required for—

- Transportation
- Storage of cannabis and cannabis products
- Import or export of cannabis and cannabis derived products
- Cultivation of low or high THC cannabis
- Possession of cannabis products/biomass for testing.

Where there is doubt about the boundary between extraction and manufacture and which licence to apply for the GSC can agree boundaries prior to the commencement of operations. Applicants will be expected to detail any processes and demonstrate how the process fits with the extraction or manufacturing processes outlined at **3.1.4 Extraction** and **3.1.5 Manufacture**.

More information on licence fees can be found at **Appendix A**.

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.

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.

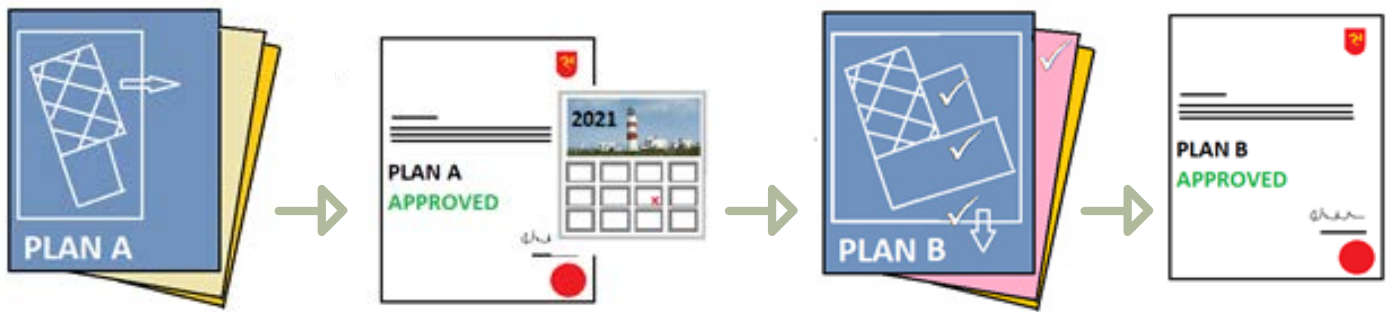
Approval may contain conditions that need to be fulfilled before the licence can be granted. If approval has been given, there are no conditions left to fulfil and the applicant is ready to commence business, then the licence can be purchased immediately.

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.

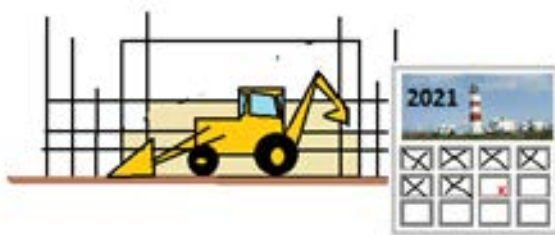
As part of the approval, the applicant is asked to agree to any interim checks the GSC requires. The GSC may use this agreement to request information and updates, inspect works in progress and so forth to ensure that the venture is progressing as agreed in the current approval letter.



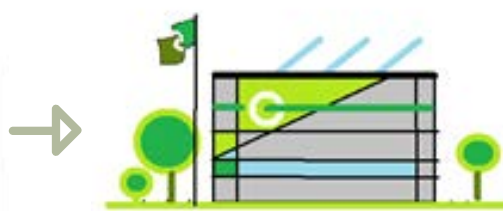
1. The GSC process the application

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

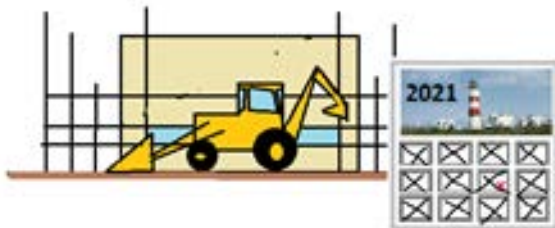
3. Any changes to the approved proposal must be notified to the GSC in order that the approval letter can be updated



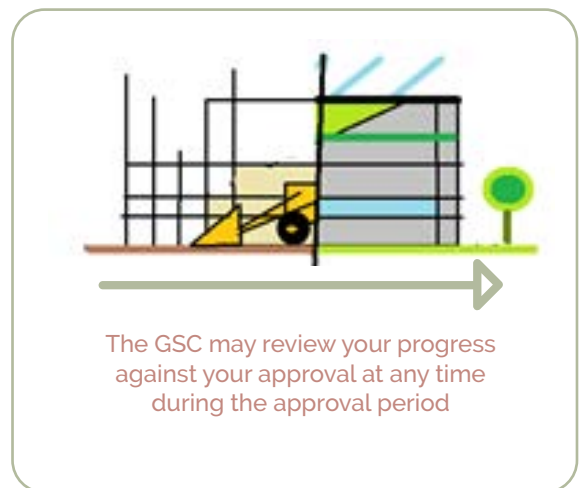
4. Any outstanding arrangements are finalised in the approval period



5. At any point in the approval period, the licence may be purchased. By default, purchase is mandatory when the approval period has lapsed



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.

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
- The route to market data should demonstrate a credible supply into a market.

"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**

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 Form 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 and will be subject to due diligence checks by the GSC.

Business/Organisation Details

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. The business plan should include—

- Activity, an outline of activity all potential activity under the licence—
 - For extraction, the material to be used for extraction, the method, the resulting product and anticipated purpose for the extracted material ([see 3.1.4 Extraction](#))
 - For manufacture, an overview of the manufacturing process and intended market for the manufactured products ([see 3.1.5 Manufacture](#))
 - Third parties involved in the operation including contractors e.g. transport, security, machinery operators etc.
 - What testing and labelling of products will be carried out (see 1.9 Testing and Labelling Requirements)
 - Details of suppliers.
- Security and Record Keeping, details relating to the following and copies of standard operating procedures (SOP) for—
 - Health and safety protocols and risk assessments
 - How products will be stored and transported
 - Procedures for record keeping, storage facility access, etc.
 - Record keeping in relation to incoming material and outgoing product.

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 Extraction

An extraction licence permits licensees to possess and take possession of cannabis biomass and seeds in order to extract cannabinoids. The extraction process treats biomass in order to remove useful chemicals and create a preparation.

If machinery is to be deployed that uses extremes of temperature or pressure, or uses hazardous materials in extraction, then evidence of the safety of that machinery is required, as well as the risk assessment that considers its safe use.

Any extraction site using machinery or potentially dangerous chemicals must meet the Isle of Man's standards for fire safety and health and safety at work. Applicants should demonstrate an understanding of these requirements.

During extraction, there are no THC/CBN limits on the materials that can be extracted.

Furthermore, preparations can be refined to the extent that unwanted contaminants (such as waxes, chlorophyll and so forth) are removed even if the precursor that enters part of the process is now technically a preparation rather than raw plant material. This concession only applies where the ongoing process is refining the initial extract to remove useless or unwanted elements. However, proceeding to actively isolate certain cannabinoids or cannabinoid/terpene profiles would be a manufacturing process (see below).

Where multiple licences are held preparations can be used in the licensees' manufacturing process.

3.1.5 Manufacture

Manufacture means possessing cannabis related product (except biomass) in order to refine or produce any cannabis derived product.

If machinery is to be deployed that uses extremes of temperature or pressure, or uses hazardous materials in extraction, then evidence of the safety of that machinery is required, as well as the risk assessment that considers its safe use.

Any extraction site using machinery or potentially dangerous chemicals must meet the Isle of Man's standards for fire safety and health and safety at work. Applicants should demonstrate an understanding of these requirements.

Manufacture never begins with biomass (that process occurs under the extraction licence). If an end product requires the incorporation of raw plant product or semi-processed plant product, then the applicant should seek the GSC's views before committing to the application.

3.1.6 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.

3.1.7 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.

3.1.8 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.

3.1.9 Security and Record Keeping

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

Records of goods inwards and outwards should be maintained detailing where the shipment originated, details of the provider and their licensed status, details of the intended recipient and their licensed status, details of person responsible for taking delivery and specific amounts and contents of the shipment.

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's 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 requests 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 re-establish 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)	£0	£0

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



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

+44 1624 694331 | email@iomgsc.com | www.iomgsc.com