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ICS 11.120

Draft Jamaican Code of Practice

for

Processing and handling of medical cannabis products

BUREAU OF STANDARDS JAMAICA

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Certification of Agricultural Produce (CAP) Mark

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Jamaican Standards establish requirements in relation to commodities, processes and practices, but do not purport to include all the necessary provisions of a contract.

The attention of those using this standard specification is called to the necessity of complying with any relevant legislation.

Amendments

No.	Date of Issue	Remarks	Entered by and date

Contents

Foreword

This code of practice was developed as a guide for manufacturers and processors of medical cannabis products. This code outlines recommended best practices for the processing and handling of medical cannabis and its derived products. This code of practice is geared at protecting the health and safety of consumers of medical cannabis products.

This standard is voluntary

Committee Representation

The preparation of this standard for the Standards Council, established under the Standards Act 1969, was carried out under the supervision of the Cannabis Technical Committee, which at the comprised the following members

Acknowledgement

Acknowledgement is extended to the following organizations for permission to reproduce contents form their publications:

ASTM International
Foundation of Cannabis Unified Standards (FOCUS)
World Health Organization (WHO)
European Commission
Ministry of Industry, Commerce, Agriculture and Fisheries (MICAF)

Related Documents

Ministry of Industry, Commerce, Agriculture and Fisheries (MICAF) - A Guide to Good Manufacturing Practices (GMPs) In Packaging Establishments

JS 36 Jamaican Standard Specification for Processed foods (General)

JS 1 Part 20 Jamaican Standard Specification for Labelling of Commodities Part 20: Labelling of Pre-packaged Goods

International Conference on Harmonisation - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients - Q7

FOCUS Extraction and Infused Products Standard

WHO good manufacturing practices for pharmaceutical products

WHO guidelines on good herbal processing practices for herbal medicines

WHO Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines

EudraLex – Volume 4 Good Manufacturing Practice (GMP) Guidelines

Jamaican Code of Practice for Processing and handling of medical cannabis products

1.0 Scope

This code of practice outlines recommended best practices for the processing and handling of medical cannabis and its derived products. These best practices will ensure the safety of those working in the facility, safety and quality of the products being made and prevention of any contamination and cross contact.

2.0 Definitions

For the purposes of this standard the following definitions apply:

2.1 active pharmaceutical ingredient (API). Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

2.2 adjuvant. substance which enhances the body's immune response to an antigen.

2.3 airlock. An enclosed space with two or more doors, which is interposed between two or more rooms, e.g. of differing classes of cleanliness, for the purpose of controlling the airflow between those rooms when they need to be entered. An airlock is designed for use either by people or for goods and/or equipment.

2.4 authorized person. The person recognized by the national regulatory authority as having the responsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country.

2.5 batch (or lot). A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.

2.6 batch number (or lot number). A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.

2.7 batch records. All documents associated with the manufacture of a batch of bulk product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

2.8 bulk product. Any product that has completed all processing stages up to, but not including, final packaging.

2.9 calibration. The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

2.10 chemical reference substance (or standard). An authenticated, uniform material that is intended for use in specified chemical and physical tests, in which its properties are compared with those of the product under examination, and which possesses a degree of purity adequate for its intended use.

2.11 clean area. An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation, and retention of contaminants within the area.

2.12 consignment (or delivery). The quantity of a pharmaceutical or pharmaceuticals, made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

2.13 constituent. Chemically defined substances or group/group(s) of substances found in a herbal material or herbal preparation.

2.14 contamination. The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

2.15 cannabis derivatives. Extracts including resin from the cannabis sativa plant, usually in the form of oil but not limited to.

2.16 critical operation. An operation in the manufacturing process that may cause variation in the quality of the pharmaceutical product.

2.17 cross-contamination. Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

2.18 finished product. A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.

2.19 in-process control. Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

2.20 intermediate product. Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.

2.21 large-volume parenterals. Sterile solutions intended for parenteral application with a volume of 100 ml or more in one container of the finished dosage form.

2.22 manufacture. All operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical products, and the related controls.

2.23 manufacturer. A company that carries out operations such as production, packaging, repackaging, labelling and relabeling of pharmaceuticals.

2.24 marketing authorization (product license, registration certificate). A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

2.25 master formula. A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

2.26 master record. A document or set of documents that serve as a basis for the batch documentation (blank batch record).

2.27 medical cannabis organization. person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

2.28 packaging. All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.

2.29 secondary package. packaging in addition to the immediate container, if applicable, that is the outermost layer visible to the consumer at the point of sale.

2.30 packaging material. Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

2.31 pharmaceutical product. Any material or product intended for human or veterinary use presented in its finished dosage form, or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state.

2.32 production. All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.

2.33 qualification. Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.

2.34 quality unit(s). An organizational unit independent of production which fulfils both quality assurance (QA) and quality control (QC) responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.

2.35 quarantine. The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

2.36 reconciliation. A comparison between the theoretical quantity and the actual quantity.

2.37 recovery. The introduction of all or part of previous batches (or of redistilled solvents and similar products) of the required quality into another batch at a defined stage of manufacture. It includes the removal of impurities from waste to obtain a pure substance or the recovery of used materials for a separate use.

2.38 reprocessing. Subjecting all or part of a batch or lot of an in-process medicine, bulk process intermediate (final biological bulk intermediate) or bulk product of a single batch or lot to a previous step in the validated manufacturing process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary for biological medicines and, in such cases, are validated and pre-approved as part of the marketing authorization.

2.39 reworking. Subjecting an in-process or bulk process intermediate (final biological bulk intermediate) or final product of a single batch to an alternate manufacturing process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and is not pre-approved as part of the marketing authorization.

2.40 self-contained area. Premises which provide complete and total separation of all aspects of an operation, including personnel and equipment movement, with well established procedures, controls and monitoring. This includes physical barriers as well as separate air-handling systems, but does not necessarily imply two distinct and separate buildings.

2.41 specification. A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

2.42 standard operating procedure (SOP). An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

2.43 starting material. Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

2.44 validation. Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).

NOTE 1 The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private

3.0 Personnel

3.1 General

3.1.1 The employment of staff in a medical cannabis processing facility should be in accordance with all national labour regulations/laws.

3.1.2 There should be an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the manufacture of medical cannabis and its derivatives.

3.1.3 The manufacturer should have a documented organizational chart and all personnel should have their specific duties recorded and communicated in a written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies with a satisfactory level of qualifications. There should be no gaps or unexplained overlaps in the responsibilities of personnel concerned with the application of Good Manufacturing Practices (GMP).

3.1.4 All personnel should be aware of the principles of GMP and receive initial and refresher training, including hygiene requirements, relevant to their specific duties.

3.1.5 All personnel should be aware of their role and responsibility in the the establishment and maintenance of a quality system.

3.2 Personnel Qualifications and Training

3.2.1 Key personnel responsible for supervising the production and quality unit(s) for pharmaceutical products should possess the qualification and technical expertise required for the manufacture and quality assurance of medical cannabis and its derivatives.

3.2.2 Management should provide training in accordance with a written programme for all personnel whose duties require access to manufacturing areas and control laboratories (including the technical, maintenance and cleaning personnel).

3.2.3 Newly recruited personnel should receive basic GMP training as well as training appropriate to the duties assigned to them. All personnel should receive proper training in post-harvest handling and medical cannabis processing.

3.2.4 All personnel required to handle chemical solvents and adjuvants should receive adequate training and possess sufficient knowledge of the appropriate techniques to be employed for their safe handling and proper use.

3.2.5 Personnel working in areas where there is a risk of contamination (such as clean areas or areas where highly active, toxic, infectious or sensitive materials are handled) should be given specific training.

3.2.6 Training records should be maintained to include the content of the training provided and the names of the employees that received the training.

3.2.7 Provision should be made for the evaluation of all training provide to staff. Periodic assessment of the effectiveness of training and instruction programmes should be made as well as routine supervision and checks to ensure that procedures are being carried out effectively.

3.2.8 Refresher training should be regularly conducted in accordance with the documented procedure.

3.3 Personnel Hygiene

3.3.1 All personnel should maintain a high degree of cleanliness and practice proper personal hygiene such as grooming, sanitation and health habits while on duty. No jewellery should be worn in the production area.

3.3.2 All personnel should be trained in the practices of good personal hygiene.

3.3.3 Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality and/or safety of products should not be allowed to handle starting materials, packaging materials, in-process materials or finished products. Management should be notified immediately of any such occurrences.

3.3.4 All personnel, prior to and during employment, as appropriate, should undergo health examinations. Personnel conducting visual inspections should also undergo periodic eye examinations.

3.3.5 Personnel should wear clean protective clothing suitable for the manufacturing activity with which they are involved. Protective clothing should be changed when appropriate. Additional protective apparel, such as head, hair, face, hand, and arm coverings, should be worn when necessary, to prevent contamination of the product.

3.3.6 Personnel hygiene procedures, including the wearing of protective clothing, should apply to all persons entering manufacturing areas, including temporary or full-time employees and non-employees, contractors' employees, visitors, senior managers and inspectors.

3.3.7 Direct contact should be avoided between the operator's hands and starting materials, primary packaging materials, cannabis derivatives and finished products. All personnel involved in the production process should wear the appropriate protective glove.

3.3.8 Smoking, eating, drinking, chewing and the storage of food should be restricted to certain designated areas separate from the manufacturing areas.

3.3.9 Personnel should be instructed to wash their hands:

a) before entering the production areas;
b) after using the bathroom
c) after coughing, sneezing, using a handkerchief or disposable tissue, smoking, eating, or drinking;
d) during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks
e) before donning gloves and after removing gloves if applicable
f) after handling soiled equipment or utensils; and
after engaging in other activities that may contaminate the hands.

3.3.10 Hand wash signs should be posted and instructions complied with.

4.0 Building and Facility

4.1 General

4.1.1 The premises should be:

a) designed to ensure the logical flow of materials and personnel corresponding to the sequence of the operations;
b) situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of contamination of materials or products;
c) suitable maintained. Repair and maintenance operations should not present any hazard to the quality and safety of products; and
d) of proper design, layout and construction to:
    1) minimize the risk of errors; and
    2) permit effective cleaning, sanitation and maintenance in order to avoid cross contamination, build-up of dust or dirt, and any adverse effect on the quality and safety of the products;
    3) afford maximum protection against the entry of insects, birds or other animals. There should be a documented procedure for rodent and pest control; and
    4) specifically designed and laid out so as to avoid contamination or cross-contamination.

4.1.2 Where dust is generated (such as during sampling, weighing, mixing and processing operations, or packaging of powder), measures should be taken to avoid cross-contamination and facilitate cleaning.

4.1.3 Premises should be cleaned and, where applicable, disinfected according to detailed written procedures. Records should be maintained.

4.1.4 Electrical supply, lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the pharmaceutical products during their manufacture and storage, or the accurate functioning of equipment.

4.1.5 The manufacture of technical poisons, such as pesticides and herbicides, should not be allowed in premises used for the manufacture of medicinal cannabis products.

4.2 Storage Area

4.2.1 Storage areas should be:

a) kept clean, organized, tidy and free of pests. Special attention should be paid to cleanliness and maintenance;
b) designed to permit effective and orderly segregation of the various categories of materials stored, and to allow rotation of stock. Different cannabis materials should be stored in separate areas;
c) labelled and materials stored in such a way as to avoid any risk of cross-contamination.

NOTE 2 The design and construction of storage areas depends on the type of materials stored.

4.2.2 Any accidental spillage in storage areas should be cleaned up immediately using methods that minimize the risk of cross contamination of other materials and should be reported.

4.2.3 An area should designated for the quarantine of all incoming cannabis materials.

4.2.4 Cannabis raw material, even when stored in fibre drums, bags or boxes, should be stored off the floor and suitably spaced to permit cleaning and inspection.

4.2.5 To protect the stored material, and reduce the risk of pest attacks, the duration of storage of any cannabis material in unpacked form should be kept to a minimum.

4.2.6 Incoming fresh cannabis materials should be processed, unless specified otherwise, as soon as possible. If appropriate, they should be stored between 2 °C and 8 °C, whereas frozen materials should be stored below –18 °C.

4.2.7 Where materials are stored in bulk, to reduce the risk of mould formation or fermentation they should be stored in aerated rooms or containers using natural or mechanical aeration and ventilation. These areas should also be equipped in such a way as to protect against the entry of insects or animals, especially rodents. Effective measures should be taken to limit the spread of animals and microorganisms brought in with the plant material and to prevent cross-contamination.

4.2.8 The storage of plants, extracts, tinctures and other preparations may require special conditions of humidity and temperature or protection from light; appropriate steps should be taken to ensure that these conditions are provided, maintained, monitored and recorded.

4.3 Production Area

4.3.1 In order to minimize the risk of a serious medical hazard due to cross contamination, dedicated and self-contained facilities should be available for the production of particular pharmaceutical products, such as highly sensitizing materials.

4.3.2 The production of certain other highly active products, such as some antibiotics, hormones, cytotoxic substances and certain non-pharmaceutical products should not be conducted in the same facilities.

4.3.3 When heating or boiling of the materials is necessary, a suitable air exhaust mechanism should be employed to prevent accumulation of fumes and vapours.

4.3.4 To facilitate cleaning and to avoid cross-contamination, adequate precautions should be taken during the sampling, weighing, mixing and processing of medicinal plants.

EXAMPLE 1 Precautions can be taken by use of dust extraction and air-handling systems to achieve the desired differential pressure and net airflow

4.3.5 The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different pharmaceutical products or their components, to avoid cross-contamination, and to minimize the risk of omission or error in application of any of the manufacturing or control steps.

4.3.6 Where starting and primary packaging materials and intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) should be smooth and free from cracks and open joints, should not shed particulate matter, and should permit easy and effective cleaning and, if necessary, disinfection.

4.3.7 Pipework, light fittings, ventilation points and other services should be designed and sited to avoid the creation of recesses that are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the production areas.

4.3.8 Drains should be of adequate size and designed and equipped to prevent back-flow. Open channels should be avoided where possible, but if they are necessary they should be shouldow to facilitate cleaning and disinfection.

4.3.9 Production areas should be:

a) effectively ventilated, with air-control facilities (including filtration of air to a sufficient level to prevent contamination and cross-contamination, as well as control of temperature and, where necessary, humidity) appropriate to the products handled, to the operations undertaken and to the external environment;
b) regularly monitored during both production and non-production periods to ensure compliance with their design specifications; and
c) well lit, particularly where visual online controls are carried out.

5.0 Security and Transport

5.1 General

5.1.1 A comprehensive security programme should be developed, documented, implemented and maintained to protect the business assets, facilities, products, workers, visitors and the community from risks and threats.

5.1.2 The organization should apply methods such as natural access controls, target hardening, image management, security-based maintenance and formal surveillance, and activity support methods such as resident/neighbour engagement and local law enforcement collaboration, to increase security effectiveness when practical.

5.1.3 The organization should establish qualifications and procedures for onsite security personnel ensure that all security personnel are trained in and follow company and security policies and procedures.

5.1.4 Security Company and personnel should be registered with the relevant local authority.

5.1.5 All electronic records should be stored on a system that is secure, password-protected and that limits data access to those who need it.

5.1.6 All hard copy files and records should be controlled by limiting access to file storage areas, locking filing systems when not in use and requiring sign-out logs when records are removed for review.

5.1.7 The organization should implement written procedures that define report writing protocols, forms, resources and templates to ensure all security breaches, attempted/actual crimes, unusual disappearance of cannabis, etc., are identified, reported, investigated, tracked, followed up and closed. The organization should ensure that corrective and preventative action is implemented to minimize the chances of a breach reoccurring.

5.2 Physical Security

5.2.1 The organization should apply physical methods to prevent unauthorized access to buildings, production areas and products, shipping/receiving, storage and parking areas.

> NOTE 3 Prevention methods include fencing, locked gates, secure doors, window protection, automatic access systems such as Radio Frequency Identification (RFID) access cards/biometric systems; and other physical barriers and reinforcements.

5.2.2 Security barriers should comply with local security, fire safety, local zoning regulations and Good Manufacturing Practices (GMP).

5.2.3 The security plan should ensure external areas are clear of obstructions, well illuminated and covered by surveillance systems.

5.2.4 Sturdy commercial-grade locks should be installed on all doors and gates.

5.2.5 External doors should have deadbolt locks and comply with local fire and building code regulations.

5.2.6 Key distribution activities should be controlled, monitored and documented.

5.2.7 Radio Frequency Identification (RFID) access cards should be controlled and monitored.

5.2.8 Biometric entry systems should be monitored, controlled and documented.

5.2.9 Procedures should ensure keys, locks, codes and biometrics are changed immediately as required by personnel access privilege changes or breaches.

5.2.10 The organization should have documented procedures to control:

a) access to the facilities which should detail access for workers, contractors, managers and visitors including customers, inspectors, law enforcement and regulators; and
b) access to restricted areas including areas containing controlled products, safety hazards, contamination risks or sensitive information.

5.2.11 All areas where cannabis or cannabis-derived products are processed or stored should be controlled and access restricted to authorized personnel.

5.2.12 Signs that read “Restricted Area – Authorized Personnel Only” or equivalent should be posted in all areas where cannabis raw material or medical cannabis products are processed and stored.

5.2.13 All visitors should be escorted by an authorized person at all times while in controlled areas of the facility.

5.2.14 An authorized worker should ensure all visitors sign in and out of the facility (name, organization, purpose of visit, date, time, and escort) in a visitor log.

5.2.15 Visitors should wear a visible identification badge while on the premises.

5.3 Intrusion Detection System

5.3.1 The organization should implement an Intrusion Detection System (IDS) to safeguard various areas considered critical to its operations.

NOTE 4 Intrusion detection devices include but not limited to, door or window contact alarms that are activated when the device is separated, such as opening; and motion detection technology that uses a passive infrared to survey the area and sounds an audible notification alarm when a person or object moves into the protected space.

NOTE 5 If any of the devices are triggered when the system is armed, an alert is sent to a 24 h on or off-site monitoring station designed to manage and monitor all intrusion detection information, along with receiving and sending notifications of all alarm activations. A notification system for alarm activations, including audible alarms, telephone, cell phone, text message, and e-mail, can notify monitoring personnel, law enforcement, public safety, or emergency services agencies.

5.3.2 The IDS should be capable of monitoring individuals and activities and coverage of all enclosed areas, unless prohibited by law, including all points of entrances to and exits from the facility.

5.3.3 The IDS should have the following capabilities among others:

a) motion detection;
b) door and window contact alarms;
c) glass-break sensors;
d) perimeter alarms and
e) connectivity to a 24 h per day, seven days per week, monitoring station either on or off-site which will be notified if any of the IDS sensors are triggered, when the alarm is armed, or both.

5.3.4 IDS devices should be positioned in and around the property including, but not limited to, loading docks, transaction areas, storage rooms; vaults; offices; areas in which product is grown, processed, manufactured, stored, handled, inventoried, sold, delivered, transported, or destroyed; rooms with exterior windows, roof hatches or skylights; rooms that contain equipment, product, currency, drop boxes, safes, vaults, data, and proprietary records

5.3.5 A panic alarm code, button, or device for use in a life-threatening or emergency situation that should be available and activated in any emergency when security, police, or fire response is needed and personnel cannot use any other form of communication to request assistance.

5.3.6 The monitoring station should have connectivity with all IDS alarm devices, including both a panic alarm, which should immediately sound an audible alarm notification in the facility, and a duress or holdup alarm, which should generate a silent alarm and notify law enforcement.

5.3.7 The IDS should be monitored at all times by personnel who determine the appropriate steps to be taken in response to an attempted or actual unauthorized access or tampering with the system.

5.3.8 The IDS should be maintained in good working order at all times.

5.3.9 The organization should conduct and document monthly maintenance inspections to ensure that any repairs, alterations, or upgrades are made for proper operation of the system.

5.3.10 All maintenance records should be maintained for a period of time in compliance with applicable regulatory standards.

5.4 Video Surveillance

5.4.1 The organization should implement a video surveillance system should have all, or some of the following basic capabilities, among others:

a) indoor;
b) outdoor;
c) daytime;
d) night-time;
e) fixed; and
f) pan, tilt, and zoom (PTZ); and

NOTE 6 A camera can be fixed to only look at one specific view or it can be movable through the use of PTZ (that is, moving left and right, up and down, and closer and far away). PTZ cameras are used to cover wider fields of views.

g) connectivity to an on or off-site monitoring station is designed to manage video surveillance information, along with receiving and sending alarm notifications.

5.4.2 Video surveillance coverage should be capable of:

5.4.2.1 monitoring all individuals, activities, and coverage of all areas, unless prohibited by law, including all points of entrances and exits from the facility from both indoor and outdoor vantage points; and

5.4.2.2 capturing clear visual identification of individuals and activities.

5.4.3 Video surveillance cameras should:

a) be positioned in the building and around the property including, but not limited to, exterior perimeter; parking lots; entrances and exits; loading dock; storage rooms; vaults; offices; areas in which product is grown, processed, manufactured, stored, handled, inventoried, sold, delivered, transported, or destroyed; rooms with exterior windows, roof hatches or skylights; and rooms that contain equipment, product, currency, drop boxes, safes, vaults, data, and proprietary records;
b) be programmed and focused to maximize the quality of the recorded image; and
c) operate under all lighting conditions of each area under surveillance with the capability to produce immediately a clear, colour or black and white, still photograph in a digital form.

5.4.4 All video data should be digitally recorded, with date and time displayed, and kept for a minimum of 60 days and if necessary, an additional number of days off site (for example, cloud storage) as required by local regulatory compliance.

5.4.5 Footage should clearly and accurately display the date and time, synchronized, and not significantly obscure the picture.

5.4.6 The video surveillance system should be maintained in good working order at all times, per the manufacturer's specifications. Records and documentation of maintenance should be maintained.

5.5 Transport

5.5.1 The organization should have documented procedures for the transportation of cannabis raw materials and medical cannabis products.

> NOTE 7 Transportation destinations may include licensed cannabis facilities in and outside of the company's system, patient and caregiver locations, laboratories and research facilities and disposal locations

5.5.2 The organization should train all workers involved in the transportation process on transportation procedures and ensure they can conduct them as required prior to transporting product without supervision.

5.5.3 The organization should document date, time and delivery route of all shipments of cannabis raw material and medical cannabis products.

5.5.4 If applicable, transport agents should use an approved, sanitary container sealed with tamper-evident tape or equivalent control. Traceability information should be clearly marked on the outside of the container. Packages inside of sealed containers (if applicable) should be closed to protect contents and sealed if required by product specification

5.5.5 Transport vehicles should be:

5.5.5.1 licensed, insured and have passed a fitness test in keeping with local regulatory requirements; and

5.5.5.2 kept in a good working condition, properly maintained and records / logs kept.

5.5.6 The organization should segregate an area of the vehicle for secure, sanitary cannabis storage during transport. The product storage area in the vehicle should be kept clean. If required, the product should be stored upright and in a temperature controlled area.

5.5.7 Transport vehicles should not be marked with any signage, lettering or other visual information that indicates the vehicle and driver are transporting cannabis raw material or medical cannabis products.

5.5.8 All medical cannabis products should be concealed from the view of moving vehicles and pedestrians during transportation and concealed while parked. The organization should use vehicles with windowless transport compartments or conceal the product with tinted glass, barriers or opaque containers.

5.5.9 The organization should install active Global Positioning System (GPS) or security tracking on vehicles used for transportation of cannabis raw materials and medical cannabis products.

6 Process Equipment Maintenance

6.1 Equipment should be

a) located, designed, constructed, adapted and maintained to suit the operations to be carried out; and

b) installed in such a way as to minimize any risk of error or of contamination.

6.2 The layout and design of equipment should aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

6.3 Production equipment should not present any hazard to the products. The parts of the production equipment that come into contact with the product should not be reactive, additive, or absorptive to an extent that would affect the quality of the product.

6.4 Closed equipment should be used whenever appropriate. Where open equipment is used or equipment is opened, precautions should be taken to minimize contamination.

6.5 Non-wooden equipment should be used unless tradition demands wooden material. Where it is necessary to use traditional equipment (such as wooden implements, clay pots, pallets, hoppers, etc.), this should be dedicated, unless otherwise justified. When such equipment is used, it is advisable that it does not come into direct contact with chemicals or contaminated material. If the use of wooden equipment is unavoidable, special consideration should be given to its cleaning as wooden materials may retain odours, be easily discoloured and are easily contaminated.

6.6 Laboratory equipment and instruments should be suited to the testing procedures undertaken.

6.7 Balances and other measuring equipment of an appropriate range and precision should be available for production and control operations, and should be calibrated according to a fixed schedule.

6.8 Pressure vessels should be tested and or inspected yearly by an approved third-party engineer.

6.9 Fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow.

6.10 All service pipework and devices should be adequately marked and special attention paid to the provision of non-interchangeable connections or adaptors for dangerous gases and liquids.

6.11 Production equipment should be thoroughly cleaned according to a fixed schedule.

6.12 If wet-cleaning is done, the equipment should be dried immediately after cleaning to prevent the growth of microorganisms. Cleaning with compressed air and brushes should be done with care and avoided if possible, as these methods increase the risk of product contamination.

NOTE 8 Processing of cannabis materials may generate dust or material which is susceptible to pest-infestation or microbiological contamination and cross contamination. Effective cleaning of the equipment is therefore particularly important. Vacuum or wet-cleaning methods are preferred.

6.13 Washing, cleaning and drying equipment should be chosen and used so as not to be a source of contamination.

6.14 Defective equipment should be removed from production and quality control areas. If this is not possible, it should be clearly labelled as defective to prevent use.

6.15 Non-dedicated equipment should be cleaned according to validated cleaning procedures between being used for production of different pharmaceutical products to prevent cross-contamination.

6.16 Current drawings of critical equipment and support systems should be maintained.

7.0 Documentation and Records

7.1 The organization should have a written procedure for document and record control to include the development, approval, review, amendment, archive and destruction of such procedure. The organization should identify a responsible officer to manage the process.

7.2 Documents should be prepared, approved, reviewed, signed and dated and distributed by the appropriate responsible persons. No document should be changed without authorization and approval. They should comply with the relevant parts of the manufacturing and marketing authorizations.

7.3 Documents should be unambiguous with the title, nature and purpose clearly stated.

7.4 Reproduced documents should be clear and legible. The reproduction of working documents from master documents should not allow any error to be introduced through the reproduction process.

7.5 Documents should be regularly reviewed and kept up-to-date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version. Superseded documents should be retained for a specific period of time.

7.6 Where documents require the entry of data, these entries should be clear, legible and indelible. Sufficient space should be provided for such entries.

7.7 Records should be made or completed when any action is taken and in such a way that all significant activities concerning the manufacture of the products are traceable. Records should be retained for at least one year after the expiry date of the finished product.

7.8 Any alteration made to a document should be signed and dated; the alteration should be done in such a way as to permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.

7.9 Data (and records for storage) may be recorded by electronic data processing systems or by photographic or other reliable means. Master formulae and detailed SOPs relating to the system in use should be available and the accuracy of the records should be checked. If documentation is handled by electronic data-processing methods:

a) only authorized persons should be able to enter or modify data in the computer system;
b) there should be a record of changes and deletions;
c) access should be restricted by passwords or other means; and
d) the entry of critical data should be independently checked.

7.10 Batch records stored electronically should be protected by back-up transfer on magnetic tape, microfilm, electronic discs, paper printouts or other means. It is particularly important that, during the period of retention, the data are readily available.

7.2 Specifications and procedures

7.2.1 General

7.2.1.1 There should be appropriately authorized and dated specifications, including parameters for identity, content, purity and quality, for starting and packaging materials and for finished products and, where appropriate, for intermediate or bulk products. Specifications for water, solvents and reagents (e.g. acids and bases) used in production should be included.

7.2.1.2 Each specification should be approved, signed and dated, and maintained by quality control, the quality assurance unit or person with responsibility for document control.

7.2.1.3 Pharmacopoeias, reference standards, reference spectra and other reference materials should be available in the quality control laboratory.

7.2.1.4 Testing procedures should be validated in the context of available facilities and equipment before they are adopted for routine use.

7.2.1.5 Periodic reviews of the specifications and test methods should be conducted to comply with new editions of the national pharmacopoeia or other official compendia.

7.3 Specifications for starting and packaging materials

7.3.1 Specifications for starting, primary and printed packaging materials should provide, if applicable, a description of the materials, including:

a) the designated name (if applicable, the International Nonproprietary Name (INN) and internal code reference;
b) the reference, if any, to a pharmacopoeia monograph; and
c) qualitative and quantitative requirements with acceptance limits.

d) Packaging, depending on the company's practice, other data may be added to the specification, such as:
e) the supplier and the original producer of the materials;
f) a specimen of printed materials;
g) directions for sampling and testing, or a reference to procedures;
h) storage conditions and precautions;
i) the maximum period of storage before re-examination.

7.3.2 Packaging material should conform to specifications, and should be compatible with the material and/or with medical cannabis product it contains. The material should be examined for compliance with the specification, for defects and for the correctness of identity markings.

7.3.3 Documents describing testing procedures should state the required frequency for re-assaying each starting material, as determined by its stability.

7.4 Specifications for intermediate and bulk products

7.4.1 Specifications for intermediate and bulk products should be available.

7.4.2 The specifications should be similar to specifications for starting materials or for finished products, as appropriate.

7.5 Specifications for finished products

7.5.1 Specifications for finished products should include:

a) the designated name of the product and the code reference, where applicable;
b) the designated name(s) of the active ingredient(s) (if applicable, with the INN(s);
c) the formula or a reference to the formula;
d) a description of the dosage form and package details;
e) directions for sampling and testing or a reference to procedures;
f) the qualitative and quantitative requirements, with acceptance limits;
g) the storage conditions and precautions, where applicable; and
h) the shelf-life.

7.6 Master formulae

7.6.1 A formally authorized master formula should exist for each product and batch size to be manufactured.

7.6.2 The master formula should include:

a) the name of the product, with a product reference code relating to its specification;
b) a description of the dosage form, strength of the product and batch size;
c) a list of all starting materials to be used (if applicable, with the INNs), with the amount of each, described using the designated name and a reference that is unique to that material (mention should be made of any substance that may disappear in the course of processing);
d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable;
e) a statement of the processing location and the principal equipment to be used;
f) the methods, or reference to the methods, to be used for preparing and operating the critical equipment, e.g. cleaning (especially after a change in product), assembling, calibrating, sterilizing, use;
g) detailed step-wise processing instructions (e.g. checks on materials, pre-treatments, sequence for adding materials, mixing times, temperatures);
h) the instructions for any in-process controls with their limits;
i) where necessary, the requirements for storage of the products, including the container, the labelling, and any special storage conditions; and
j) any special precautions to be observed.

7.7 Standard operating procedures (SOPs) and records

7.7.1 Standard operating procedures and associated records of actions taken or, where appropriate, conclusions reached should be available for:

a) equipment assembly and validation;
b) analytical apparatus and calibration;
c) maintenance;
d) cleaning and sanitation
e) personnel matters including qualification, training, clothing and hygiene;
f) environmental monitoring;
g) pest control;
h) complaints;
i) receipt of each delivery of starting material and primary and printed packaging material;
j) sampling;
k) batch (lot) numbering system;
l) internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate;
m) release and rejection for materials and products, and in particular for the release for sale of the finished product by an authorized person;
n) testing materials and products at different stages of manufacture, describing the methods and equipment to be;
o) recalls; and
p) returns.

7.7.2 Standard operating procedures should be available for each instrument and piece of equipment (e.g. use, calibration, cleaning, maintenance) and placed in close proximity to the equipment.

7.7.3 Written procedures for cleaning and sanitation should assigning responsibility and describing in sufficient detail the cleaning schedules, methods, equipment and materials to be used and facilities and equipment to be cleaned.

7.7.4 Standard operating procedures for sampling should specify the person(s) authorized to take samples and should include:

a) the method of sampling and the sampling plan;
b) the equipment to be used;
c) any precautions to be observed to avoid contamination of the material or any deterioration in its quality;
d) the amount(s) of sample(s) to be taken;
e) instructions for any required subdivision of the sample;
f) the type of sample container(s) to be used, and whether they are for aseptic sampling or for normal sampling, and labelling;
g) any specific precautions to be observed, especially in regard to the sampling of sterile or noxious material.

7.7.5 The standard operating procedure describing the details of the batch (lot) numbering system should ensure that each batch of intermediate, bulk or finished product is identified with a specific batch number; and ensure that the same batch numbers will not be used repeatedly; this applies also to reprocessing. The standard operating procedures for batch numbering that are applied to the processing stage and to the respective packaging stage should be related to each other.

7.7.6 Records should be maintained of the distribution of each batch of a product in order, e.g. to facilitate the recall of the batch if necessary.

7.7.7 Records should be kept for major and critical equipment, as appropriate, of any validations, calibrations, maintenance, cleaning, or repair operations, including dates and the identity of the people who carried these operations out.

7.7.8 The use of major and critical equipment and the areas where products have been processed should be appropriately recorded in chronological order

7.8 Batch processing records

7.8.1 A batch processing record should be kept for each batch produced. It should be based on the relevant parts of the currently approved specifications on the record. The method of preparation of such records should be designed to avoid errors.

NOTE 9 Copying or validated computer programs are recommended. Transcribing from approved documents should be avoided

7.8.2 Before any processing begins, an inspection should be conducted to ensure that the equipment and work station are clear of previous products, documents, or materials not required for the planned process, and that the equipment is clean and suitable for use. This inspection should be recorded.

7.8.3 Batch number allocation should be done in accordance with batch (lot) numbering system as outlined in clause 7.9. Batch numbers should be immediately recorded, e.g. in a logbook. The record should include at least the date of allocation, product identity and size of batch.

7.8.4 During processing, the following information should be recorded at the time each action is taken, and after completion the record should be dated and signed by the person responsible for the processing operations:

a) the name of the product;
b) the number of the batch being manufactured;
c) dates and times of commencement, of significant intermediate stages, and of completion of production;
d) the name of the person responsible for each stage of production;
e) the initials of the operator(s) of different significant steps of production and, where appropriate, of the person(s) who checked each of these operations (such as weighing);
f) the batch number and/or analytical control number and the quantity of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added);
g) any relevant processing operation or event and the major equipment used;
h) the in-process controls performed, the initials of the person(s) carrying them out, and the results obtained;
i) the amount of product obtained at different and pertinent stages of manufacture (yield), together with comments or explanations for significant deviations from the expected yield; and
j) notes on special problems including details, with signed authorization for any deviation from the master formula.

7.9 Batch packaging records

7.9.1 A batch packaging record should be kept for each batch or part batch processed. It should be based on the relevant parts of the approved packaging instructions, and the method of preparing such records should be designed to avoid errors.

NOTE 10 Copying or validated computer programs are recommended. Transcribing from approved documents should be avoided.

7.9.2 Before any packaging operation begins, inspections should be conducted to ensure that the equipment and work station are clear of previous products, documents or materials not required for the planned packaging operations, and that equipment is clean and suitable for use. These inspections should be recorded.

7.9.3 The following information should be recorded at the time each action is taken, and the date and the person responsible should be clearly identified by signature or electronic password:

a) the name of the product, the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained, the quantity actually obtained and the reconciliation;
b) the date(s) and time(s) of the packaging operations;
c) the name of the responsible person carrying out the packaging operation;
d) the initials of the operators of the different significant steps;
e) the checks made for identity and conformity with the packaging instructions, including the results of in-process controls;
f) details of the packaging operations carried out, including references to equipment and the packaging lines used, and, when necessary, the instructions for keeping the product unpacked or a record of returning product that has not been packaged to the storage area;
g) whenever possible, samples of the printed packaging materials used, including specimens bearing the approval for the printing of and regular check (where appropriate) of the batch number, expiry date, and any additional overprinting;
h) notes on any special problems, including details of any deviation from the packaging instructions, with written authorization by an appropriate person;
i) the quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and the quantities of product obtained to permit an adequate reconciliation.

8.0 Incoming materials

8.1 General

8.1.1 All incoming materials should be quarantined immediately after receipt or processing, until they are released for use or distribution.

NOTE 11 The main objective is to produce finished products for patients' use from a combination of materials (starting and packaging). Materials include starting materials, packaging materials, gases, solvents, process aids, reagents and labelling materials.

8.1.2 No materials used for operations such as cleaning, lubrication of equipment and pest control, should come into direct contact with incoming materials. Where possible, such materials should be of a suitable grade (such as food grade) to minimize health risks.

8.1.3 All materials should be stored under the appropriate conditions established by the manufacturer to permit batch segregation and stock rotation by a first-in, first-out rule and in accordance with 4.2

8.1.4 Water used in the manufacture of medical cannabis products should be suitable for its intended use and in accordance with 18.2.

8.2 Starting materials

8.1.1 The purchase of starting materials should involve staffs who have a particular and thorough knowledge of the products and suppliers.

8.1.2 Starting materials should be purchased only from approved suppliers and, where possible, directly from the producer.

NOTE 12 It is also recommended that the specifications established by the manufacturer for the starting materials be discussed with the suppliers. It is of benefit that all critical aspects of the production and control of the starting material in question, including handling, labelling and packaging requirements as well as complaints and rejection procedures, are contractually agreed between the manufacturer and the supplier.

8.1.3 For each consignment, the containers should be checked, at least for integrity of package and seal and for correspondence between the order, the delivery note, and the supplier's labels.

8.1.4 All incoming materials should be checked to ensure that the consignment corresponds to the order. Containers should be cleaned where necessary and labelled, if required, with the prescribed information. Where additional labels are attached to containers, the original information should not be lost.

8.1.5 Damage to containers and any other problem that might adversely affect the quality of a material should be recorded and reported to the quality control department and investigated.

8.1.6 If one delivery of material is made up of different batches, each batch should be considered as separate for sampling, testing and release.

8.1.7 Starting materials in the storage area should be appropriately labelled. Labels should bear at least the following information:

a) the designated name of the product and the internal code reference where applicable;
b) the batch number given by the supplier and, on receipt, the control or batch number given by the manufacturer, if any, documented so as to ensure traceability;
c) the status of the contents (e.g. in quarantine, on test, released, rejected, returned, recalled);
d) where appropriate, an expiry date or a date beyond which retesting is necessary.

8.1.8 There should be appropriate procedures or measures to ensure the identity of the contents of each container of starting material. Bulk containers from which samples have been drawn should be identified.

8.1.9 Only starting materials released by the quality control department and within their shelf-life should be used.

8.1.10 Starting materials should be dispensed only by designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers.

8.1.11 Each dispensed material and its weight or volume should be independently checked and the check recorded.

8.1.12 Materials dispensed for each batch of the final product should be kept together and conspicuously labelled as such.

8.2 Packaging materials

8.2.1 The purchase, handling and control of primary and printed packaging materials should be as for starting materials.

8.2.2 Particular attention should be paid to printed packaging materials. They should be stored in secure conditions so as to exclude the possibility of unauthorized access. Roll-feed labels should be used wherever possible. Cut labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mix-ups. Packaging materials should be issued for use only by designated personnel following an approved and documented procedure.

8.2.3 Each delivery or batch of printed or primary packaging material should be given a specific reference number or identification mark.

8.2.4 Outdated or obsolete primary packaging material or printed packaging material should be destroyed and its disposal recorded.

8.2.5 All products and packaging materials to be used should be checked on delivery to the packaging department for quantity, identity and conformity with the packaging instructions.

8.3 Record keeping

8.3.1 The records of the receipts of material should include:

a) the name of the material on the delivery note and the containers;
b) the “in-house” name and/or code of material if different from (a);
c) the date of receipt;
d) the supplier’s name and, if possible, manufacturer’s name;
e) the manufacturer’s batch or reference number;
f) the total quantity, and number of containers received;
g) the batch number assigned after receipt;
h) any relevant comment (e.g. state of the containers

9 Intermediate and bulk products

9.1 Intermediate and bulk products should be kept under appropriate conditions.

9.2 Intermediate and bulk products purchased as such should be handled on receipt as though they were starting materials.

10 Finished products

10.1 Finished products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer.

10.2 The evaluation of finished products and the documentation necessary for release of a product for sale are described in clause 15.

11 Rejected, recovered, reprocessed and reworked materials

11.1 The organization should establish procedures to reject all products that do not meet product specifications.

11.2 Workers should have documented training in the selection/rejection process.

11.3 Rejected materials should be clearly marked as such and stored separately in restricted areas. They should either be returned to the suppliers or, where appropriate, reprocessed or destroyed in a timely manner. Actions taken should be approved by authorized personnel and recorded.

11.4 Rejected product should be labelled and quarantined in a secure location until released.

11.5 Rejected product can be either reworked or disposed. The rework or recovery of rejected products should only be permitted if the quality of the final product is not affected, if the specifications are met, and if it is done in accordance with a defined and authorized procedure after evaluation of the risks involved. A record should be kept of the rework or recovery. A reworked batch should be given a new batch number

11.6 Reworked product should be tracked, retested and should meet product specifications before release.

11.7 The introduction of all or part of earlier batches, conforming to the required quality, into a batch of the same product at a defined stage of manufacture should be authorized beforehand. This recovery should be carried out in accordance with a defined procedure after evaluation of the risks involved, including any possible effect on shelf-life. The recovery should be recorded.

11.8 The need for additional testing of any finished product that has been reprocessed reworked or into which a recovered product has been incorporated, should be considered by the quality control department.

11.9 Workers should render cannabis waste unusable and record the waste amount in harvest/inventory records. Waste should be disposed of in accordance with clause 18.4.

11.10 All rejected, quarantined product should be disposed within 30 days.

12 Returned goods

12.1 Products returned from the market should be destroyed unless it is certain that their quality is satisfactory; in such cases they may be considered for resale or relabelling, or alternative action

taken only after they have been critically assessed by the quality control function in accordance with a written procedure.

12.2 The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it should not be considered suitable for reissue or reuse. Any action taken should be appropriately recorded.

13 Production and Processing

13.1 Extraction Process

13.1.1 The organization should develop and maintain a process flow diagram for the production process.

13.1.2 All employees involved with the extraction process should receive training on the equipment and processes they are using as well as safety training on equipment, materials and risks such as explosion, fire, gas release, evacuation, etc. This training should be provided to new hires and refresher training provided to existing workers periodically.

13.1.3 Training records should be maintained.

13.2 Solvent-less Extraction

13.2.1 All extraction equipment should be made of food grade material and be able to be taken apart to be cleaned and or sanitized to prevent cross contamination.

13.2.2 Potable drinking water should be used in the production of water-based extraction, and preferably filtered, purified or treated by reverse osmosis.

13.2.3 Water analysis or other proof of potability should be documented.

13.2.4 Care should be taken to dry the resin before packaging.

13.3 Carbon dioxide (CO_2) Extraction

13.3.1 Carbon dioxide (CO_2) in liquid or air form used in the extraction process should be at minimum food grade quality.

13.3.2 The organization should install a CO_2 monitoring and audible alarm system in the extraction room and where CO_2 is stored. The CO_2 monitor should include real-time reports of CO_2 levels and should activate at pre-set triggers.

13.3.3 Extraction should be done in a closed loop extractor with capability to reclaim the CO_2. If not, the CO_2 should be vented to the outside.

13.3.4 The extraction system should be constructed of materials that meet international or equivalent standards.

13.3.5 All pressure relief valves and venting of CO_2 should be done to the outside and not inside of the building.

13.3.6 The extraction area should have adequate ventilation (air exchange 6 times per hour).

13.3.7 All necessary personal protective equipment (PPE) should be worn, including eye protection around high pressure vessels.

13.3.8 Warning signs should be posted in the extraction area to advise of CO_2 storage and possible hazard of suffocation or asphyxiation.

13.4 Ethanol Extraction

13.4.1 Ethanol should be food grade and at least 190-proof purity; isopropanol alcohol is not recommended.

13.4.2 Ethanol should be stored in a properly labelled and secure area.

13.4.3 Extraction should take place in a well vented area. The extraction are shall have a spill kit and fire extinguisher in close proximity. The fire extinguisher should be approved for Class B fires: Dry Chemical or Clean Agent.

13.4.4 Areas containing ethanol in production facilities should maintain no more than a 0.83 percent by volume ethanol vapour in the ambient air.

13.4.5 Flammable signage should be in place for no smoking, matches or open flame.

13.4.6 Ethanol should be reclaimed in a closed loop recovery system, rotary evaporator or falling film evaporator. The purity of reclaimed ethanol should be verified before re-use.

13.5 Light Hydrocarbon Extraction

13.5.1 Includes methane, propane, butane, pentane and hexane.

13.5.2 Equipment for solvent extraction should be installed in a room separate from other production areas.

13.5.3 The extraction area should have:

13.5.3.1 proper ventilation (air change 6 times per hour unless certified installer provides specifications) including at floor level;

13.5.3.2 a gas monitoring system as required by local regulations; and

13.5.3.3 a fire suppression system as required by local fire code.

13.5.4 The organization should:

a) establish maximum amount of flammable solvents or materials authorized for storage within the licensed premises;
b) install Division-1 Class-1 electrical equipment (or regulatory equivalent) in production area and solvent storage area in accordance with applicable regulations to control ignition and spark sources;
c) ensure use of ground straps/grounded workstations and non-static clothing;
d) ensure proper control of solvent gas release during open cycle of extractor with the use of an exhaust hood and hand-held leak detector;
e) establish procedures for safe handling of compressed gas cylinders; and

f) ensure all support equipment meets spark/ignition requirements and is UL certified or equivalent.

13.5.5 All equipment should be professional grade and the system should perform closed-loop extraction that is capable of recovering the solvent.

13.5.6 The extraction system should be constructed of materials that meet ASME, ASTM or equivalent standards.

13.5.7 Pumps used to assist with recovery of a flammable solvent should not produce any ignition source (e.g., pneumatic, compressed-air-driven piston pump).

13.5.8 For extraction units plumbed to permanent water supply, operation should ensure water temperature remains between 60°F and 100°F and is flushed weekly.

13.5.9 Self-contained units should be visually inspected weekly and flushing-fluid changed according to manufacturer instructions.

13.5.10 Solvent should be collected and stored in medical-grade containers when practical to maintain purity.

13.5.11 Solvent containers should be replaced or safely purged, cleaned and sanitized periodically.

13.5.12 Flammable warning signs should be posted for no smoking, matches or open flame.

13.5.13 If no additional refinement process is done the extract should be purged in a vacuum oven to achieve below the necessary residual solvent limit especially if the solvent used is toxic for human consumption.

13.5.14 The organization should ensure that all solvents used in the extraction process are the highest purity practical; at a minimum, food-grade solvent should be used.

13.5.15 A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process should be kept on file.

13.5.16 For all solvents used, the organization should retain a certificate of analysis (COA) from the original manufacturer with purity and impurity limits and results. COAs should be retained for two years.

14 Packaging and Labelling

14.1 Packaging

14.1.1 All medical cannabis products should package in tamper resistant containers.

EXAMPLE 2 tamper-evident bag or tamper-evident seal placed on the product itself

14.1.2 The package should keep the product clean and free from contamination.

14.1.3 Packaging should contain and securely hold a stated quantity of product without leaking, seeping or oozing. It should also protect the product from loss of quality by evaporation of volatile ingredients and against oxidation and other chemical reactions.

14.1.4 Containers in direct contact with medical cannabis products should be sterile, made of non-toxic material and should be child-resistant.

14.1.5 Secondary packaging that does not come in direct contact with the product should be made of material that can be recycled and not in excess in order to reduce the impact on the environment.

14.2 Labelling

14.2.1 The label should be printed on food safe durable material.

14.2.2 Each product label should contain the following:

a) Name of product;
b) Listing of ingredients (the ingredients should be declared in descending order of predominance);
c) Concentration of active ingredient(s), i.e. Cannabinoids;
d) Directions for use/application/dosage;
e) Precautionary statements necessary for particular product;
f) Conditions for storing (e.g. Store in a cool dry place)
g) Date of expiration or best by date;
h) Batch number;
i) Manufacturer name and address;
j) Country of origin;
k) Net weight declaration ; and

14.2.3 Products containing THC should include the universal “THC symbol” on the label.

14.2.4 The label should not bear any unsubstantiated health claims.

14.2.5 The label should include any other relevant information for the consumer in regards to the intended use and efficacy of the product.

14.2.6 The label statements should appear on the primary and secondary packaging. The information on the label should be legible and written in the English Language.

14.2.7 Design and placement of the label should be in conformance with relevant Jamaican Standards.

15 Quality Control

15.1 General

15.1.1 Each manufacturer of medical cannabis (the holder of a manufacturing authorization) should have a quality control function. The quality control function should be independent of other departments and under the authority of a person with appropriate qualifications and experience, who has one or several control laboratories at his or her disposal.

NOTE 13 Quality control is the part of GMP concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory

organizations but should be involved in all decisions concerning the quality of the product. The independence of quality control from production is considered fundamental.

15.1.2 Adequate resources should be available to ensure that all the quality control is effectively and reliably carried out. The basic requirements for quality control are as follows:

a) adequate facilities, trained personnel and approved procedures should be available for sampling, inspecting, and testing starting materials, packaging materials, and intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;
b) samples of starting materials, packaging materials, intermediate products, bulk products and finished products should be taken by methods and personnel approved of by the quality control department;
c) qualification and validation should be performed;
d) records should be maintained (manually and/or by recording instruments) demonstrating that all the required sampling, inspecting and testing WHO guidelines on good manufacturing practices (GMP) for herbal medicines procedures have actually been carried out and that any deviations have been fully recorded and investigated;
e) the finished products should contain ingredients complying with the qualitative and quantitative composition of the product described in the marketing authorization;
f) the ingredients should be of the required purity, in their proper container and correctly labelled;
a) records should be maintained of the results of inspecting and testing the materials and intermediate, bulk and finished products against specifications;
b) product assessment should include a review and evaluation of the relevant production documentation and an assessment of deviations from specified procedures;
c) no batch of product is to be released for sale or supply prior to certification by the authorized person(s) that it is in accordance with the requirements of the marketing authorization.
d) sufficient samples of starting materials and products should be retained to permit future examination of the product if necessary.

15.1.3 Quality control should:

a) establish, validate and implement all quality control procedures;
b) evaluate, maintain, and store the reference standards for substances
c) ensure the correct labelling of containers of materials and products;
d) ensure that the stability of the active pharmaceutical ingredients and products is monitored, to participate in the investigation of complaints related to the quality of the product; and
e) participate in environmental monitoring.

These functions should be carried out in accordance with written procedures and, where necessary, recorded.

15.1.4 Assessment of finished products should include all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished package.

15.1.5 Quality control personnel should have access to production areas for sampling and investigation as appropriate.

15.1.6 Quality Control Personnel is responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply.

15.2 Product Testing Plan

15.2.1 Controls for tests conducted during the process should be described. A description of the tests, their methods and the acceptance criteria should be given. These include appearance (i.e. colour), particle size (amount expected to pass through a specified sieve size), water or alcohol content, and/or relative density.

15.2.2 Chemical test: cannabinoid potency and terpene analysis

15.2.3 Contaminants: microbial, heavy metals, residual solvent, mycotoxins, pesticide residue

15.3 Sampling

15.3.1 All tests should follow the instructions given in the relevant written test procedure for each material or product. The result should be checked by the supervisor before the material or product is released or rejected.

15.3.2 Samples should be representative of the batches of material from which they are taken in accordance with the approved written procedure.

15.3.3 Sampling should be carried out so as to avoid contamination or other adverse effects on quality. The containers that have been sampled should be marked accordingly and carefully resealed after sampling.

15.3.4 Care should be taken during sampling to guard against contamination or mix-up of, or by, the material being sampled. All sampling equipment that comes into contact with the material should be clean. Some particularly hazardous or potent materials may require special precautions.

15.3.5 Sampling equipment should be cleaned and, if necessary, sterilized before and after each use and stored separately from other laboratory equipment.

15.3.6 Each sample container should bear a label indicating:

a) the name of the sampled material;
b) the batch or lot number;
c) the number of the container from which the sample has been taken;
d) the number of the sample;
e) the signature of the person who has taken the sample;
f) the date of sampling.

15.3.7 Out-of-specification results obtained during testing of materials or products should be investigated in accordance with an approved procedure. Records should be maintained.

15.4 Finished Products testing

15.4.1 For each batch of finished product, there should be an appropriate laboratory determination of satisfactory conformity to its finished product specification prior to release.

15.4.2 Products failing to meet the established specifications or any other relevant quality criteria should be rejected.

15.4.3 Identified criteria should be met for release of the final product. These criteria generally include appearance, organoleptic characteristics, relative density, herbal preparation or a specific dosage form, as indicated above, can be prepared as per established pharmacopoeia methods.

15.4.4 Finished products should be tested for chemical identity including specified quantities for chemical constituent(s), as well as limits for heavy metals, microbial contamination and residual matter:

a) Chemical profile, that is, TLC/HPLC fingerprint of chemical constituents;
b) Pharmacopoeia/standard quantitation of chemical markers, where applicable;
c) Heavy metals: limits defined;
d) Microbial: limits defined; and
e) Residuals: limits for pesticides, fertilizers, foreign matter, solvent residue, mycotoxins, etc.

15.5 Test Records

15.5.1 A certificate of analysis should be generated following completion of quality control testing. This document should include the test methods as well as the results obtained using those methods.

15.5.2 Finished product analysis records should include at least the following data:

a) the name of the material or product and, where applicable, dosage form;
b) the batch number and, where appropriate, the manufacturer and/or supplier;
c) references to the relevant specifications and testing procedures;
d) test results, including observations and calculations, and reference to any specifications (limits);
e) date(s) and reference number(s) of testing;
f) the initials of the persons who performed the testing;
g) the date and initials of the persons who verified the testing and the calculations, where appropriate;
h) a clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person.

15.6 Record review

15.6.1 Production batch records and quality control records should be reviewed as part of the approval process of batch release.

15.6.2 Any divergence or failure of a batch to meet its specifications should be thoroughly investigated. The investigation should, if necessary, extend to other batches of the same product and other products that may have been associated with the specific failure or discrepancy. A written record of the investigation should be documented and should include the conclusion and follow-up action.

15.7 Retention samples and stability studies

15.7.1 Retention samples from each batch of finished product should be kept for at least one year after the expiry date. Finished products should usually be kept in their final packaging and stored under the recommended conditions. If exceptionally large packages are produced, smaller samples might be stored in appropriate containers.

15.7.2 Samples of active starting materials should be retained for at least one year beyond the expiry date of the corresponding finished product. Other starting materials (other than solvents, gases, and water) should be retained for a minimum of two years if their stability allows.

15.7.3 Retention samples of materials and products should be of a size sufficient to permit at least two full re-examinations.

15.7.4 Quality control should:

a) evaluate the quality and stability of finished pharmaceutical products and, when necessary, of starting materials and intermediate products; and
b) establish expiry dates and shelf-life specifications on the basis of stability tests related to storage conditions.

15.7.5 A written programme for ongoing stability determination should be developed and implemented to include elements such as:

a) a complete description of the medical cannabis product involved in the study;
b) the complete set of testing parameters and methods, describing all tests for potency, purity, and physical characteristics and documented evidence that these tests indicate stability;
c) provision for the inclusion of a sufficient number of batches;
d) the testing schedule for each medical cannabis product ;
e) provision for special storage conditions;
f) provision for adequate sample retention;
g) a summary of all the data generated, including the evaluation and the conclusions of the study.

15.7.6 Stability should be determined prior to marketing and following any significant changes in processes, equipment, packaging materials, etc.

16 Validation

16.1 The organization should have a documented procedure outlining the methods, responsible person and frequency of validation. The procedure should specify critical process steps and factors (such as extraction time, temperature and solvent purity) and acceptance criteria, as well as the type of validation to be conducted (such as retrospective, prospective or concurrent) and the number of process runs.

NOTE 14 Qualification of critical equipment, process validation and change control are particularly important in the production of cannabis medicines with unknown therapeutically active constituents. In this case, the reproducibility of the production process is the main means for ensuring consistency of quality, efficacy and safety between batches.

16.2 A formal change control system should be established to evaluate the potential effects of any changes on the quality of the cannabis medicines, particularly content of the active ingredients.

Scientific judgement should be used to determine which additional testing and validation studies are appropriate to justify a change in a validated process.

17 Traceability, Complaints and Recall

17.1 Traceability

17.1.1 The organization should have a documented traceability system that is able to uniquely identify incoming material from the suppliers to the consumer distribution point.

17.1.2 The organization should be able to identify products by batch number in the production records.

17.1.3 The organization should document supplier inputs and materials used to produce each batch to the maximum extent feasible.

17.1.4 Traceability should be maintained for reworked products.

17.2 Complaints

17.2.1 The organization should have written procedures to describe the action to be taken to handle complaints.

NOTE 15 There are two types of complaint, product quality complaints and adverse reactions/events

17.2.2 The person responsible for handling complaints and deciding on the measures to be taken to deal with them should have appropriate training and/or experience in the specific features of the quality control of cannabis medicines.

17.2.3 Product quality complaints, such as faulty manufacture, product defects or deterioration as well as, particular to cannabis medicines, adulteration of the cannabis material, should be recorded in detail and the causes thoroughly investigated. There should also be

EXAMPLE 3 Investigation may be done by comparison with the reference samples kept from the same batch

17.2.4 Complaints/reports of any adverse reaction/event should be entered in a separate register in accordance with national and international requirements. An investigation should be conducted to find out whether the adverse reaction/event is due to a quality problem and whether such reactions/events have already been reported in the literature or whether it is a new observation.

17.2.5 Complaint records should be reviewed regularly to detect any specific or recurring problems requiring special attention and possible recall of marketed products.

NOTE 16 The WHO guidelines on safety monitoring of cannabis medicines in pharmacovigilance systems deal with specific issues relating to adverse reactions and adverse events following treatment with cannabis medicines (9).

17.2.6 The licensing authority should be kept informed of any complaints leading to a recall or restriction on supply. Records of complaints should be available for inspection.

17.3 Rejection

17.3.1 The operation shall establish procedures to reject all products that do not meet established product specifications.

17.3.2 Workers shall have documented training in the selection/rejection process.

17.3.3 Rejected product shall be labelled and quarantined in a secure location until released.

17.3.4 Rejected product can be either reworked or disposed.

17.3.5 Reworked product shall be tracked, retested and shall meet product specifications before release.

17.3.6 Workers shall render cannabis waste unusable and record the waste amount in harvest/inventory records.

17.3.7 All rejected, quarantined products should be disposed of within 30 days.

17.4 Product Recall

17.4.1 Recall is the procedure(s) conducted by responsible handlers to remove or correct a product that regulatory authorities consider, or may consider to be in violation of their food laws. The ability to remove products from the marketplace quickly and effectively is very important. It takes on added importance, since we have entered an era in which terrorists could use the food supply as a mechanism to disrupt commerce and cause public panic.

17.4.2 Prompting a recall

There are many situations that can result in a product recall. Some are emergency situations, others are not. Following is a list of potential causes of product recall.

- **Allergens** – A product or component containing an unlabelled ingredient that may cause an allergic reaction in humans.
- **Bacterial contamination** – Contamination by spoilage organisms or harmful bacteria (E. coli, Salmonella, Listeria, etc).
- **Chemical contamination** – The presence of unapproved pesticides and/or residues of these items in amounts greater than the established residue tolerance levels; naturally occurring chemical contaminants such as Aflatoxins.
- **Communicable diseases** – Human illnesses that can be transmitted through foods.
- **Processor-generated information** – Food safety problems discovered through food processor's internal records.
- review and examination processes.
- **Foreign materials** – Presence of materials such as glass, plastic or metal.
- Illnesses identified by food safety regulators.
- In-house sabotage.
- Misbranding – violations of labelling laws.
- Real or fraudulent customer or consumer claims.
- Tampering and tampering threats.
- Undeclared ingredients.

17.4.3 Recall classifications

A **Class I** recall means there is a reasonable probability that the use of the contaminated product will cause serious adverse health consequences or death.

Examples of **Class I** recalls are:

- Salmonella contamination
- Undeclared allergens.

A **Class II** recall means the use of a contaminated product may cause temporary or medically reversible adverse health consequences.

Examples of **Class II** recalls are:

- the presence of spoilage organisms
- the presence of unapproved additives or ingredients
- mislabelling, such as incorrect weight declaration or
- non-organic almonds being labelled as organic.
- food produced under unsanitary conditions.

A **Class III** recall is for products that violate national regulations, but are unlikely to cause adverse health consequences.

17.4.4 Recalls shall be reported to Ministry of Health in accordance with Food and Drugs Act 1975

17.4.5 Recalled products shall be identified and stored separately in a secure area until a decision is taken on their fate. The decision shall be made as soon as possible.

18 Sanitation, Waste Management and Pest Control

18.1 General

18.1.1 Because of their origin, cannabis materials may contain microbiological contaminants. Furthermore, during the course of harvesting and processing, cannabis products that may be especially prone to microbiological contamination are produced. To avoid alterations and to reduce contamination in general, a high level of sanitation and hygiene during manufacture is necessary (for guidelines on personal hygiene see section 3.3)

18.2 Water

18.2.1 Water used for processing or contact surfaces or used in the facility for employee services should be potable and meet local regulations for drinking water.

NOTE 17 Water can be a carrier of many harmful microorganisms, such as coliforms, Salmonella spp., Vibrio cholerae and Shigella spp. Even small amounts of contamination with some of these organisms can result in food-borne illness

18.2.2 All water should be tested at least once a year for microbes, pesticide residue and heavy metals.

18.2.3 The water supply should be monitored, and, if necessary, treated appropriately to ensure consistency of quality.

18.2.4 If self-chlorination of water is done, the concentration of residual chlorine should be monitored daily.

18.2.5 There should be no cross-connections between potable and non-potable water supplies. A plumbing diagram should be maintained to verify this.

18.2.6 All hoses, taps, and piping systems should be designed to prevent back-flow or siphonage of standing water and/or have backflow prevention devices installed. A map of any back-flow devices that are installed in the water lines should be available. Piping should not have any 'dead ends'.

18.2.7 For municipal sources, a certificate of analysis should be obtained and maintained as a record.

18.2.8 If water is from a non-municipal source, the operator should ensure that the water meet the potability requirements of the authority with jurisdiction. This should be done via a testing programme with an accredited third-party laboratory.

18.2.9 Equipment designed to harvest water and maintain quality (chlorine injectors, filtration systems, and back-flow prevention devices), should be routinely inspected to ensure efficient operation. A map detailing the location of the equipment should be available.

18.2.10 For pre-cleaning/sanitization of produce, water should be to be changed frequently in accordance with an established schedule.

18.2.11 The water supply (hot and cold) should be adequate for peak usage, and for clean-up requirements.

18.2.12 The sewage-disposal system should be in accordance with the national standards and approved by the relevant agencies.

18.3 Toilets

18.3.1 Each processing facility should provide employees with adequate, readily accessible toilet facilities. Signs should be posted showing where restrooms are located

18.3.2 Hand wash signs should be posted in restrooms instructing users to wash their hands after using the toilet.

18.3.3 Toilet facilities should

18.3.3.1 have self-closing doors. Doors should not open into operation areas, except where alternative means have been taken to protect against contamination, such as double doors or positive airflow systems;

18.3.3.2 be kept clean, neat and in good repair. Basins, toilets, urinals, walls, and floors should be frequently cleaned and sanitized (at least once daily).

18.3.3.3 a bathroom cleaning schedule should be maintained and visibly displayed;

18.3.3.4 be adequately supplied with toilet paper, soap, hand sanitizer and paper towels or air-dryers for drying hands. Multiple-use towels should not be used;

18.3.3.5 be checked daily and restocked as necessary to ensure adequate supplies; and

18.3.3.6 have adequate waste disposal. Disposal bins should be covered and 'hands-free' operated.

18.4 Waste Management

18.4.1 General waste disposal

18.4.1.1 Waste should be disposed of regularly so as to maintain a high standard of hygiene in accordance with requirements of the local authority.

18.4.2 Waste material should not be allowed to accumulate in the production area. It should be collected in suitable receptacles for removal to collection points outside the building and disposed of safely and in a sanitary manner at regular and frequent intervals.

18.4.3 Waste containers in the facility should be available, emptied and cleaned as needed, but at least daily.

18.4.4 All waste containers should be labelled clearly and covered at all times.

18.4.5 Provision should be made for the proper and safe storage of waste materials awaiting disposal.

18.4.6 Toxic substances and flammable materials shall be stored in suitably designed, separate, enclosed cupboards, as required by national legislation.

18.4.7 Waste disposal shall be made in accordance with National Solid Waste Management Authority and National Environment & Planning Agency.

18.4.8 Provision shall be made for the proper and safe storage of waste materials awaiting disposal. Toxic substances and flammable materials shall be stored in suitably designed, separate, enclosed cupboards, as required by national legislation.

18.4.9 Waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.

18.5 Cannabis Disposal

18.5.1 The disposal of cannabis and its derivatives should comply with relevant standards and requirement of the authority with jurisdiction.

18.6 Pest Control

18.6.1 Premises shall be designed and equipped so as to afford maximum protection against the entry of insects, birds or other animals.

18.6.2 There should be a procedure for rodent and pest control.

18.6.3 Pest management plan shall include monitoring at regular intervals by a qualified third-party provider (relevant authority).

18.6.4 On building exteriors, a perimeter space of 24 inches should be maintained clear of plants, structures or decorations to facilitate the positioning of exterior pest traps and to discourage pest harbourage areas.

18.6.5 All equipment and materials should be stored to discourage the harbourage of pests such as insects, rodents or birds.

18.6.6 Pest control inspections should be conducted monthly.

18.6.7 Pest control devices (traps, light traps, etc.) should be placed to prevent contamination of raw materials, work-in-process, finished goods, packaging, production equipment or tools). Baited traps (baited with poison) should only be used outside of the facility and should never be used in production, product handling, and processing or storage areas. A bait map should be available in house.

18.6.8 All pest control devices should be marked, numbered and coded and be in working order.

EXAMPLE 4 for sticky traps, glue should still be sticky, not covered with dust

18.6.9 Pest control devices should be monitored regularly. Records of regular device monitoring should be maintained and should reference trap numbers and locations.

18.6.10 No animals or pets are permitted in production areas or areas that contain raw materials, work-in-process, finished goods or stored products, production equipment, product containers or packaging.

18.6.11 The facility should be free of pest contaminants such as whole or parts of insects, rodents, birds, reptiles or mammals, faeces, hair and other pest waste.

18.6.12 Records of all pest control applications, inspection and resulting corrective actions should be maintained.

Standards Council

The Standards Council is the controlling body of the Bureau of Standards Jamaica and is responsible for the policy and general administration of the Bureau.

The Council is appointed by the Minister in the manner provided for in the Standards Act, 1969. Using its powers in the Standards Act, the Council appoints committees for specified purposes.

The Standards Act, 1969 sets out the duties of the Council and the steps to be followed for the formulation of a standard.

Preparation of standards documents

The following is an outline of the procedure which must be followed in the preparation of documents:

1. The preparation of standards documents is undertaken upon the Standard Council's authorisation. This may arise out of representation from national organisations or existing Bureau of Standards' Committees of Bureau staff. If the project is approved it is referred to the appropriate sectional committee or if none exists a new committee is formed, or the project is allotted to the Bureau's staff.

2. If necessary, when the final draft of a standard is ready, the Council authorises an approach to the Minister in order to obtain the formal concurrence of any other Minister who may be responsible for any area which the standard may affect.

3. The draft document is made available to the general public for comments. All interested parties, by means of a notice in the Press, are invited to comment. In addition, copies are forwarded to those known, interested in the subject.

4. The Committee considers all the comments received and recommends a final document to the Standards Council

5. The Standards Council recommends the document to the Minister for publication.

6. The Minister approves the recommendation of the Standards Council.

7. The declaration of the standard is gazetted and copies placed on sale.

8. On the recommendation of the Standards Council the Minister may declare a standard compulsory.

9. Amendments to and revisions of standards normally require the same procedure as is applied to the preparation of the original standard.

Overseas standards documents

The Bureau of Standards Jamaica maintains a reference library which includes the standards of many overseas standards organisations. These standards can be inspected upon request.

The Bureau can supply on demand copies of standards produced by some national standards bodies and is the agency for the sale of standards produced by the International Organization for Standardization (ISO) members.

Application to use the reference library and to purchase Jamaican and other standards documents should be addressed to:

Bureau of Standards Jamaica
6 Winchester Road
P.O. Box 113,
Kingston 10
JAMAICA, W. I.