MCAZ Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-20

GUIDELINES ON THE PRODUCTION OF CANNABIS FOR MEDICINAL AND SCIENTIFIC USE

EFFECTIVE DATE: 22/11/2024

Medicines Control Authority of Zimbabwe

106 Baines Avenue

P O Box 10559

Harare

Email: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

Written by:	..... Signature	19/11/2024 Date
Checked by HoD/HoU:	..... Signature	19/11/2024 Date
Authorised for use by: Quality Manager	..... Signature	19/11/2024 Date
Approved by: Director-General	..... Signature	22/11/2024 Date

1.0 APPLICATION

These guidelines apply to the production of cannabis intended for medicinal or scientific purposes.

2.0 PURPOSE AND SCOPE

These guidelines seek to explain the processes involved in applying for licences and the conditions to produce cannabis for medical and scientific purposes in Zimbabwe. These guidelines are meant to outline the following:

2.1 Requirements for a complete application for a Cannabis production licence.
2.2 Security requirements
2.3 Personnel
2.4 Conditions for production
2.5 Import and Export requirements
2.6 Record Keeping
2.7 Advertisement
2.8 Inspections
2.9 Quality Control

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*] The Authority`s mandate is set out in this Act and its accompanying regulations. It is also responsible for administering the Dangerous Drugs Act (Chapter 15:02) and its regulations, Dangerous Drugs Regulations (RGN 1111 of 1975) on behalf of the Ministry of Health and Child Care.

The Dangerous Drugs Act [Chapter 15:02] is an Act that provides for the control of the importation, exportation, production, possession, sale, distribution and use of dangerous drugs; and to provide for matters incidental thereto. In terms of Section 6 of the Dangerous Drugs Act [Chapter 15:02], the Minister of Health and Child Care published the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018, Statutory Instrument 62 of 2018, hereinafter referred to as *"Regulations"*.

MCAZ therefore administers the Regulations on behalf of the Ministry of Health and Child Care. MCAZ works with various stakeholders to ensure that medicinal Cannabis, is handled effectively and legally throughout the supply chain. This encompasses monitoring activities of all licensed cannabis cultivation sites to ensure compliance to the Regulations. The following stakeholders play different roles in the regulation of medicinal Cannabis ***(list not exhaustive):*

3.1 Ministry of Lands, Agriculture, Fisheries, Water and Rural Development (MLAFWRD), Department of Research and Specialist Services (DR&SS).
3.2 Zimbabwe Investment and Development Agency (ZIDA)
3.3 National Biotechnology Authority (NBA).
3.4 Ministry of Health and Child Care (MOHCC).

3.5 Zimbabwe Republic Police (ZRP) Criminal Investigation Department (CID) Drugs and Narcotics.
3.6 President's Department, Counter Narcotics and Drug Trafficking.

These guidelines have been prepared with particular reference to the Regulations.

4.0 DEFINITIONS

4.1 **Act:** refers to the Dangerous Drugs Act [*Chapter 15:02*];
4.2 **Cannabis:** includes fresh or dried cannabis, cannabis oil, cannabis plants or cannabis seeds.
4.3 **Director-General:** means the Director-General of the Authority appointed in terms of section twenty-six of the MASCA;
4.4 **Licensed producer**: means the holder of a licence issued by the Minister of Health and Child Care for production of cannabis
4.5 **Minister:** means the Minister of Health and Child Care
4.6 **Production:** means cultivation, drying, extraction, packaging, labelling, storage, and processing of cannabis;
4.7 **Regulations:** refers to the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [S.I 62 of 2018]
4.8 **Secretary:** means the Secretary for Health in the Ministry of Health and Child Care
4.9 **Site:** means
  4.9.1 a building or a place in a building used by a licensed producer; or
  4.9.2 an area occupied exclusively by buildings used by a licensed producer

5.0 GUIDELINES

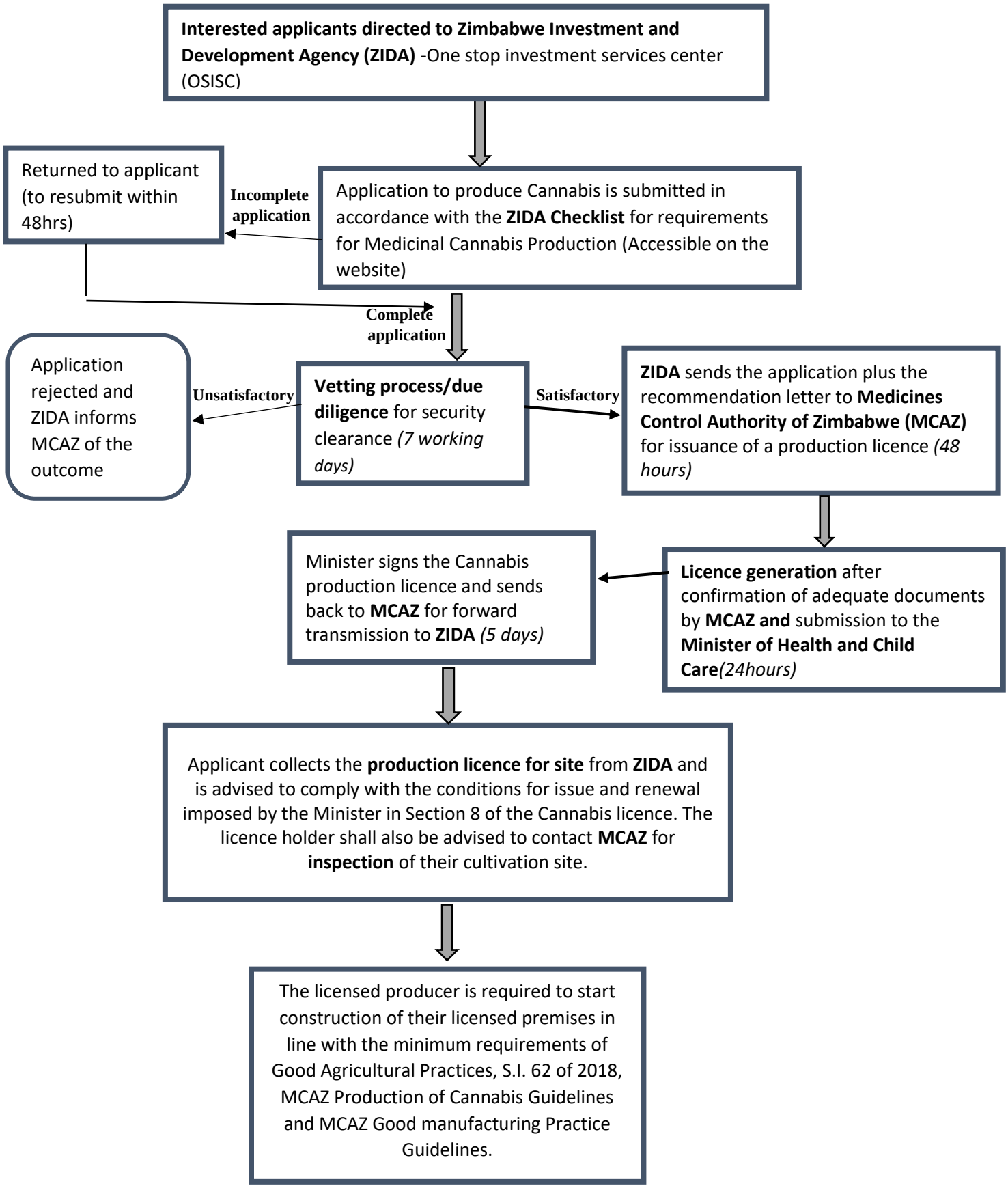
APPLICATION FOR A PRODUCERS` LICENCE

5.1 Application for a producers` licence may be done by:

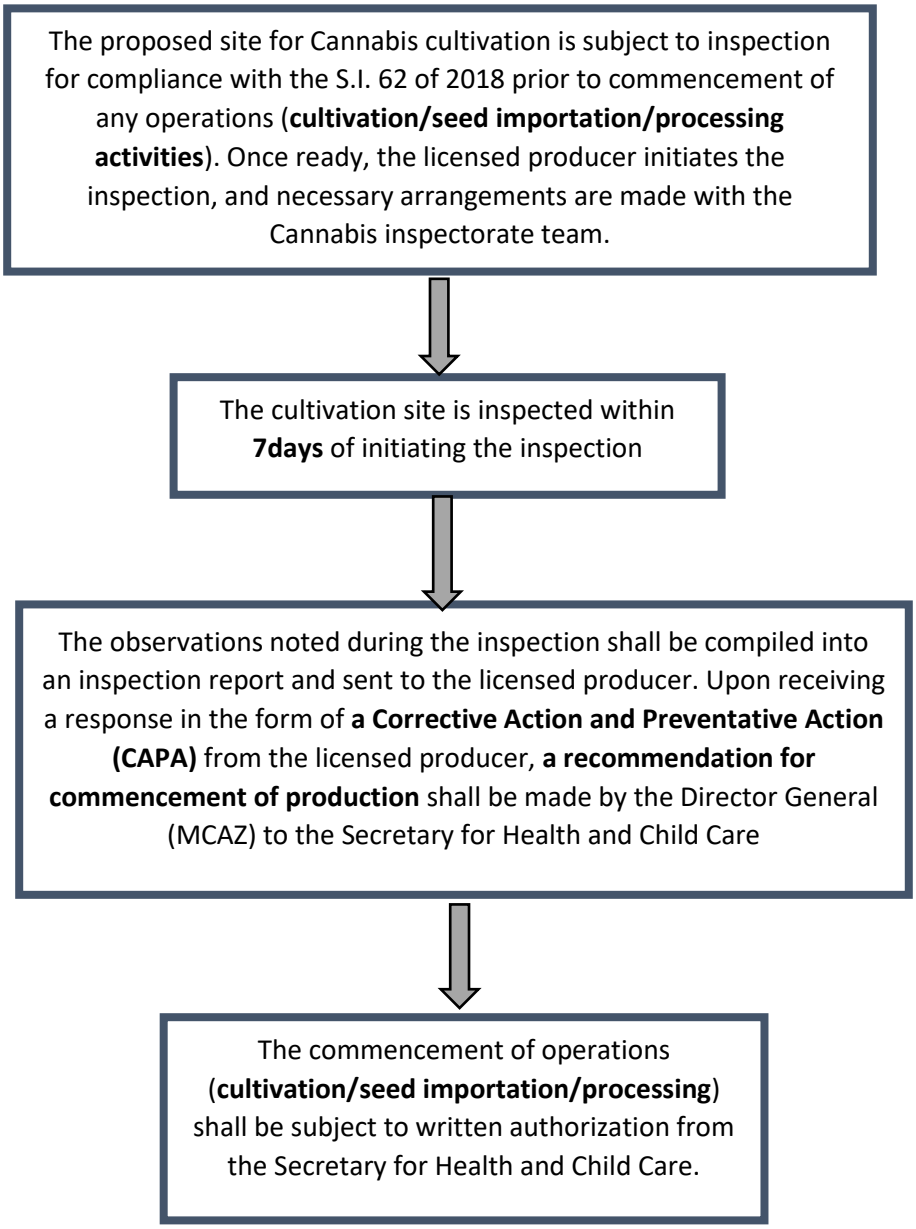
5.1.1 A company duly registered by the Registrar of Companies, with the majority of the directors with proof of citizenship or being ordinarily resident in Zimbabwe or with proof of exemption by the Minister;
5.1.2 An individual with proof of citizenship or residence in Zimbabwe or proof of exemption by the Minister.

5.2 Requirements for the issuance of a producers` licence

5.2.1 Application forms and accompanying documents are submitted to the Zimbabwe Investment and Development Agency, Zimbabwe Investment and Development Agency – One Stop Investment Services Centre, (ZIDA OSISC) as more fully illustrated in the chart below.


Interested applicants directed to Zimbabwe Investment and Development Agency (ZIDA) -One stop investment services center (OSISC)
Application to produce Cannabis is submitted in accordance with the ZIDA Checklist for requirements for Medicinal Cannabis Production (Accessible on the website)
Incomplete application
Returned to applicant (to resubmit within 48hrs)
Complete application
Vetting process/due diligence for security clearance (7 working days)
Unsatisfactory
Application rejected and ZIDA informs MCAZ of the outcome
Satisfactory
ZIDA sends the application plus the recommendation letter to Medicines Control Authority of Zimbabwe (MCAZ) for issuance of a production licence (48 hours)
Licence generation after confirmation of adequate documents by MCAZ and submission to the Minister of Health and Child Care(24hours)
Minister signs the Cannabis production licence and sends back to MCAZ for forward transmission to ZIDA (5 days)
Applicant collects the production licence for site from ZIDA and is advised to comply with the conditions for issue and renewal imposed by the Minister in Section 8 of the Cannabis licence. The licence holder shall also be advised to contact MCAZ for inspection of their cultivation site.
The licensed producer is required to start construction of their licensed premises in line with the minimum requirements of Good Agricultural Practices, S.I. 62 of 2018, MCAZ Production of Cannabis Guidelines and MCAZ Good manufacturing Practice Guidelines.

5.2 Commencement of Cultivation activities



5.3 Amendments of Licences

5.3.1 Should the applicant, for justifiable cause, wish to amend their licence, the request shall be submitted to the Minister in writing. These should be submitted to the ZIDA OSISC.

5.3.2 The request for amendment should be submitted together with the following:

5.3.1.1 A description of the proposed amendment, including the following documents:

i. application form DDPC1
ii. copy of the original licence
iii. for change in company directors an updated CR6 Form

iv. for change in the authorized and responsible person and
v. directors: - certified copies of I.D., fingerprints taken by the
vi. ZRP or police clearance form the country of origin.

vii. the appropriate fee plus VAT

5.3.1.2 If applicable, a declaration signed and dated by the authorised person in charge stating that the notices to local authorities have been provided and specifying the names, titles and addresses of the senior officials to whom they were addressed and the dates on which they were provided, together with a copy of each notice.

Note: An expired licence shall not be amended. If the applicant is unable to submit the original copy, they will be required to reapply for the issuance of another licence.

5.4 Validity of Licence

5.4.1 Upon successful application, a licence shall be issued in terms of section 6 of the Regulations**.**

5.4.2 The licence shall be valid for a period of five (5) years from the date of issue and may be renewed thereafter before its expiry

5.4.3 A licence is valid if it has a stamp and signature of the Minister for Health and Child Care

5.5 Requirements for Security

A SITE

5.5.1 **Security measures**

5.5.1.1 The licensed producer shall ensure that the following security measures are in place for the perimeter of the site and for the areas where cannabis is handled:

5.5.2 **Perimeter of Site**

5.5.2.1 The licensed producer`s site shall be designed in a manner that prevents unauthorized access to the site.

5.5.2.2 The perimeter of the site shall be visually monitored at all times by visual recording devices to detect any attempted or actual unauthorized access

5.5.2.3 The perimeter shall be secured by means of an intrusion detection system that operates at all times and allows detection of any attempted or actual unauthorized access to or movement in the site or tempering with the system

5.5.2.4 The intrusion detection system shall be monitored at all times by personnel

5.5.3 Areas Where Cannabis Is Handled

5.5.3.1 There should be restricted access to these areas. This shall be done through the following ways:

i. Access to areas within the site where cannabis is present shall be restricted to persons whose presence in those areas is required by their work duties
ii. The responsible person in charge or alternate responsible person in charge shall be physically present while other personnel are in those areas
iii. A record shall be made of the identity of every person who would be entering, reasons thereof and exiting those areas

5.5.3.2 There should be physical barriers provided to prevent unauthorised access within a site where cannabis is present.

5.5.3.3 There should be visual monitoring devices at all times by visual recording devices to detect illicit conduct.

5.5.3.4 There should be an intrusion detection system that operates at all times and allows detection of any attempted or actual unauthorized access to or movement in the site or tempering with the system

5.5.3.5 The areas where cannabis is present should be equipped with a system that filters air to prevent the escape of odours and if present, pollen.

5.5.3.6 The intrusion detection system shall be monitored at all times by Personnel

B. PERSONS

5.5.4 Key persons are subject to security clearance. Security clearance should be provided for the following persons:

5.5.4.1 company directors
5.5.4.2 the authorised person in charge
5.5.4.3 the responsible person in charge;
5.5.4.4 if applicable, the alternate responsible person in charge;
5.5.4.5 if a producer`s licence is applied for by an individual.

5.6 Personnel

5.6.1 A licensed producer shall designate:

5.6.1.1 One authorised person in charge. This person shall have the overall responsibility for the management of the activities conducted by the licensed producer under their licence at their site.

5.6.1.2 One responsible person in charge to work at the licensed producer's site. This person shall be responsible for:

i. supervising the activities pertaining to cannabis production

conducted by the licensed producer under the licence at that site;

ii. ensuring that the activities at that site comply with the Act and its Regulations.

5.6.1.3 A licensed producer may designate one or more alternate responsible persons who can replace the responsible person in his or her absence.

5.6.2 Quality assurance personnel

The licensed producer shall employ quality assurance personnel with training, experience and technical knowledge relating to the activity conducted and the requirements for Quality assurance of the product. The personnel shall be responsible for:

5.6.2.1 Assuring the quality of the fresh or dried cannabis, cannabis oil or cannabis plants or seeds before they are made available for sale, and

5.6.2.2 Investigating every complaint received in respect of the quality of those substances and, if necessary, takes corrective and preventative measures.

5.6.2.3 Approval of methods and procedures for production, packaging, labelling and storage prior to their implementation,

5.6.2.4 Approval of very batch of the substances before it is made available for sell.

5.6.2.5 Audit the company processes to ensure adherence to regulations and standards.

5.6.2.6 Inspect processes and procedures to ensure measurements comply with predefined standards.

5.6.2.7 Review and maintain QA, manufacturing and audit documentation

5.6.2.8 Ensure compliance of company processes to cGMP regulations

5.6.2.9 Review third party lab test results, logbooks and batch records and ensure compliance with good documentation practices

5.6.2.10 Ensure full implementation of company standard operating procedures

5.6.2.11 Investigate test results that deviate from standards

5.6.2.13 Coordinate investigation of quality issues with customers and suppliers

5.6.2.14 Review, approve and communicate root cause and corrective action to stakeholders

5.6.3 Change of personnel

5.6.3.1 The licensed producer shall apply for and obtain approval from the Minister before making any changes involving the replacement or addition of:

i. the authorised person in charge
ii. the responsible person in charge or the alternative responsible person in charge
iii. if applicable, an officer or director of the company
iv. An individual authorised to place an order for cannabis on behalf of the licensed producer

5.6.3.2 Except in the case of change of the responsible person, the licensed producer shall notify the Minister, not later than five days after the person ceases to carry out their duties; and when a director of the company ceases to be a director.

5.6.3.3 The licensed producer shall notify the Minister not later than the next business day if the responsible person in charge ceases to carry out their duties and there is no person designated as an alternate responsible person in charge.

5.6.3.4 The licensed producer with the application for approval of change of personnel shall submit the following information and documents with respect to the new person:

i. A cover letter written and signed by the Authorised person detailing all the changes to be made
ii. in the case of the replacement of the senior person in charge or the responsible person in charge or the replacement or addition of an alternate responsible person in charge—
iii. they shall complete form DDPC1 and form DDPC2, and submit the relevant accompanying documents

5.7 General Conditions of Production

5.7.1 The following conditions should be adhered to during production:

5.7.1.1 All handling of product including ordering, receiving, sampling, storage, labelling, processing, packaging and dispatch should be done in line with written procedures or instructions and should be recorded. The procedures shall be in accordance with the Good Agricultural Practices, Good Manufacturing Practices and Good Laboratory Practices

5.7.1.2 Whenever there is a deviation from the instructions or procedures, authorization of the deviation should be approved in writing by a designated person, with the involvement of the QA personnel when appropriate.

5.7.1.3 Checks on yields and reconciliation of quantities of cannabis should be carried out as necessary to ensure that there are no discrepancies.

5.7.1.4 There should be appropriate labelling of materials during production. This should be done at all times to indicate the description of a

product or material being processed, its strength (where applicable) and the batch number.

5.7.1.5 During packaging operations particular attention should be given to minimise the risk of contamination, mix ups or substitutions.

5.7.1.6 Equipment and instruments for measuring, weighing, analysis and recording should be serviced and calibrated at pre-specified intervals and records should be maintained.

5.7.1.7 To ensure satisfactory functioning of instruments/equipment, these should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated on a label attached to the instrument

5.7.1.8 There should be a Sanitation Program established by the licensed producer.

5.7.1.9 Personal hygiene procedures, including the wearing of protective clothing, should apply to all persons entering production areas.

5.7.1.10 The licensed producer should ensure training of all personnel is conducted in accordance with a written program.

5.7.1.11 There should be electrical supply, lighting, temperature, humidity and ventilation to ensure that the product is not adversely affect, directly or indirectly, during production, storage and transportation.

5.7.1.12 The site should be carefully maintained, and it should be ensured that repair and maintenance operations do not present any hazard to the quality of products.

5.7.1.13 QC laboratories should be designed to suit the processes to be carried out in them. There should be sufficient space to avoid mix ups and contamination. Adequate storage space should be provided for samples, reference standards (if necessary, with cooling), solvents, reagents and records.

5.7.1.14 A recall and adverse reporting system should be available for reporting recalls and adverse drug reactions to fresh or dried cannabis or cannabis oil. This system should be in line with the Regulations.

5.7.1.15 There should be an effective transportation system for fresh or dried cannabis, cannabis oil which ensures safekeeping of the package. The package containing cannabis to be transported, should be prepared in a manner that ensures that :

i. The package is secure, cannot be opened without seal being broken.
ii. The cannabis odour does not escape.
iii. The contents of the package cannot be identified without being opened.

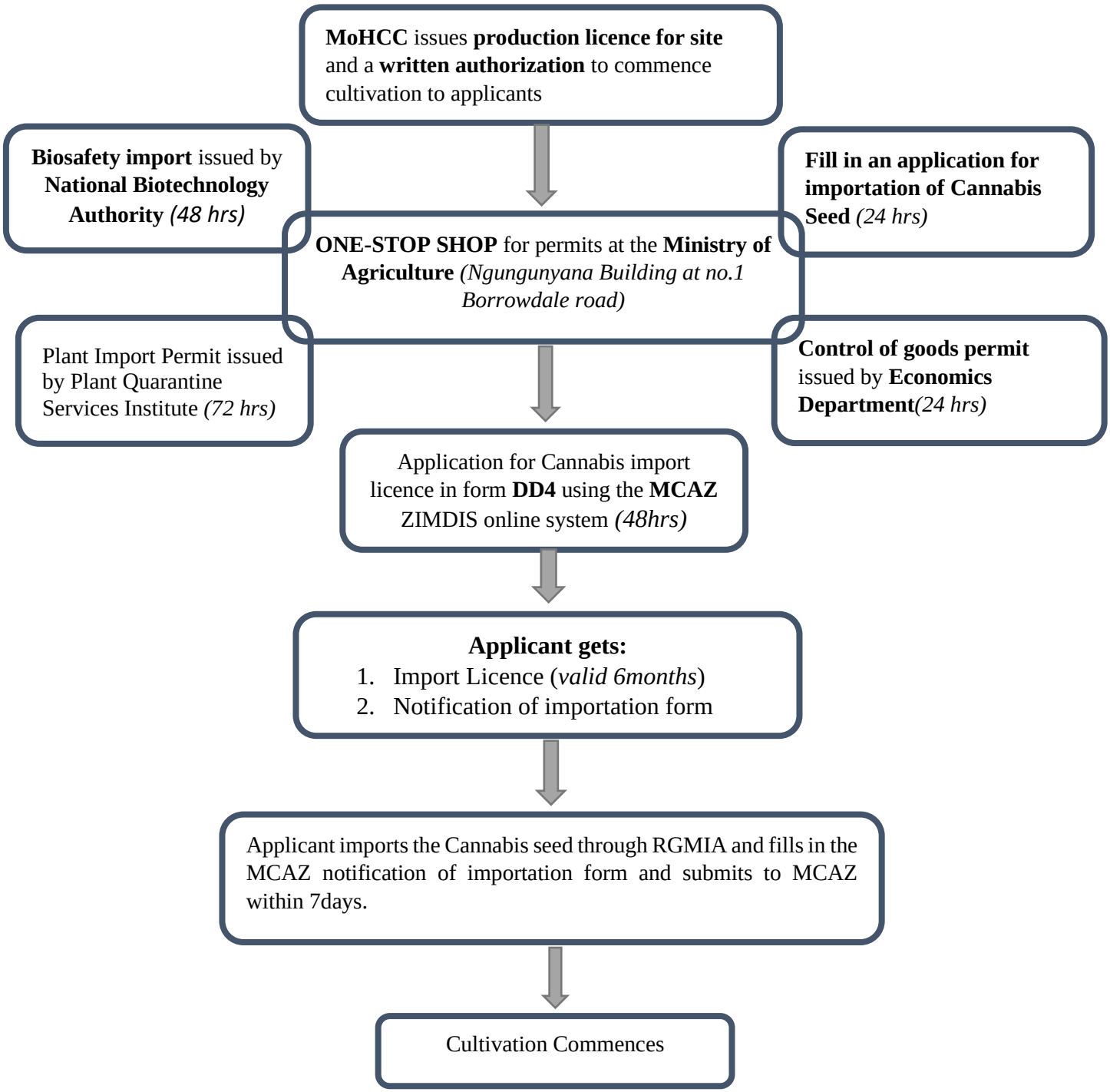
5.8 Import and Export

5.8.1 Requirements for the importation of Cannabis.

5.8.1.1 This section shall apply to the importation of Cannabis seeds only.

5.8.1.2 An applicant should get import Authorisation from Ministry of Agriculture, National Biotechnology Authority and the Secretary for Health and Child Care (Through MCAZ)

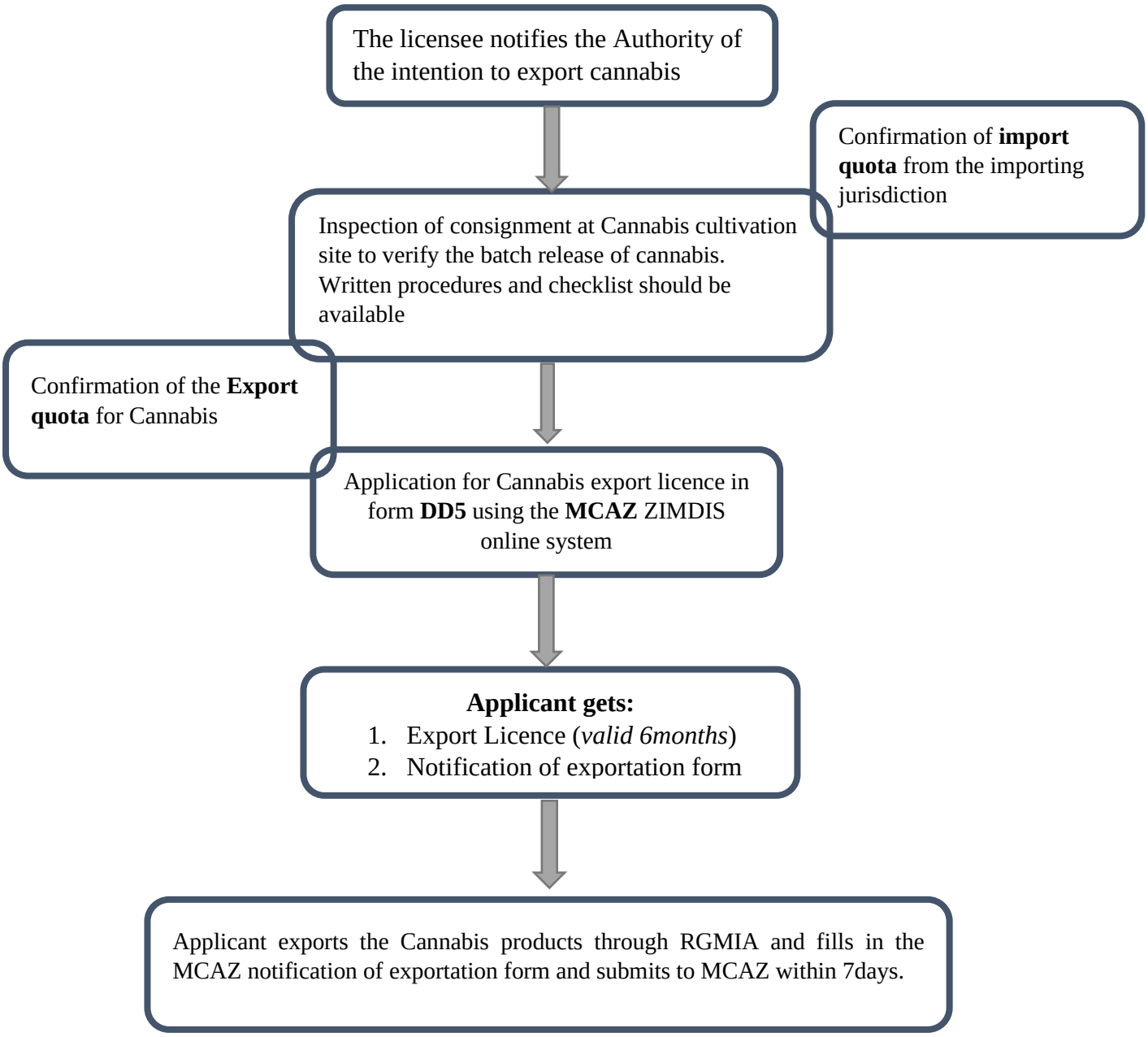
5.8.1.3 The process flow is outlined below:



5.9 Requirements for Exportation of Cannabis and its products.

5.9.1 This process shall apply to the export of dried Cannabis, Cannabis oils or any finished Cannabis products that may include Trichomes, distillates, Isolates.

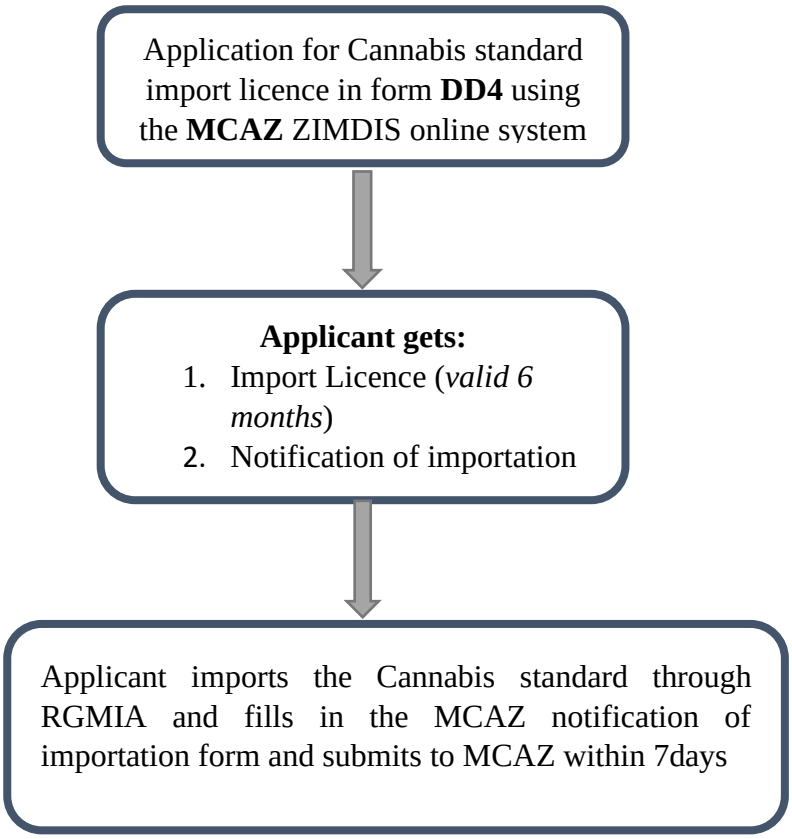
5.9.2 Export licence applications are done online using the MCAZ ZIMDIS system as outlined in the process flow below.



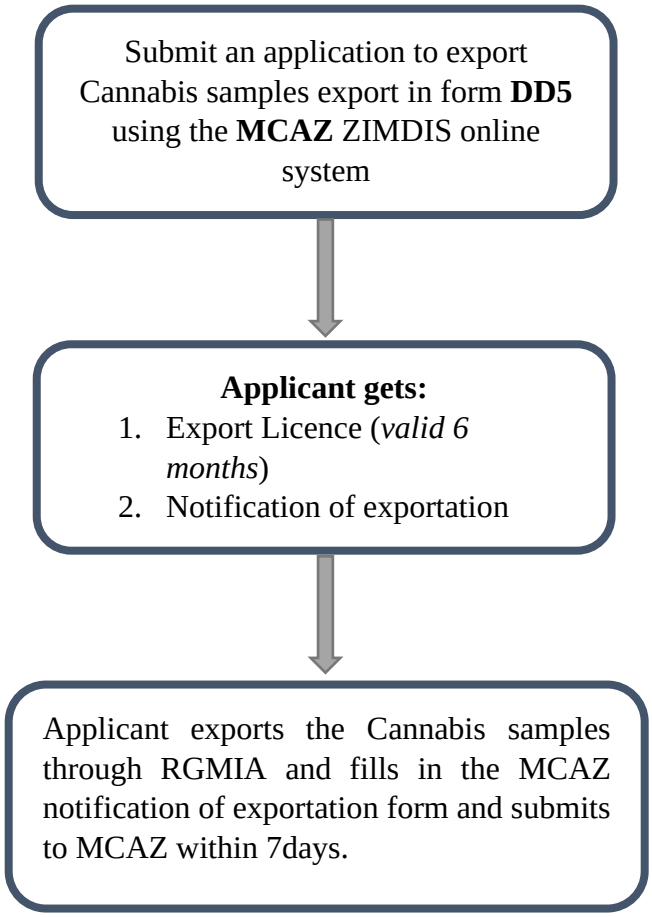
5.10 Requirements for importation of medicinal Cannabis standards

5.10.1 This section applies to medicinal Cannabis standards containing Tetrahydrocannabinol (THC).

5.10.2 For cannabis standards containing Cannabidiol (CBD) or any other form of Cannabinoids other than THC, the applicant shall only submit a letter showing their intent to import the cannabis standard and the Authority shall issue a letter of no objection to the importation.



5.10 Requirements for exportation of medicinal Cannabis samples for analysis



This section applies to medicinal Cannabis samples containing Tetrahydrocannabinol (THC). For cannabis samples containing Cannabidiol (CBD) or any other form of Cannabinoids other than THC, the applicant shall only submit a letter showing their intent to export the cannabis samples and the Authority shall issue a letter of no objection to the exportation.

5.11 Record Keeping

5.11.1 Type of records and documents

The following records and documents are required to be present on site:

5.11.1.1 Cultivation

i. Stock records for Cannabis seed, cannabis plants, dried cannabis, cannabis oils and cannabis products records
ii. Cultivation procedures and records tracking every seed/plant in the germination, propagation, vegetative, flowering, harvesting, drying, trimming, extraction, packaging stage of production.
iii. Destruction records which include records for pruned and finished product (dried flowers, dried leaves, and processed cannabis)
iv. Drying/curing procedures

5.11.1.2 Post harvest facilities

i. Pest control program for post-harvest facilities
ii. Cleaning and sanitation records for post-harvest facilities
iii. Schematic diagrams showing man, material flow, pressure zoning and area classifications
iv. Temperature and humidity control and monitoring records for storage areas

5.11.1.3 Extraction facilities and processes

i. Batch processing/reconciliation records
ii. Specific and detailed approach for control of microbial contamination of equipment, air, surfaces, and personnel, and for rest rooms, utilities, ancillary and supporting systems (for example, water and compressed air).

5.11.1.4 Qualification and validation

i. Qualification records for critical equipment, calibration records for measuring devices e.g weighing balances. All equipment should have the following qualification documents:
    1. User Requirement Specification
    2. Design Qualification
    3. Factory Acceptance Test and Site Acceptance Test
    4. Installation Qualification
    5. Operational Qualification
    6. Performance Qualification
ii. Equipment register and maintenance records
iii. Validation records for all processes e.g cultivation, drying/curing, extraction, packaging processes etc

iv. Cleaning validations

v. Records for water and water/fertigation system qualification, and periodic control and monitoring should be available onsite. Sampling points for water and frequency of sampling should be well defined in a procedure

5.11.1.5 Quality assurance and Quality management systems

i. Quality Manual and/or Quality policy
ii. Site master file
iii. Data integrity policy
iv. Deviation and incident management
v. Change control/ management
vi. Failure investigations and root cause analysis
vii. Corrective action and preventive action, CAPA.
viii. Quality risk management

5.11.1.6 Security systems

i. A security protocol detailing steps to be taken for various kinds of emergencies, the number and location of visual monitoring systems on site
ii. There was inadequate training of personnel monitoring and controlling CCTV.
iii. SOPs on how security footage shall be stored, retrieved and backed up.
iv. Access control procedure and records tracking the names and times of the different personnel handling cannabis
v. Qualification records for security system including evidence of challengetests done for the security system

5.11.1.7 Other records *(list not exhaustive)*

i. Standard test procedures for final product release to ensure product consistence with regards to quality and safety.
ii. Cleaning and sanitation records
iii. Import and export records
iv. Transportation records
v. Technical agreements with service providers e.g vendors, contract laboratories, security companies etc.

5.12 Inspections

All licensed cannabis cultivation sites are subject to inspections by the Cannabis inspectorate team to verify compliance with the Regulations. The Cannabis inspectorate team can inspect the operations of a cannabis cultivation site at any reasonable time to confirm that the legislative and regulatory requirements are being met.

5.12.1 Cannabis inspectorate team

The Cannabis inspectorate team is a cross functional team whose role shall be to inspect licensed cannabis cultivation sites and to ensure that all controlled substances (including cannabis), are handled effectively and legally throughout the supply chain. This shall encompass monitoring activities of all licensed cannabis cultivation sites to ensure compliance to the Dangerous Drugs (Production of Cannabis for medicinal and scientific use) 2018, Statutory Instrument 62 of 2018 Regulations "The Regulations", licensing requirements, Dangerous Drugs Act {Chapter 15:02}, Dangerous Drugs Regulations, Statutory Instrument 1111 of 1975, and MCAZ production of Cannabis guidelines.

5.12.2 Cannabis inspectorate team membership

The Cannabis inspectorate team shall consist of at least four (4) members with each of the following agencies represented:

5.12.2.1 Medicines Control Authority of Zimbabwe (MCAZ)

5.12.2.2 Zimbabwe Republic Police (ZRP) Criminal Investigation Department (CID) Drugs and

5.12.2.3 Narcotics, President's Department Counter Narcotics and Drug Trafficking, and

5.12.2.4 Ministry of Lands, Agriculture, Fisheries, Water, Climate and Rural Development (MLAFWCR).

5.12.3 Inspection Types

There are four types of inspections that will be conducted to assess and monitor compliance with the Regulations:

5.12.3.1 New premises inspections – these are conducted prior to recommending the licence holder to commence cultivation activities.

5.12.3.2 Routine inspections – these are done yearly to monitor progress and compliance to the minimum licensing requirements

5.12.3.3 Investigative inspections – conducted as follow up inspections to investigate regulatory complaints related to cannabis cultivation sites.

5.12.3.4 Supervisory/Unannounced inspections – these are random inspections of cannabis cultivation sites to check for compliance to the minimum licensing requirements.

5.13 General Conduct of inspections

5.13.1 Inspections shall be done in an open and cooperative manner, and ample time shall be required on site to fully assess compliance to the legislation and GAP/GMP.

5.13.2 The Cannabis inspectorate team shall execute its duties in a professional and competent manner as guided by the cannabis inspectorate team terms of reference.

5.13.3 An inspection report summarizing the inspection findings shall be written and dispatched within thirty days.

5.13.4 The licensee shall be advised to respond to the inspection report within 30days of receipt of the report. The response shall be in the form of a Corrective Action and Preventative Actions format, which addresses inspection findings wholistically by identification of the root cause, corrective actions applied and preventative actions planned to reduce incidence of the same observations

5.14 Analytical testing

5.14.1 The Authority established a Cannabis laboratory responsible for analysing Cannabis for regulatory purposes.

5.14.2 The Cannabis Laboratory provides analytical support to the compliance and enforcement activities of the Cannabis inspectorate.

5.14.3 The Cannabis Laboratory offers chemical analysis services for samples taken as part of inspections conducted to monitor or verify licence holder's compliance with the requirements.

5.14.4 The Cannabis Laboratory's chemical analysis services include and are not limited to:

5.14.4.1 Content in total THC, CBD and other cannabinoids
5.14.4.2 Heavy metals
5.14.4.3 Residual solvents
5.14.4.4 Pesticide screening
5.14.4.5 Foreign particulate matter
5.14.4.6 Mycotoxins
5.14.4.7 Terpenes
5.14.4.8 Microbiological contaminants

5.14.5 Compliance of test result is guided by the authorised monography used during analysis.

5.14.6 The results for analysis will only be valid for the batch collected and submitted to the lab and will not apply to any other sample other than the same batch number obtained from the sampling site.

5.15 Transportation of cannabis

5.15.1 The key principle of transport security is to develop arrangements that adapt according to the risk associated with the movement.

5.15.2 The licence holder shall use a transporting method that ensures the tracking and safekeeping of the package during transportation;

5.15.3 The following Factors to be considered when preparing transport security arrangements include (but are not limited to):

5.15.3.1 security requirements at the point of origin

5.15.3.2 security requirements at the destination point (including handover)

5.15.3.3 the duration of travel

5.15.3.4 security considerations specific to any areas traverse

5.15.3.5 size of consignment

5.15.3.4 means of transport

5.15.3.4 areas where consignments may be travelling outside of the licensee's control.

5.16 Submission of Annual Returns

5.16.1 Every licensed producer shall submit to the Minister, at every anniversary of the licence and upon payment of annual return fees specified in the First Schedule, records of all transactions which are required to be kept in terms of the Regulations in accordance with section 16 of the Regulations.

5.16.2 The following form shall be submitted

6.0 KEY RELEVANT DOCUMENTS

6.1 Application forms

6.2 Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*]

6.3 Medicines and Allied Substances Control Regulations, S.I 150 of 1991

6.4 Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [S.I 57 of 2008]

6.5 Cannabis inspectorate team, Terms of Reference

6.6 Dangerous Drugs Act, Chapter 15:02

6.7 Dangerous Drugs Regulations, RGN 1111 of 1975

6.8 Dangerous Drugs (Production of Cannabis for medicinal and scientific use) Regulations, S.I. 62 of 2018

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
N/A	N/A	New Document

APPENDICES

Appendix I: Submission of Annual Returns Form (LEF 101)

Medicines Control Authority of Zimbabwe

LEF 101

LICENSING AND ENFORCEMENT DIVISION

SUBMISSION OF ANNUAL RETURNS FOR CANNABIS FORM

Cultivation of the cannabis plant	Area Cultivated (hectares)		Quantity produced (kgs.)	Quantity sold/ exported (kgs.)	Quantity destroyed (kgs.)	Quantity on hand (kgs.)	Explanatory Notes
	Sown	Harvested					
1. Production for medicinal purposes							
2. Production for scientific purposes							

Company Name: …… **Physical Address**:……

Licence Number:……

Responsible Person: Name:……..**Signature**……..