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Safety, security and sustainability of cannabis facilities and operations —

Part 3: Good production practices (GPP)

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

International Workshop Agreement IWA 37 was approved at a series of workshops hosted by the Standards Council of Canada (SCC), in association with Underwriters Laboratories of Canada (ULC), held virtually between December 2020 and June 2021.

A list of all parts in the IWA 37 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

While cannabis has been fully legalized in Canada and in many states in the USA, it is a new and emerging industry that is moving at a very fast pace in many other parts of the world. While legalization is being deliberated by governments and legislative bodies, companies are creating their own infrastructure in anticipation of legal approval. Meanwhile, government regulators and the societies they serve are grappling with the lack of consistent rules and guidance to deliver safety, security and sustainability of cannabis facilities and operations, while growers and producers use their own judgment on how to establish and operate facilities.

It has become very clear that the global cannabis market is opening up very rapidly. The cannabis product and the industry will become more and more ubiquitous as the global barriers start to lower and come down. If the current trend continues, it is predicted that well over one third of the globe will accommodate cannabis by 2024.

What is unique about this new and emerging industry is that it is coming from an illicit status into decriminalization and evolving into a legitimate burgeoning business. Due to its pioneering status, very little exists in terms of research, studies, historical experience and best practices. Standardization is likewise very slow on the uptake and the cannabis industry remains severely underserved.

There are therefore distinct challenges for the safety, security and sustainability of cannabis facilities and operations, which the IWA 37 series seeks to address as follows:

— Part 1: Requirements for the safety of cannabis buildings, equipment and oil extraction operations;

— Part 2: Requirements for the secure handling of cannabis and cannabis products;

— Part 3 (this document): Good production practices (GPP).

The good production practices (GPP) specified in this document are intended to ensure product quality by mitigating threats of mislabelling or adulterating cannabis products. These practices are compatible with the requirements for safety, product security and facility safety specified in IWA 37-1 and IWA 37-2.

To align with international best practices, this document builds upon the internationally recognized framework and principles used in good manufacturing practices (GMP) and GPP, which comprise a system of processes, procedures and documentation that help to ensure products are consistently produced and controlled in accordance with quality standards. These practices are typically required to conform to guidelines and regulations recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug products and active pharmaceutical products. The application of these guidelines require that manufacturers, processors and packagers of drugs, medical devices and food take proactive steps to ensure that their products are safe, pure and effective.

The production of cannabis products presents unique and challenging hazards and requires additional control measures and prerequisite programmes, from the perspectives of safety, product quality and safety, product security and facility safety, as well as from the perspective of compliance with statutory or regulatory requirements, which in most jurisdictions are in addition to those governing conventional product manufacturing.

The production and sale of cannabis products encompasses the full supply chain from the cultivation and harvesting of the cannabis plant, through the processing of the plants and the extraction of concentrated oils to the manufacturing of cannabis products using conventional methods, and it includes the storage, handling, distribution and retailing of these products.

Given the unique aspects associated with cannabis edibles, this sub-set of cannabis products is considered separately. It is felt that the most effective approach for the development of future ISO standards for cannabis edibles is to build upon the strong foundation for food safety management systems set out in ISO 22000 and in ISO/TS 22002-1 together with the technical guidance contained in the main body of this document, rather than to develop a new set of GPP exclusively for cannabis edibles. Annex B outlines this approach in more detail.

Supporting material to accompany the IWA 37 series is available at the following website: IWA 37 — Safety, security and sustainability of cannabis facilities and operations.

A list of workshop participants is available from the Standards Council of Canada (SCC).

Safety, security and sustainability of cannabis facilities and operations —

Part 3:
Good production practices (GPP)

1 Scope

This document specifies requirements and recommendations for organizations directly or indirectly involved in the cannabis supply chain, to enable them to:

— plan, implement, operate, maintain and update a good production practice programme for providing products that are safe, according to their intended use;

— demonstrate compliance with applicable statutory and regulatory requirements;

— evaluate and assess mutually agreed customer requirements and demonstrate conformity to them;

— effectively communicate with interested parties and demonstrate conformity to relevant interested parties;

— demonstrate conformity to stated policies in a cannabis quality programme (CQP) for product safety, product quality, product security and facility safety;

— support the evaluation of quality programmes by external organizations or to permit self-assessment or self-declaration of adherence to some or all of the guidance contained in this document.

All requirements in this document are generic and intended to be applicable to all organizations in the cannabis supply chain, regardless of size and/or complexity. Organizations that are directly or indirectly involved include (but are not limited to) growers/cultivators, harvesters, primary processors, producers of cannabis, manufacturers of cannabis derivatives, cannabis edibles and/or cannabis products, testing providers, retailers and organizations providing transportation, storage and distribution services, suppliers of equipment, packaging materials and other contact materials.

This document intended to enable any organization, including small and/or less developed organizations, to implement externally developed elements in its CQP.

NOTE 1 Organizations in the cannabis supply chain are diverse in nature and not all the requirements specified in this document apply to each establishment or process. Justifications for exclusions or the use of alternative measures can be documented by a risk assessment/hazard analysis or other appropriate means.

This document provides guidance related to the following categories of cannabis, cannabis derivatives and cannabis products:

— cannabis plant seeds;

— cannabis plants;

— fresh cannabis;

— dried cannabis;

— cannabis derivatives;

— cannabis topicals;

— inhalable cannabis.

NOTE 2 Annex B provides additional guidance on applying GPP to cannabis edibles with respect to requirements and recommendations in existing food safety standards.

Where buildings or premises combine cultivation and processing of cannabis plants, including ancillary activities, along with other operational activities, the requirements and recommendations in this document apply only to that portion of the facility.

NOTE 3 Where joint use activities are present in a common building, specific statutory and regulatory requirements can apply for each category.

This document does not address the following:

— requirements related to research and development activities for finished products;

— general fire prevention or building construction features that are normally a function of local building and fire codes where applicable;

— premises used exclusively for operational activities, such as office space, call centres and retail outlets, used for the distribution, marketing, or sale of cannabis;

NOTE 4 Shipping and receiving of products from the production facility for further distribution are not considered as a retail outlet.

— the safe consumption or use of the cannabis or cannabis products produced by organizations applying these good production practices;

— occupational health and safety requirements governing cannabis workers and personnel except as identified in A.8.4 and A.8.6;

— the protection of the environment;

— security of the supply chain monitoring system, including cybersecurity and notifications;

NOTE 5 Security and monitoring of the supply chain are dealt with specifically in IWA 37-2.

— outdoor cultivation of cannabis and industrial hemp;

— growing of cannabis intended for personal use;

— the use of cannabinoids as ingredients that are derived from plants other than cannabis, or derived from other organisms, or created synthetically.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
acceptable level
level of a *safety hazard* (3.38) not to be exceeded in the *end product* (3.18) provided by the *organization* (3.27)

[SOURCE: ISO 22000:2018, 3.1]

3.2
audit
systematic, independent and documented *process* (3.32) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.27) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management.

[SOURCE: ISO 22000:2018, 3.3]

3.3
cannabis
genus of flowering plants made up of many different phytocannabinoids and chemical compounds

Note 1 to entry: Research into cannabis by governing bodies and organizations is ongoing around the world, and drug classifications are constantly under review. Regulation of cannabis legalization frameworks can vary between jurisdictions, based on the levels of tetrahydrocannabinol (THC) available in the plant.

3.4
cannabis derivative
secondary *product* (3.33) that can be extracted or obtained from a *cannabis* (3.3) biomass

Note 1 to entry: Classification of synthetically derived cannabinoids can vary between jurisdictions.

3.5
cannabis edible
food (3.19) which includes *cannabis* (3.3) or *cannabis derivative* (3.4) as an ingredient

Note 1 to entry: Dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds are not in themselves considered food.

3.6
cannabis product
packaged goods containing *cannabis* (3.3) or *cannabis derivative* (3.4), available in multiple formats for commercial and/or retail distribution

3.7
cannabis waste
solid, liquid or gaseous material that is a *cannabis product* (3.6), contains *cannabis* (3.3) or has come into contact with cannabis, destined for disposal and not intended for sale or for use in any way other than for agronomic purposes such as compost

Note 1 to entry: Definitions of cannabis waste can vary between jurisdictions. For example, in a jurisdiction that sets a specific tetrahydrocannabinol (THC) threshold to define cannabis waste at a specific concentration of THC (e.g. 10 µg/g), waste that has a concentration below that threshold is not considered to be cannabis waste.

3.8
competence
ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO 22000:2018, 3.4]

3.9
conformity
fulfilment of a *requirement* (3.35)

[SOURCE: ISO 22000:2018, 3.5]

3.10
contamination
introduction or occurrence of a contaminant including a *safety hazard* (3.38) in a *product* (3.33) or processing environment

[SOURCE: ISO 22000:2018, 3.6]

3.11
continual improvement
recurring activity to enhance *performance* (3.29)

[SOURCE: ISO 22000:2018, 3.7]

3.12
control measure
action or activity that is essential to prevent a *safety hazard* (3.38) and/or *significant safety hazard* (3.39) or reduce it to an *acceptable level* (3.1)

Note 1 to entry: Control measure(s) is (are) identified by risk assessment/hazard analysis.

[SOURCE: ISO 22000:2018, 3.8, modified — The words "a significant food safety hazard" have been replaced with "a safety hazard and/or significant safety hazard" in the definition; the original Note 1 to entry has been deleted and the words "risk assessment" have been added to the remaining Note to entry.]

3.13
corrective action
action to eliminate the cause of a *nonconformity* (3.25) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

[SOURCE: ISO 22000:2018, 3.10]

3.14
documented information
information required to be controlled and maintained by an *organization* (3.27) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

— the *management system* (3.22), including related *processes* (3.32);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

[SOURCE: ISO 22000:2018, 3.13]

3.15
durable life
period, commencing on the day on which a *cannabis product* (3.6) is packaged as an *end product* (3.18), during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, normal palatability and any other qualities claimed for it

3.16
durable life date
date on which the *durable life* (3.15) of a *cannabis product* (3.6) ends

3.17
effectiveness
extent to which planned activities are realized and planned results achieved

[SOURCE: ISO 22000:2018, 3.14]

3.18
end product
product (3.33) that will undergo no further processing or transformation by the *organization* (3.27)

Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material, an input, or an ingredient in the context of the second organization.

[SOURCE: ISO 22000:2018, 3.15, modified — The words "an input" have been added in the Note to entry.]

3.19
food
substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

[SOURCE: ISO 22000:2018, 3.18, modified — The original Note to entry has been deleted.]

3.20
interested party
person or *organization* (3.27) that can affect, be affected by, or perceive itself to be affected by a decision or activity

[SOURCE: ISO 22000:2018, 3.23, modified — The admitted term "stakeholder" has been deleted.]

3.21
lot
defined quantity of a *product* (3.33) produced and/or processed and/or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the *organization* (3.27) and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product.

[SOURCE: ISO 22000:2018, 3.24]

3.22
management system
set of interrelated or interacting elements of an *organization* (3.27) to establish *policies* (3.30) and *objectives* (3.26) and *processes* (3.32) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.

[SOURCE: ISO 22000:2018, 3.25]

3.23
measurement
process (3.32) to determine a value

[SOURCE: ISO 22000:2018, 3.26]

3.24
monitoring
determining the status of a system, a *process* (3.32) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

Note 2 to entry: In the context of cannabis *safety* (3.37), monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

Note 3 to entry: Distinctions are made in this document between the terms *validation* (3.44), monitoring and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of *conformity* (3.9).

[SOURCE: ISO 22000:2018, 3.27, modified — The words "food safety" have been replaced with "cannabis safety" in Note 2 to entry.]

3.25
nonconformity
non-fulfilment of a *requirement* (3.35)

[SOURCE: ISO 22000:2018, 3.28]

3.26
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and *safety* (3.37), and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, *product* (3.33), and *process* (3.32).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a food safety *management system* (3.22) objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of food safety management systems, objectives are set by the *organization* (3.27), consistent with the food safety *policy* (3.30), to achieve specific results.

[SOURCE: ISO 22000:2018, 3.29]

3.27
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.26)

Note 1 to entry: 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.

[SOURCE: ISO 22000:2018, 3.31]

3.28
outsource
make an arrangement where an external *organization* (3.27) performs part of an organization's function or *process* (3.32)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.22), although the outsourced function or process is within the scope.

[SOURCE: ISO 22000:2018, 3.32]

3.29
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.32), *products* (3.33) (including services), systems or *organizations* (3.27).

[SOURCE: ISO 22000:2018, 3.33]

3.30
policy
intentions and direction of an *organization* (3.27) as formally expressed by its *top management* (3.41)

[SOURCE: ISO 22000:2018, 3.34]

3.31
potency
amount per unit of the standardized component(s) which further characterizes the quantity of the ingredient

Note 1 to entry: For further clarification of the calculation of potency, see 6.7.1.4.

Note 2 to entry: The use of the term potency in this document is not intended to refer to *product* (3.33) efficacy.

3.32
process
set of interrelated or interacting activities which transforms inputs to outputs

[SOURCE: ISO 22000:2018, 3.36]

3.33
product
output that is a result of a *process* (3.32)

Note 1 to entry: A product can be a service.

[SOURCE: ISO 22000:2018, 3.37]

3.34
purity
extent to which an ingredient or *cannabis derivative* (3.4) is free from undesirable or adulterating chemical, biological or physical entities as defined by specifications

Note 1 to entry: Requirements can vary between jurisdictions.

3.35
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.27) and *interested parties* (3.20) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.14).

[SOURCE: ISO 22000:2018, 3.38]

3.36
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected – positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

[SOURCE: ISO 22000:2018, 3.39, modified — The original Note 5 to entry has been deleted.]

3.37
safety
assurance that the *product* (3.33) will not cause an adverse health effect for the consumer when it is prepared and/or used according to its intended use

Note 1 to entry: Safety is related to the occurrence of *safety hazards* (3.38) in *end products* (3.18) and does not include other health aspects.

3.38
safety hazard
source or situation with the potential to cause an adverse health effect

Note 1 to entry: The term hazard is not to be confused with the term *risk* (3.36) which, in the context of *safety* (3.37), means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard.

Note 2 to entry: Safety hazards include allergens and radiological substances.

[SOURCE: ISO 22000:2018, 3.22, modified — The word "food" has been deleted from the term and from Notes 1 and 2 to entry; the words "biological, chemical or physical agent in food" have been replaced with "source or situation" in the definition; the original Notes 3 and 4 to entry have been deleted.]

3.39
significant safety hazard
safety hazard (3.38), identified through the hazard assessment, which needs to be controlled by *control measures* (3.12)

[SOURCE: ISO 22000:2018, 3.40, modified — The word "food" has been deleted from the term and the definition.]

3.40
stability
period of time during which the *cannabis product* (3.6), after being packaged for sale as an *end product* (3.18), will continue to comply with its specifications when it is stored under its recommended storage conditions or, if it does not have recommended storage conditions, when it is stored at room temperature

3.41
top management
person or group of people who directs and controls an *organization* (3.27) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.22) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

[SOURCE: ISO 22000:2018, 3.41]

3.42
traceability
ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the *product* (3.33).

Note 2 to entry: An object can be a product, a material, a unit, equipment, a service, etc.

[SOURCE: ISO 22000:2018, 3.42, modified — The word "food" has been replaced with "product" in Note 1 to entry.]

3.43
update
immediate and/or planned activity to ensure application of the most recent information

Note 1 to entry: Update is different from the terms maintain and retain:

— maintain is to keep something on-going/to keep in good condition;

— retain is to keep something that is retrievable.

[SOURCE: ISO 22000:2018, 3.43]

3.44
validation
obtaining evidence that a *control measure* (3.12) (or combination of control measures) will be capable of effectively controlling the significant *safety hazard* (3.38)

Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 2 to entry: Distinctions are made in this document between the terms validation, *monitoring* (3.24) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of *conformity* (3.9).

[SOURCE: ISO 22000:2018, 3.43, modified — The word "food" has been deleted from the definition.]

3.45
verification
confirmation, through the provision of objective evidence, that specified *requirements* (3.35) have been fulfilled

Note 1 to entry: Distinctions are made in this document between the terms *validation* (3.41), *monitoring* (3.24) and verification:

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of *conformity* (3.9).

[SOURCE: ISO 22000:2018, 3.45]

4 General

4.1 Understanding the organization and its context

4.1.1 The organization should determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its cannabis quality programme (CQP).

4.1.2 The organization should identify, review and update information related to these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the context can be facilitated by considering external and internal issues including, but not limited to, legal, technological, competitive, market, cultural, social, economic environments, cybersecurity and fraud, defence and intentional contamination or product sabotage, knowledge and performance of the organization, whether international, national, regional or local.

NOTE 3 For an organization that manufactures cannabis products, understanding can be facilitated by considering external and internal issues including: product quality and safety, security issues related to the production, storage, handling and distribution of cannabis, cannabis derivatives and cannabis products and safety issues for personnel and for facilities.

4.2 Understanding the needs and expectations of interested parties

4.2.1 To ensure that the organization is able to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard to product quality and safety, the organization should determine:

a) the interested parties that are relevant to the CQP;

b) the relevant requirements of the interested parties of the CQP.

4.2.2 The organization should identify, review and update information related to the interested parties and their requirements. When taking decisions, the organization should take into consideration the best interest of all interested parties.

4.3 Establishing the CQP

4.3.1 General

4.3.1.1 The organization should establish, implement, maintain, update and continually improve its CQP, including the processes needed and their interactions, in accordance with the requirements of this document.

4.3.1.2 If the organization establishes, maintains, updates and continually improves its CQP by using externally developed elements of a CQP, including GPP, the organization's risk assessment/hazard analysis and the hazard control plan should ensure that the elements provided externally are:

a) developed in conformance with requirements of this document;

b) applicable to the sites, processes and products of the organization;

c) specifically adapted to the processes and products of the organization by the quality and safety team;

d) implemented, maintained and updated as required by this document;

e) retained as documented information.

4.3.2 Control of externally provided processes, products or services

The organization should:

a) establish and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers of processes, products and/or services;

b) ensure adequate communication of requirements to the external provider(s);

c) ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of the CQP;

d) retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

4.4 Licences

Organizations can be required to obtain licences in order to meet applicable statutory or regulatory requirements related to their activities, including licences needed for the production of cannabis and/or cannabis products.

4.5 Policy

4.5.1 Establishing the CQP policy

The organization should establish, implement and maintain a CQP policy that:

a) is appropriate to the purpose and context of the organization;

b) provides a framework for setting and reviewing the objectives of the CQP;

c) includes a commitment to satisfy applicable product quality and safety requirements, including statutory and regulatory requirements, and mutually agreed customer requirements related to cannabis product quality and safety;

d) addresses internal and external communication;

e) includes a commitment to continual improvement of the CQP;

f) addresses the need to ensure competencies related to product quality and safety.

4.5.2 Communicating the CQP policy

The CQP policy should:

a) be available and maintained as documented information;

b) be communicated, understood, and applied at all levels within the organization;

c) be available to relevant interested parties, as appropriate.

4.6 Organizational roles, responsibilities and authorities

4.6.1 General

The organization, as part of its CQP, should document the organizational structure and specific roles and responsibilities with respect to the management of the CQP throughout the organization.

4.6.2 Quality and safety team leader

4.6.2.1 The product quality and safety team leader should be responsible for:

a) ensuring the CQP is established, implemented, maintained and updated;

b) managing and organizing the work of the product quality and safety team;

c) ensuring relevant training and competencies for the quality and safety team;

d) reporting to top management on the effectiveness and suitability of the CQP;

e) investigating every quality complaint received in respect of the quality of the cannabis and cannabis products, and if necessary, immediately taking measures to mitigate risk;

f) conducting an immediate investigation and, if necessary, immediately take measures to mitigate any risk, on reasonable grounds, that the cannabis and cannabis products or anything that will be used as an ingredient presents a risk of injury to human health not being met;

g) cannabis and cannabis products or anything that will be used as an ingredient is produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by the identified product quality and safety team leader;

h) approving the control measures prior to their implementation;

i) approving every lot or batch of cannabis and cannabis product before it is made available for sale.

4.6.2.2 All persons should have the responsibility to report problem(s) with regards to the CQP to identified person(s).

4.6.2.3 The product quality and safety team leader should have the training, experience and technical knowledge related to the scope of the organization's operations, including control measures and GPP that are applicable to the cannabis products and activities of the organization.

4.6.3 Product security

4.6.3.1 The organization should ensure that the responsibilities and authorities relevant to the security of the production of cannabis products are assigned, communicated and understood within the organization.

4.6.3.2 The organization should assign the responsibility and authority for:

a) ensuring that the security systems conform to the requirements of this document;

b) reporting on the performance of the security systems to the appropriate individual responsible;

c) appointing the security team leader;

d) designating persons with defined responsibility and authority to initiate and document action(s).

4.6.3.3 The security team leader should be responsible for:

a) ensuring the security systems are established, implemented, maintained and updated;

b) managing and organizing the work of the security team;

c) ensuring relevant training and competencies for the security team;

d) reporting to the appropriate individual responsible on the effectiveness and suitability of the security systems.

4.6.3.4 All persons should have the responsibility to report problem(s) with regards to the security systems to identified person(s).

4.7 Planning of changes

4.7.1 When the organization determines the need for changes to the CQP, including personnel changes, the changes should be carried out and communicated in a planned manner.

4.7.2 The organization should consider the:

a) purpose of the changes and their potential consequences;

b) continued integrity of the CQP;

c) availability of resources to effectively implement the changes;

d) allocation or re-allocation of responsibilities and authorities.

5 Support

5.1 Resources

5.1.1 General

The organization should determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the CQP.

5.1.2 People

5.1.2.1 The organization should ensure that persons necessary to operate and maintain an effective CQP are competent.

5.1.2.2 Where the assistance of external experts is used for the development, implementation, operation or assessment of the CQP, evidence of agreement or contracts defining the competency, responsibility and authority of external experts should be retained as documented information.

5.1.3 Infrastructure

The organization should provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity with the requirements of the CQP.

NOTE Infrastructure can include:

a) land, vessels, buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation;

d) information and communication technology.

5.1.4 Work environment

The organization should determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the CQP.

NOTE A suitable environment can be a combination of human and physical factors such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, air flow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

5.2 Documented information

5.2.1 General

The organization's CQP should include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the CQP.

NOTE The extent of documented information for a CQP can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

5.2.2 Creating and updating

When creating and updating documented information the organization should ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

5.2.3 Control of documented information

5.2.3.1 Documented information required by the CQP and by this document should be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

5.2.3.2 For the control of documented information, the organization should address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

5.2.3.3 Documented information of external origin determined by the organization to be necessary for the planning and operation of the CQP should be identified, as appropriate, and controlled.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

5.2.4 Data integrity and backup

5.2.4.1 Computer software programs used in good production/processing practices are to be backed up on a regular basis to ensure loss of information is avoided. Computer programs that are custom made or modified should be validated.

5.2.4.2 Data security and integrity should be adopted and implemented.

6 Designing and implementing GPP within the operation

6.1 Development of processes

6.1.1 The organization should plan, implement and control the processes needed to implement its CQP, including:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria;

c) keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.

6.1.2 The organization should control planned changes and review the consequences of unintended changes to processes, taking action to mitigate any adverse effects, as necessary.

6.1.3 The organization should ensure that outsourced processes are controlled.

6.2 Establishing criteria for processes

6.2.1 Characteristics of raw materials, ingredients and product contact materials

6.2.1.1 The organization shall ensure that all applicable statutory and regulatory product quality and safety requirements are identified for all raw materials, ingredients and product contact materials.

6.2.1.2 The organization shall maintain documented information, including specifications, concerning all raw materials, ingredients and product contact materials to the extent needed to conduct a risk assessment/hazard analysis, including the following, as appropriate:

a) biological, chemical and physical characteristics;

b) composition of formulated ingredients, including additives and processing aids;

c) source (e.g. animal, mineral or vegetable);

d) place of origin (provenance);

e) method of production;

f) packaging and delivery methods;

g) storage conditions and durable [shelf] life;

h) preparation and/or handling before use or processing;

i) product quality and safety related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended use.

6.2.2 Characteristics of end products (finished products)

6.2.2.1 The organization shall ensure that all applicable statutory and regulatory safety, product quality and safety requirements are identified for all the end products intended to be produced.

6.2.2.2 The organization shall maintain documented information concerning the characteristics of end products to the extent needed to conduct a risk assessment/hazard analysis, including information on the following, as appropriate:

a) product name or similar identification;

b) composition;

c) biological, chemical and physical characteristics relevant for product quality and safety;

d) intended durable life (shelf life) and storage conditions;

e) packaging;

f) labelling relating to product quality and safety and/or instructions for handling, preparation and intended use;

g) method(s) of distribution and delivery.

6.2.3 Intended use

6.2.3.1 The intended use, including reasonably expected handling of the end product, and any unintended use but reasonably expected mishandling and misuse of the end product, shall be considered and shall be maintained as documented information to the extent needed to conduct a risk assessment/hazard analysis.

6.2.3.2 Where appropriate, groups of consumers/users shall be identified for each product.

6.2.3.3 Groups of consumers/users known to be especially vulnerable to specific product quality and safety hazards shall be identified.

6.2.4 Flow diagrams and description of processes

6.2.4.1 Preparation of the flow diagrams

6.2.4.1.1 The product quality and safety team shall establish, maintain and update flow diagrams as documented information for the products or product categories and the processes covered by the CQP.

6.2.4.1.2 The flow diagrams shall be used when conducting a risk assessment/hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of product quality and safety hazards.

6.2.4.1.3 Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct a risk assessment/hazard analysis. Flow diagrams shall, as appropriate, include the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes;

c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;

d) where reworking and recycling take place;

e) where end products, intermediate products, by-products and waste are released or removed.

6.2.4.2 On-site confirmation of flow diagrams

The product quality and safety team shall confirm on-site the accuracy of the flow diagrams, update the flow diagram where appropriate and retain as documented information.

6.2.4.3 Description of processes and process environment

6.2.4.3.1 The product quality and safety team shall describe, to the extent needed to conduct a risk assessment/hazard analysis, the following:

a) layout of premises, including product and non-product handling areas;

b) processing equipment and contact materials, processing aids and flow of materials;

c) existing GPP, process parameters, control measures if any and/or the strictness with which they are applied, or procedures that can influence product quality and safety;

d) external requirements (e.g. from statutory and regulatory authorities or customers) that can impact the choice and the strictness of the control measures.

6.2.4.3.2 Any variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

6.2.4.3.3 The descriptions shall be updated as appropriate and maintained as documented information.

6.3 Risk assessment/Hazard analysis

6.3.1 General

The product quality and safety team shall conduct a risk assessment/hazard analysis, based on the preliminary information to determine the hazards that need to be controlled within the CQP. The degree of control shall ensure product quality and safety and, where appropriate, a combination of control measures shall be used.

6.3.2 Hazard identification and determination of acceptable levels

6.3.2.1 The organization shall, as part of its CQP development process, identify and document all product quality and safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

NOTE 1 Cannabis product quality and safety hazards include the management of microbiological, chemical and physical hazards, allergen management and management of cannabinoids and phytocannabinoids.

NOTE 2 With respect to cannabis products, the event, likelihood and consequence of hazards are still being investigated, and there remains uncertainty as to the probability of adverse effects.

6.3.2.2 The hazard identification shall be based on:

a) preliminary information and data collected;

b) experience;

NOTE 1 Experience can include information from staff and external experts who are familiar with the product and/or processes in other facilities.

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the cannabis supply chain on product quality and safety hazards that could be of relevance for the safety of the intermediate products and the cannabis products at consumption;

e) customer requirements.

NOTE 2 Statutory and regulatory requirements can apply.

6.3.2.3 Hazards should be considered in sufficient detail to enable hazard assessment and the selection of appropriate control measures as part of the CQP.

6.3.2.4 The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each product quality and safety hazard can be present, be introduced, increase or persist.

6.3.2.5 When identifying hazards, the organization shall consider:

a) the stages preceding and following in the cannabis supply chain;

b) all steps in the process flow as defined in the process in the flow diagram;

c) the process equipment, utilities/services, process environment and persons.

6.3.2.6 The organization shall determine the acceptable level in the end product of each product quality and safety hazard identified, whenever possible.

6.3.2.7 When determining acceptable levels, the organization shall:

a) ensure that applicable statutory, regulatory and customer requirements are identified;

b) consider the intended use of end products;

c) consider any other relevant information.

6.3.2.8 The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

6.3.3 Hazard assessment

6.3.3.1 The organization shall conduct, for each identified product quality and safety hazard, a hazard assessment to determine whether its prevention or reduction to an acceptable level is essential.

6.3.3.2 The organization shall evaluate each product quality and safety hazard with regard to:

a) the likelihood of its occurrence in the end product prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use.

6.3.3.3 The organization shall identify any significant product quality and safety hazards.

6.3.3.4 The methodology used shall be described, and the result of the hazard assessment shall be maintained as documented information.

NOTE Methodologies for product quality and safety hazard assessment used in the cannabis industry include, but are not limited to, Failure Mode Effects Analysis (FMEA), Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Risk Assessment/Hazard Analysis and Critical Control Points (HACCP) and Hazard Operability Analysis (HAZOP).

6.3.4 Selection and categorization of control measures

6.3.4.1 Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified product quality and safety hazards to defined acceptable levels.

6.3.4.2 The organization shall categorize the selected identified control measure(s) to be managed as GPP or as control measures for significant hazards.

6.3.4.3 The categorization shall be carried out using a systematic approach. For each of the control measures for significant hazards selected, there shall be an assessment of the following:

a) the likelihood of failure of its functioning;

b) the severity of the consequence in the case of failure of its functioning; this assessment shall include:

   1) the effect on identified significant product quality and safety hazards;

   2) the location in relation to other control measure(s);

3) whether it is specifically established and applied to reduce the hazards to an acceptable level;

4) whether it is a single measure or is part of combination of control measure(s).

6.3.4.4 In addition, for each control measure for a significant hazard, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

6.3.4.5 The decision-making process and results of the selection and categorization of the control measures (GPP and those for significant hazards) shall be maintained as documented information.

6.3.4.6 External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

6.4 Implementing process controls

6.4.1 Good production practices (GPP)

6.4.1.1 General

6.4.1.1.1 The organization shall establish, implement, maintain and update GPP to facilitate the prevention and/or reduction of hazards (including contaminants) in the products, product processing and work environment.

6.4.1.1.2 The GPP shall be:

a) appropriate to the organization and its context with regard to product quality and safety;

b) appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;

c) implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process;

d) approved by the product quality and safety team.

6.4.1.2 Selection/Establishment of GPP

6.4.1.2.1 When selecting and/or establishing GPP, the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified.

6.4.1.2.2 When establishing GPP for the safety, security and sustainability of cannabis facilities and operations, the organization shall respect the GPP for cannabis and cannabis product quality and safety specified in Annex A.

6.4.1.2.3 Documented information shall specify the selection, establishment, applicable monitoring and verification of the GPP.

6.4.2 Control measures for significant hazards

6.4.2.1 General

6.4.2.1.1 Based on the results of the risk assessment/hazard analysis (see 6.3), the organization shall establish, implement, maintain and update hazard control plan for control measures for significant product quality and safety hazards to facilitate the prevention and/or reduction of these hazards in the products, product processing and work environment.

6.4.2.1.2 The hazard control plan shall include for each control measure for a significant hazard the following information:

a) product safety or quality hazard to be controlled;

b) critical limits or action criteria for the control measure;

c) monitoring procedure(s);

d) correction(s) to be taken if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) documented information of monitoring.

6.4.2.2 Selection/establishment of control measures for significant hazards

6.4.2.2.1 When selecting and/or establishing control measures for significant hazards, the organization shall ensure that the applicable statutory, regulatory and mutually agreed customer requirements are identified.

6.4.2.2.2 External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

6.4.2.2.3 Documented information shall specify the selection, establishment, applicable monitoring, verification and validation of the control measures for significant hazards.

6.4.3 Validation of control measures for significant hazards

6.4.3.1 The product quality and safety team shall validate that the selected control measures are capable of achieving the intended control of the significant hazards(s) prior to implementation of control measure(s) and combination(s) of control measures (s) to be included in the hazard control plan and after any change therein,

6.4.3.2 When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the product quality and safety team shall modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

6.4.3.3 The product quality and safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended control as documented information.

NOTE Modification can include changes in control measure(s) (i.e. process parameters, rigour and/or their combination) and/or change(s) in the manufacturing technologies for raw materials, end product characteristics, methods of distribution and intended use of the end products.

6.4.4 Control of monitoring and measuring methods

6.4.4.1 The organization shall provide evidence that the specified monitoring and measuring methods and equipment in use is adequate for the monitoring and measuring activities related to the GPP and the hazard control plan.

6.4.4.2 The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results;

e) protected from damage and deterioration.

6.4.4.3 The results of calibration and verification shall be retained as documented information.

6.4.4.4 The calibration of all the equipment shall be traceable to international or national measurement standards. Where no standards exist, the basis used for calibration or verification shall be retained as documented information.

6.4.4.5 The organization shall assess the validity of the previous measurement results when the equipment or process environment is found not to conform to requirements.

6.4.4.6 The organization shall take appropriate action in relation to the equipment or process environment and any product affected by the non- conformance.

6.4.4.7 The assessment and resulting action shall be maintained as documented information.

6.4.4.8 Software used in monitoring and measuring within the CQP shall be validated by the organization, the software supplier, or a third party prior to use. Documented information on validation activities shall be maintained by the organization and the software shall be updated in a timely manner.

6.4.4.9 Whenever there are changes, including software configuration/modifications to commercial off-the- shelf software, they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

6.5 Process control documentation

6.5.1 Master manufacturing records (MMRs)

6.5.1.1 Procedures for creating master manufacturing records (MMRs) shall be established to ensure that the product and quality team leader reviews and approves MMRs.

6.5.1.2 The site master manufacturing record shall contain the following information:

a) The name of the cannabis product to be manufactured;

b) The strength, concentration, weight, or measure of each ingredient with the unique number for each batch size;

c) A complete list of cannabis derivatives to be used;

d) The identity and weight or measure of each cannabis derivative that will be declared on the label;

e) The identity of each ingredient that will be declared on the ingredient list;

f) A statement of theoretical yield expected at each point, step or stage where control is needed to ensure quality;

g) The expected yield when manufacturing is completed, including the maximum and minimum percentages of theoretical yield beyond on which a deviation investigation of a batch is necessary and a material review and disposition decision is made;

h) A description of packaging;

i) The identity of equipment and processing lines used;

j) The date and time of the maintenance, cleaning and sanitizing of the equipment and processing lines used or a cross- reference to documented information where this information is stored;

k) The results of any testing or examination performed during the batch production or a cross-reference to the such results;

l) Documentation that the finished cannabis product meets specifications.

NOTE Additional details can be required by the regulatory requirements of the country of production and/or country of sale.

6.5.2 Batch manufacturing records

6.5.2.1 Procedures for issuance of batch records shall be documented and implemented.

6.5.2.2 Batch records are created for every batch of cannabis product processed.

6.5.2.3 Batch records shall include the following items:

a) The name of the cannabis product to be manufactured;

b) The strength, concentration, weight, or measure of each ingredient with the unique number for each batch size;

c) A complete list of cannabis derivative to be used;

d) The identity and weight or measure of each cannabis derivative that will be declared on the label;

e) The identity of each ingredient that will be declared on the ingredient list;

f) A statement of theoretical yield expected at each point, step or stage where control is needed to ensure quality;

g) The expected yield when manufacturing is completed, including the maximum and minimum percentages of theoretical yield beyond on which a deviation investigation of a batch is necessary and a material review and disposition decision is made;

h) A description of packaging;

i) The identity of equipment and processing lines used;

j) The date and time of the maintenance, cleaning and sanitizing of the equipment and processing lines used or a cross-reference to documented information where this information is stored;

k) The results of any testing or examination performed during the batch production or a cross-reference to the such results;

l) Documentation that the finished cannabis product meets specifications.

NOTE Additional details can be required by the regulatory requirements of the country of production and/or country of sale.

6.5.2.4 Batch records shall contain the date on which the steps are performed and the initials of the person performing the step.

6.5.2.5 There shall be a quality plan for monitoring in-process points, steps, or stages where control is necessary to ensure the quality of the cannabis products.

6.5.2.6 Appropriate documentation of material review and disposition decisions shall be available supported by documented information.

6.5.2.7 Written procedures, i.e. standard operating procedures (SOPs), that ensure effective measures are used to protect against the inclusion of metal or other foreign material in cannabis derivatives, in-process materials shall be available.

6.5.2.8 Batch records shall be reviewed and approved by the quality and safety team or designee and maintained electronically.

6.6 Verification related to GPP and the hazard control plan

6.6.1 Verification

6.6.1.1 The organization shall establish, implement and maintain verification activities. The verification planning shall define purpose, methods, frequencies and responsibilities for the verification activities.

6.6.1.2 The verification activities shall confirm that:

a) the GPP are implemented and effective;

b) the hazard control plan is implemented and effective;

c) hazard levels are within identified acceptable levels;

d) input to the risk assessment/hazard analysis is updated;

e) other actions determined by the organization are implemented and effective.

6.6.1.3 The organization shall ensure that verification activities are not carried out by the person responsible for monitoring the activities.

6.6.2 Verification results

6.6.2.1 Verification results shall be retained as documented information and shall be communicated.

6.6.2.2 Where verification is based on testing of end product samples or direct process samples and where such test samples show nonconformity with the acceptable level of the product safety or quality hazard the organization shall handle the affected lot(s) of product as potentially unsafe and apply corrective actions according to 6.8.3.

6.6.3 Analysis of results of verification activities

The product quality and safety team shall conduct an analysis of the results of verification that shall be used as an input to the CQP performance evaluation (see 4.3).

6.7 Laboratory system/Product testing

6.7.1 Testing for phytocannabinoids

6.7.1.1 Testing for the quantity (or concentration) of tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD) and cannabidiolic acid (CBDA) and any additional cannabinoids of interest shall be conducted on each lot (or batch) of cannabis, cannabis derivatives, other than cannabis plants or cannabis plant seeds, that:

a) is or will become a cannabis product; or

b) is or will be contained in a cannabis accessory that is or will become a cannabis product.

6.7.1.2 Testing shall provide an indication of the potency (see 6.7.1.4) of the cannabis, cannabis product or cannabinoids that will become an ingredient of a consumer product.

6.7.1.3 Testing can also measure cannabinol (CBN) as this is a known oxidation product of THC.

6.7.1.4 Testing can also measure the THC potential (total THC) and the CBD potential (total CBD).

NOTE 1 Measurement of the THC potential and the CBD potential can be required for regulatory purposes.

NOTE 2 The THC potential is defined as a sum of the mass of THC plus the decarboxylation equivalent mass of THCA, taking into account the loss of CO2 from the acid form.

NOTE 3 The CBD potential is defined as a sum of the mass of CBD plus the decarboxylation equivalent mass of CBDA, taking into account the loss of CO2 from the acid form.

6.7.1.5 If an end product includes product claims (such as notable biological effects) testing shall also measure additional cannabinoids if these are relevant to the product use, stability or claims (i.e. delta-8-THC, CBG and others).

6.7.1.6 All test methods used should be properly validated and documented information of this validation be made available when requested to ensure verification.

6.7.1.7 When a cannabis product claims to have a standardized composition, it shall be clearly stated what phytocannabinoids this statement refers to, and what the maximum range of accepted variability is.

6.7.1.8 The organization shall maintain and make available for verification, test reports.

6.7.2 Testing for contaminants

6.7.2.1 Testing for microbial and chemical contaminants other than residues of a pest control product or its components or derivatives shall be done on:

a) each lot or batch of cannabis other than cannabis plants, cannabis plant seeds or cannabis edibles that is or will become a cannabis product, or is or will be contained in a cannabis accessory that is or will become a cannabis product; or

b) each lot or batch of cannabis other than cannabis plant seeds that is used to produce the cannabis or is used to produce cannabis edibles that is or will become a cannabis product, or that is or will be contained in a cannabis accessory that is or will become a cannabis product.

6.7.2.2 Test reports shall be available for verification.

6.7.2.3 If a cannabis product is intended to be used in a device that heats the product so that the resulting vapours are consumed by inhalation, both additives and final formulation shall be tested at the recommended temperature of use or the highest recommended temperature of use, to verify that the heated inhalants (HI) vapours do not contain chemical agents that would be harmful for health.

NOTE Consumed chemical agents are collectively referred to as Heated Inhalants (HI).

6.7.2.4 If a HI cannabis product has been prescribed by a physician as a medicinal product, it shall be tested using an accepted test methodology to indicate the dose of cannabinoids, terpenes and other agents to be delivered to the product user.

6.7.2.5 Consumer cannabis products (e.g. cigarettes, related materials) that are sold as consumer products intended to be used as a combustion product or to be smoked, shall be labelled in a similar manner to tobacco products with similar health hazards.

6.7.3 Testing for pesticides

6.7.3.1 Test laboratories shall document the pesticides that may be used by a processor at the time of cultivation.

NOTE Statutory and regulatory requirements with respect to cultivation can vary between jurisdictions.

6.7.3.2 Test laboratories shall test end products for known pesticides to ensure that only permissible pesticides are present and that the level of pesticides does not exceed maximum allowed levels.

6.7.4 Sample retention

6.7.4.1 Procedures shall be available for collecting cannabis raw materials and retaining samples of finished products. The quantity collected should be at least twice the quantity required for testing purposes.

6.7.4.2 Samples shall be retained for a period of 5 years past the expiration date of the product.

6.7.4.3 Documented information regarding the retention of samples shall be maintained. This includes the exact amount (numbers, grams) and form of the cannabis products stored.

6.7.4.4 Retained samples shall be stored at a temperature and relative humidity that ensures sufficient sample stability. Temperature of the storage space shall be monitored 24/7 and have an alarm function.

6.7.4.5 Finished product retained samples shall be evaluated periodically, at least annually for any product deterioration.

6.7.5 Durable life/Durable life date

6.7.5.1 Durable life or durable life dates shall be set for all end products, packaged, labelled cannabis products and the organization shall have data to support the durable life or durable life date of the products it produces.

NOTE In certain circumstances, derogations from the above requirement are permissible, providing they are documented and justified.

6.7.5.2 Durable life studies shall be conducted in accordance with International Conference on Harmonization (ICH) methods, conducted with cannabis products in their final packaging.

6.7.5.3 Durable life studies shall be maintained as documented information.

6.7.5.4 At least one batch of cannabis product per type shall be subjected to durable life or durable life date studies annually if no changes have been made to the product or its packaging.

6.7.5.5 Durable life dates shall be based on the time from the initial production, as opposed to the time delivered to the distributor or retailer.

6.8 Control of product and process nonconformities

6.8.1 General

The organization shall ensure that data derived from the monitoring of GPP and the hazard control plan are evaluated by designated persons who are competent and have the authority to initiate corrections and corrective actions.

6.8.2 Corrections

6.8.2.1 The organization shall ensure that when critical limits and/or action criteria for control measures for significant hazards are not met, the products affected are identified and controlled with regard to their use and release.

6.8.2.2 The organization should establish, maintain and update documented information that includes:

a) a method of identification, assessment and correction for affected products to ensure their proper handling;

b) arrangements for review of the corrections carried out.

6.8.2.3 When critical limits and/or action criteria are not met, the following should be carried out:

a) identification of the affected products and handling in accordance with 6.8.3;

b) determination of the cause(s) of failure;

c) determination of the consequences of that failure with respect to product quality and safety .

6.8.2.4 The organization should retain results of the evaluation as documented information.

6.8.2.5 Documented information should be retained to describe corrections taken on nonconforming products and processes, including the:

a) nature of the nonconformity;

b) cause(s) of the failure;

c) consequences as a result of the nonconformity.

6.8.3 Corrective actions

6.8.3.1 The need for corrective actions should be evaluated when critical limits and/or action criteria are not met.

6.8.3.2 The organization should establish and maintain documented information that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.

6.8.3.3 These actions should include:

a) reviewing nonconformities identified by customer and/or consumer complaints;

b) inspection reports;

c) reviewing trends in monitoring results that can indicate loss of control;

d) determining the cause(s) of nonconformities;

e) determining and implementing actions to ensure that nonconformities do not recur;

f) documenting the results of corrective actions taken;

g) verifying corrective actions taken to ensure that they are effective.

6.8.3.4 The organization should retain documented information on all corrective actions.

6.8.4 Handling of potentially unsafe products

6.8.4.1 General

6.8.4.1.1 The organization shall take action(s) to prevent potentially unsafe products from entering the cannabis supply chain unless it can demonstrate that the:

a) product quality and safety hazard(s) of concern is (are) reduced to the defined acceptable levels;

b) product quality and safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the supply chain; or

c) product still meets the defined acceptable level(s) of the product safety or quality hazard(s) of concern despite the nonconformity.

6.8.4.1.2 The organization shall retain products that have been identified as potentially unsafe under its control until the products have been evaluated and the disposition has been determined.

6.8.4.1.3 If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall (see 6.8.4.4).

6.8.4.1.4 The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

6.8.4.2 Evaluation for release

6.8.4.2.1 Each lot of products affected by the nonconformity shall be evaluated.

6.8.4.2.2 Products affected by failure to remain within critical limits shall not be released but be handled in accordance with 6.8.4.3;

6.8.4.2.3 Products affected by failure to meet action criterion shall only be released as safe when any of the following conditions apply:

a) evidence other than the monitoring system demonstrates that the control measures have been effective;

b) evidence shows that the combined effect of the control measures for that particular product conforms with the performance intended (i.e. identified acceptable levels);

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected products conform with the identified acceptable levels for the safety hazard(s) concerned.

6.8.4.2.4 Results of evaluation for release of products shall be retained as documented information.

6.8.4.3 Disposition of nonconforming products

6.8.4.3.1 Products that are not acceptable for release shall be:

a) reprocessed or further processed within or outside the organization to ensure that the product safety or quality hazard is reduced to acceptable levels; or

b) redirected for other use as long as product safety or quality in the cannabis supply chain is not affected; or

c) destroyed and/or disposed of as waste.

6.8.4.3.2 Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority shall be retained.

6.8.4.4 Withdrawal/recall

6.8.4.4.1 The organization shall be able to ensure the timely withdrawal/recall of lots or batches of cannabis or cannabis products sold or distributed that have been identified as potentially unsafe by appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall effectively and rapidly to minimize adverse public health impact.

6.8.4.4.2 The organization shall establish and maintain documented information for:

a) notifying relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers);

b) handling withdrawn/recalled products as well as products still in stock;

c) performing the sequence of actions to be taken.

6.8.4.4.3 Withdrawn/recalled products and end products still in stock shall be secured or held under control of the organization until they are managed in accordance with A.12.

6.8.4.4.4 Withdrawn/recalled and returned or rejected cannabis products shall be secured or held under the control of the organization until they are managed for warehousing (see A.12), waste disposal (see A.9) and traceability and reconciliation (see 6.10).

NOTE Statutory and regulatory requirements can apply.

6.8.4.4.5 The cause, extent and result of a withdrawal/recall shall be retained as documented information and reported to the organization as input for the management review (see 6.3).

6.8.4.4.6 The organization shall verify the implementation and effectiveness of withdrawals/recalls through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain the results as documented information.

6.8.4.4.7 Recall procedures shall be periodically challenged at least annually.

Documented information regarding mock recalls are to be maintained at least for two years after the completion of mock recall exercises.

6.9 Complaint management

6.9.1 There shall be a documented procedure for managing complaints to ensure that it includes provision for complaint assessment and investigation, and quality assurance oversight and approval, including adverse event reporting.

6.9.2 Documented information shall be maintained of all complaints, including investigation, action taken and reply to the originator of complaints.

6.9.3 Complaints shall be periodically trended.

6.10 Identification and traceability

6.10.1 The organization shall document and implement a system to uniquely identify and trace: incoming materials, components, in-process products, and end products to ensure proper traceability from the suppliers to the first stage of the distribution of the end product.

6.10.2 When establishing and implementing its traceability system, the organization shall ensure that statutory, regulatory and customer requirements are identified.

6.10.3 When establishing and implementing the traceability system, the following shall be considered as a minimum:

a) relation of lots of received materials, ingredients and intermediate products to the end products;

b) reworking of materials/products;

c) distribution of the end product.

6.10.4 Documented information shall be maintained for a period of 5 years past the product durable (shelf) life.

6.10.5 For cannabis, cannabis derivatives, the traceability system shall include the establishment of a procedure to reconcile, at least annually, quantities in end products with the quantity of ingredients (e.g. mass balance reconciliation).

6.10.6 Reconciliation will also be applied to rework, waste products, non-conforming product including withdrawn or recalled products, rejected products and returned products containing cannabis or cannabis derivatives.

6.10.7 The effectiveness of the reconciliation procedures shall be validated and challenged as required or at any time.

6.10.8 Systems of data should be interoperable to permit traceability across supply chains and markets.

6.10.9 Documented information shall be retained.

NOTE Additional information on traceability system design and implementation can be found in ISO 22005.

6.11 Packaging system

6.11.1 General

6.11.1.1 The organization shall ensure it develops a packaging system.

6.11.1.2 The organization shall ensure that containers, packaging, wrappers and labels on cannabis products meet customer requirements in the country of production and/or the country of sale.

NOTE Statutory and regulatory requirements can apply.

6.11.2 Packaging: Sustainability, safety and quality

6.11.2.1 The organization should use sustainable wrapping and packaging materials and consider:

a) the possible impact on product safety or quality, consumer health and the conservation and durable life (shelf life) of products;

b) the environmental impact of the materials-production sector, preferring (when possible and when a recovery procedure exists) the use of materials that are biodegradable or from renewable resources;

c) prevention of waste and losses (product restitution rate);

d) reuse and recycle in order to minimize the impacts of these materials on the environment.

6.11.2.2 The organization should put practices in place to reduce its wrapping and packaging and should train/educate operators in charge of packaging design about eco-design and, if necessary, about product life-cycle assessment.

6.11.2.3 Packaging containers shall include required safety mechanisms (e.g. child safety caps, tamper resistant mechanisms).

6.11.2.4 Packaging shall protect safety and efficacy of the product inside the container (e.g. UV and temperature exposure, and other environmental conditions that could degrade the product inside the container).

6.11.3 Packaging: Containers and wrappers

6.11.3.1 Packaging fulfilment and operations

6.11.3.1.1 Packaging operations shall be documented.

6.11.3.1.2 The organization shall establish and maintain documented information to ensure traceability of finished product in accordance with 6.10, such that customers, consumers, regulators, or other relevant third parties can determine that required product safety, product quality, and consumer protection systems have been followed.

6.11.3.1.3 The organization shall follow its established SOPs/documented procedures related to filling, assembling, packaging, labelling and other related operations for cannabis products to ensure product quality and safety.

6.11.3.1.4 Packaging operations shall be controlled to ensure environmental conditions (i.e. temperature, relative humidity, UV exposure, etc.) requirements are met based on the organization's stability studies.

6.11.3.2 Packaging type

6.11.3.2.1 All packaging shall be designed and selected to protect product safety, product quality, and product efficacy.

6.11.3.2.2 Packaging should be adjusted for each product's characteristics related to its intended form of consumption or use by consumers, including accessibility.

6.11.3.2.3 Packaging shall sufficiently protect its contents from environmental degradation and unintended use.

6.11.3.2.4 Packaging containers shall generally be free of contaminants or characteristics that could be harmful to a container's contents or consumers.

6.11.3.2.5 Packaging containers shall indicate their proper method of opening and closing.

6.11.3.2.6 Packaging containers shall indicate their proper method of disposal, such as composting, recycling, or reuse.

6.11.3.2.7 Packaging labels may be integrated with a packaging container or applied to a container separately.

6.11.4 Packaging labelling: Product identifiers

6.11.4.1 Container labels shall not be easily removed or separated from the container to which the label is applied.

6.11.4.2 Container labels shall provide the following product-identifying information:

a) the name, telephone number and email address of the manufacturer; a clear indication of the product inside the container, that is not misleading to consumers;

b) a clear indication of the intended method of consumption of the product inside the container;

c) the brand name;

d) the lot number, preceded by one of the following designations: "Lot number", "Lot no.", "Lot", or "(L)";

e) the packaging date;

f) the durable life date or a statement that no durable life date has been determined;

g) warning messages including, but not limited to, the following:

   1) health warnings;

   2) allergen statements;

3) safety statements (such as “Keep out of reach of children”) or to distinguish product not for sale direct to consumers;

h) in the case of a cannabis product that contains THC in specific regulated concentration, taking into account the potential to convert THCA into THC;

i) the standardized cannabis symbol;

NOTE Requirements with respect to packaging labelling and product identifiers can vary between jurisdictions.

j) the statement “Contains the equivalent of the quantity of dried cannabis, depending on the product format;

k) a clear indication of the product inside the container, that is not misleading to consumers;

l) a clear indication of the intended method of consumption of the product inside the container;

m) storage/handling conditions optimal to the shelf stability of product when not in use;

n) a list of cannabinoid or active and other ingredients (including potency and moisture content where appropriate).

6.11.5 Packaging labelling: Advertising

6.11.5.1 Advertising regarding any specific product shall be considered an extension of a product’s container and label, and therefore shall meet the requirements set forth in this document.

6.11.5.2 Advertising, generally, regarding a brand or the availability of any class of product shall be subject to the general requirement that it should be truthful and not misleading in any way.

6.11.5.3 The organization is responsible for its advertising, including traditional media, social media, and without limitation other forms of advertising to consumers, and shall ensure that all parties in a product’s supply chain advertise products in accord with principles of truthfulness, accuracy, and the other requirements of this document.

6.11.5.4 The organization shall establish and maintain documented information regarding advertising to establish traceability of advertising, and to ensure products are not inappropriately advertised to children or other vulnerable populations.

6.11.5.5 In the event a product is advertised by a third party, or advertisements are created by a third party, such third parties shall be bound to these same requirements by contract. Likewise, in the event that third parties are involved in the advertising or labelling of any product, such third parties shall enter into contracts such that clarity exists with respect to the party controlling and responsible for packaging.

6.11.5.6 Secondary packaging, tertiary packaging, dunnage packaging, and other packaging not intended for consumer purposes is outside the scope of these requirements.

6.11.5.7 Data related to the distribution or sale of cannabis products, including interactions with a product or brand in digital forums such as websites or social media platforms, shall be treated as personally-identifying information, entitled to relevant protections for sensitive and/or private data.

Annex A
(normative)

GPP for cannabis and cannabis product quality and safety

A.1 Construction and layout of buildings

A.1.1 General requirements

Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the cannabis and cannabis product operations to be carried out, the safety hazards associated with those operations, and the potential sources of contamination from the facility and its surroundings. Buildings shall be of durable construction which presents no hazard to the product.

EXAMPLE An example of durable construction is self-draining roofs which do not leak.

A.1.2 Environment

A.1.2.1 Consideration shall be given to potential sources of contamination from the local environment.

A.1.2.2 Cannabis and cannabis product operations should not be carried out in areas where potentially harmful substances could enter the product.

A.1.2.3 The effectiveness of measures taken to protect against potential contaminants shall be periodically reviewed.

A.1.3 Locations of establishments

A.1.3.1 The site boundaries shall be clearly identified.

A.1.3.2 Access to the site shall be controlled.

NOTE Additional information on the minimum level of protection and safety of occupants, and buildings or parts thereof, which are used for cannabis cultivation or the production of cannabis products can be found in IWA 37-1.

A.1.3.3 The site shall be maintained in good order. Vegetation shall be tended or removed. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

A.2 Layout of premises and workspace

A.2.1 General requirements

Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and production practices. The movement patterns of materials, products and people, and the layout of equipment, shall be designed to protect against potential contamination sources.

A.2.2 Internal design, layout and traffic patterns

A.2.2.1 The building shall provide adequate space, with a logical flow of materials, products and personnel, and physical separation of raw from processed areas.

NOTE Examples of physical separation include walls, barriers or partitions, or sufficient distance to minimize risk.

A.2.2.2 Openings intended for transfer of materials shall be designed to minimize entry of foreign matter and pests.

A.2.3 Internal structures and fittings

A.2.3.1 Process area walls and floors shall be washable or cleanable, as appropriate for the process or product hazard. Materials of construction shall be resistant to the cleaning system applied.

A.2.3.2 Wall floor junctions and corners shall be designed to facilitate cleaning. Wall floor junctions should be rounded in processing areas.

A.2.3.3 Floors shall be designed to avoid standing water.

A.2.3.4 In wet process areas, floors shall be sealed and drained. Drains shall be trapped and covered.

A.2.3.5 Ceilings and overhead fixtures shall be designed to minimize build-up of dirt and condensation.

A.2.3.6 External opening windows, roof vents or fan, where present, shall be insect screened.

A.2.3.7 External opening doors shall be closed or screened when not in use.

A.2.4 Drains and drainage

A.2.4.1 Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided.

A.2.4.2 Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over processing lines.

A.2.4.3 Drainage direction shall not flow from a contaminated area to a clean area.

A.2.5 Location of equipment

A.2.5.1 Equipment shall be designed and located so as to facilitate good hygiene practices and monitoring.

A.2.5.2 Equipment shall be located to permit access for operation, cleaning and maintenance.

A.2.6 Laboratory facilities

A.2.6.1 In-line and on-line test facilities shall be controlled to minimize risk of product contamination.

A.2.6.2 All laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production area.

A.2.7 Temporary or mobile premises

A.2.7.1 Temporary structures shall be designed, located and constructed to avoid pest harbourage and potential contamination of products.

A.2.7.2 Additional hazards associated with temporary structures shall be assessed and controlled. Temporary or mobile premises provided by external suppliers should be treated no differently from other parts of the organization's overall CQP and should be considered part of the facility.

A.3 Cultivation

A.3.1 The organization shall establish, implement and maintain GPP for the indoor cultivation of cannabis that are appropriate to the type of grow area (e.g. greenhouse, grow rooms) and the method of production (e.g. in soil/growing medium, hydroponic, aeroponic) to prevent contamination of the product and ensure product quality.

A.3.2 The GPP shall include documentation and justification for the selection, sourcing and application of, among others:

a) propagation materials;

b) growing media;

c) agronomic inputs (e.g. soil amendments, nutrients);

d) agricultural chemicals, including those for pest control;

e) biological controls;

f) compressed gases (e.g. carbon dioxide).

A.3.3 The GPP shall include documentation and justification for the selection, maintenance and cleaning of, amongst others:

a) equipment for growing (e.g. pots, trays, conveyances, sprayers);

b) workwear for personnel engaged in cultivation;

c) utensils used in growing (e.g. pruning).

A.3.4 The GPP shall include measures for the control of: temperature, humidity, light and other factors appropriate to the type of grow area and the method of production.

A.3.5 Personnel engaged in cultivation activities shall ensure that the materials and products are handled to prevent damage or product contamination.

A.3.6 Cannabis waste and other waste from the grow area shall be handled appropriately (see A.9.2).

A.3.7 Cultivation areas shall be inspected to remove risks from foreign materials (e.g. glass, brittle plastic, wood, etc.) during the cultivation period.

A.3.8 Access to the grow areas (e.g. greenhouses, grow rooms) shall be controlled.

A.3.9 Documented information on cultivation activities shall be retained.

NOTE Additional information on the minimum level of protection and safety of occupants, and buildings or parts thereof, which are used for the cultivation of cannabis can be found in IWA 37-1.

A.4 Harvesting

A.4.1 The organization shall establish, implement and maintain GPP for the harvesting of cannabis that are appropriate to the type of grow area and the method of production to prevent product contamination and ensure product quality.

A.4.2 The GPP shall include documentation and justification for the selection, maintenance and cleaning of:

a) workwear for personnel engaged in harvesting;

b) harvest containers;

c) harvest utensils (e.g. knives, cutting instruments);

d) other harvest equipment (e.g. cloths, towels, cleaning materials).

A.4.3 The GPP shall include documentation and justification for the handling of:

a) harvested product that has minimal processing (e.g. drying, curing, sorting, freezing);

b) damaged, culled or waste cannabis;

c) non-cannabis waste.

A.4.4 Pre-harvest intervals for agricultural chemicals shall be monitored and respected.

A.4.5 Grow areas shall be inspected to remove risks from foreign materials (e.g. glass, brittle plastic, wood, etc.) during the harvest.

A.4.6 Personnel engaged in harvesting activities shall ensure that the materials and products are handled to prevent damage or product contamination.

A.4.7 Documented information on harvesting activities shall be retained.

A.5 Utilities: Air, water, energy

A.5.1 General requirements

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities' quality shall be monitored to minimize product contamination risk.

A.5.2 Water supply

A.5.2.1 The supply of potable water shall be sufficient to meet the needs of the production process(es). Facilities for storage, distribution and, where needed, temperature control of the water shall be designed to meet specified water quality requirements.

A.5.2.2 Water used as a product ingredient, including ice or steam (including culinary steam), or in contact with products or product surfaces, shall meet specified quality and microbiological requirements relevant to the product.

A.5.2.3 Water for cleaning or applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application.

A.5.2.4 Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.

A.5.2.5 Non-potable water shall have a separate supply system that is labelled and not connected to the potable water system. Measures shall be taken to prevent non-potable water refluxing into the potable system. Water that can come into contact with the product should flow through pipes that can be disinfected.

A.5.3 Boiler chemicals

A.5.3.1 Boiler chemicals, if used, shall be either:

a) approved food additives which meet relevant additive specifications, or

b) additives which have been approved by the relevant regulatory authority as safe for use in water intended for human consumption.

A.5.3.2 Boiler chemicals shall be stored in a separate, secure (locked or otherwise access-controlled) area when not in immediate use.

A.5.4 Air quality and ventilation

A.5.4.1 The organization shall establish requirements for filtration, humidity (RH%) and microbiology of air used as an ingredient or for direct product contact. Where temperature and/or humidity are deemed critical by the organization, a control system shall be put in place and monitored.

A.5.4.2 The facility where cannabis that will be used as an ingredient is produced, packaged, labelled, stored or tested shall be equipped with a system that:

a) filters air to prevent the escape of odours associated with cannabis, cannabis derivatives or cannabis products to the outdoors;

b) provides natural or mechanical ventilation with sufficient air exchange to provide clean air and to remove unclean air in order to prevent the contamination, including microbiological, of cannabis products or of personnel;

c) designed to remove excess or unwanted steam, dust and odours, and to facilitate drying after wet cleaning;

d) designed and constructed such that air does not flow from contaminated or raw areas to clean areas.

A.5.4.3 Specified air pressure differentials shall be maintained. Systems shall be accessible for cleaning, filter changing and maintenance.

A.5.4.4 Protocols for air quality monitoring and control shall be established in areas where products which support the growth or survival of microorganisms are exposed.

A.5.4.5 Exterior air intake ports shall be examined periodically for physical integrity.

NOTE Additional guidance on air quality and ventilation of cannabis and cannabis product operations is given in IWA 37-1.

A.5.5 Compressed air and other gases

A.5.5.1 Compressed air, carbon dioxide, nitrogen and other gas systems used in cannabis production and/or filling shall be constructed and maintained so as to prevent contamination.

A.5.5.2 Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.

A.5.5.3 Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade.

A.5.5.4 Use of oil free compressors is recommended.

A.5.6 Lighting

A.5.6.1 Any light fixtures in the building or part of the building where the activities are conducted shall:

a) be capable of withstanding repeated cleaning and, if necessary, to prevent contamination of the cannabis or an ingredient, repeated sanitizing;

b) not present a risk of contamination of the cannabis or material that will be used as an ingredient or a packaging component in the event of breakage.

A.5.6.2 The intensity of the lighting should be appropriate to the nature of the operation and mode of production, taking into consideration storage conditions or exposure to air, heat or light or other conditions that might adversely affect the product or its packaging.

NOTE Additional guidance on lighting and fixtures related to cannabis and cannabis product operations is given in IWA 37-1.

A.6 Equipment suitability, cleaning and maintenance

A.6.1 General requirements

A.6.1.1 Product contact equipment shall be designed and constructed to facilitate cleaning, disinfection and maintenance.

A.6.1.2 Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

A.6.1.3 Product contact equipment shall be constructed of durable materials able to resist repeated cleaning.

NOTE Cannabis, cannabis derivatives and cannabis products can pose challenges where cannabis products are manufactured alongside conventional products (not containing cannabis or a cannabis derivative), especially where cannabis oils are used with equipment or utensils that are hard to clean. These challenges will affect decisions taken with respect to hygienic design (see A.6.2), product contact surfaces (see A.6.3), cleaning (see A.6.5) and maintenance (see A.6.6) of equipment and utensils.

A.6.2 Hygienic design

A.6.2.1 Equipment and any alterations to equipment shall meet established principles of hygienic design, including:

a) smooth, accessible, cleanable surfaces, self-draining in wet process areas;

b) use of materials compatible with intended products and cleaning or flushing agents;

c) framework not penetrated by holes or nuts and bolts.

A.6.2.2 Piping and ductwork shall be cleanable, drainable, and with no dead ends.

A.6.2.3 Equipment shall be designed to minimize contact between the operator's hands and the products.

A.6.3 Product contact surfaces

Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust or corrosion free.

A.6.4 Temperature control and monitoring equipment

A.6.4.1 Equipment used for thermal processes shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.

A.6.4.2 Equipment shall provide for the monitoring and control of the temperature.

A.6.5 Cleaning plant, utensils and equipment

A.6.5.1 Wet and dry cleaning programmes shall be documented to ensure that all facilities, utensils and equipment are cleaned at defined frequencies.

A.6.5.2 The programmes shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning [e.g. cleaning in place (CIP), cleaning out of place (COP)], the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning.

A.6.6 Preventive and corrective maintenance

A.6.6.1 A preventive maintenance programme shall be in place and documented information maintained.

A.6.6.2 The preventive maintenance programme shall include all devices used to monitor and/or control product safety hazards.

EXAMPLE Examples of such devices include screens and filters (including air filters), magnets, metal detectors and X-ray detectors.

A.6.6.3 Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

A.6.6.4 Maintenance requests which impact product quality or product safety shall be given priority.

A.6.6.5 Temporary fixes shall not put product quality or product safety at risk. A request for replacement by a permanent repair shall be included in the maintenance schedule.

A.6.6.6 Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.

A.6.6.7 The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, time period(s), where applicable, for holding clean equipment for sanitization effectiveness, and pre-use inspection.

A.6.6.8 Local area GPP requirements shall apply to maintenance areas and maintenance activities in process areas.

A.6.6.9 Maintenance personnel shall be trained in the product hazards associated with their activities.

A.7 Cleaning and sanitizing

A.7.1 General requirements

Cleaning and sanitizing programmes shall be established to ensure that the production and packaging equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

A.7.2 Cleaning and sanitizing agents and tools

A.7.2.1 Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.

A.7.2.2 Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade or generally recognized as safe (GRAS), stored separately and used only in accordance with the manufacturer's instructions.

A.7.2.3 Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter.

A.7.3 Cleaning and sanitizing programmes

A.7.3.1 Cleaning and sanitizing programmes shall be established, validated and documented information maintained by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.

A.7.3.2 Cleaning and/or sanitizing programmes shall specify at a minimum:

a) areas, items of equipment and utensils to be cleaned and/or sanitized;

b) responsibility for the tasks specified;

c) cleaning/sanitizing method and frequency;

d) monitoring and verification arrangements;

e) post-clean inspections;

f) pre start-up inspections.

A.7.4 Cleaning in place (CIP) systems

A.7.4.1 CIP systems shall be separated from active product lines.

A.7.4.2 Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

A.7.5 Monitoring sanitation effectiveness

Cleaning and sanitation programmes shall be monitored at frequencies specified by the organization to ensure their continuing suitability and effectiveness.

A.8 Personnel hygiene and employee facilities

A.8.1 General requirements

Requirements for personal hygiene and behaviours proportional to the hazard posed to the process area or product shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.

A.8.2 Personnel hygiene facilities and toilets

A.8.2.1 Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

A.8.2.2 Establishments shall:

a) provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash-basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer);

b) have sinks designated for hand washing, whose taps should not be hand operated, separate from sinks for food use and equipment-cleaning stations;

c) provide an adequate number of toilets of appropriate hygienic design, each with hand-washing, drying and, where required, sanitizing facilities;

d) have employee hygiene facilities that do not open directly on to production, packing or storage areas;

e) have adequate changing facilities for personnel;

f) have changing facilities sited to enable personnel handling product to move to the production area in such a way that risk to the cleanliness of workwear is minimized.

A.8.3 Staff canteens and designated eating areas

A.8.3.1 Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross-contamination of production areas is minimized.

A.8.3.2 Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods. Storage conditions and storage, cooking and holding temperatures, and time limitations, shall be specified.

A.8.3.3 Employees' own food shall be stored and consumed in designated areas only.

A.8.4 Workwear and protective clothing

A.8.4.1 Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).

A.8.4.2 Clothing necessary for the prevention of the contamination of product or hygiene purposes shall not be used for any other purpose.

A.8.4.3 Workwear shall not have buttons. Workwear shall not have outside pockets above waist level. Zips or press stud fastenings are acceptable.

A.8.4.4 Workwear shall be laundered to standards and at intervals suitable for the intended use of the garments.

A.8.4.5 Workwear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.

A.8.4.6 Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints unless risk assessment/hazard analysis indicates otherwise.

A.8.4.7 Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves should be avoided where possible.

A.8.4.8 Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.

A.8.4.9 Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

NOTE Additional information on personal protective equipment (PPE) can be found in ISO 45001 and in the related ISO Handbook.

A.8.5 Health status

A.8.5.1 Employees shall undergo a medical examination prior to employment in product contact operations (including site catering) unless documented hazard or medical assessment indicates otherwise.

NOTE Legal requirements can apply.

A.8.5.2 Additional medical examinations, where permitted, shall be carried out at intervals defined by the organization.

A.8.6 Illness and injuries

A.8.6.1 Employees shall be required to report the following conditions to management for possible exclusion from product-handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.

NOTE Legal requirements can apply.

A.8.6.2 People known or suspected to be infected with, or carrying, a disease or illness transmissible through products shall be prevented from handling product or materials which come into contact with product.

A.8.6.3 In product-handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately. Dressings should be brightly coloured and metal detectable where appropriate.

A.8.7 Personal cleanliness

A.8.7.1 Personnel in production areas shall be required to wash and, where required, sanitize hands:

a) before starting any product-handling activities;

b) immediately after using the toilet or blowing the nose;

c) immediately after handling any potentially contaminated material.

A.8.7.2 Personnel shall be required to refrain from sneezing or coughing over materials or products. Spitting (expectorating) shall be prohibited.

A.8.7.3 Fingernails shall be kept clean and trimmed.

A.8.8 Personal behaviour

A.8.8.1 A documented policy shall describe the behaviours required of personnel in processing, packing and storage areas. The policy shall at a minimum cover:

a) permissibility of smoking, eating, chewing in designated areas only;

b) control measures to minimize hazards presented by permitted jewellery, such as that worn by personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives;

c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;

d) prohibition of the use of nail polish, false nails and false eyelashes;

e) prohibition of carrying of writing implements behind the ears;

f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;

g) prohibition of storage of product contact tools and equipment in personal lockers;

h) control measures to minimize impact to quality of applicable products (e.g. cosmetics) by individual fragrances and makeup worn by personnel in processing and packaging areas;

i) consumption of cannabis, cannabis edibles or any other cannabis product while at work.

NOTE Statutory and regulatory requirements with respect to the medical use of cannabis can vary between jurisdictions.

A.8.8.2 Where the organization conducts research and development of cannabis products using personnel to undertake sensory testing activities, the organization shall have a protocol to address health and safety issues. The protocol should be reviewed by a competent third-party ethical research and scientific advisory organization.

NOTE Further information on research practices using human subjects can be found in ISO 14155.

A.9 Waste disposal

A.9.1 General requirements

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

A.9.2 Cannabis waste

A.9.2.1 A segregated system shall be in place to ensure that cannabis waste materials, including cannabis ingredients (e.g. cannabis and cannabis derivatives) and cannabis products (e.g. nonconforming product, recalled product, rejected product and returns) are disposed of in a manner that prevents their reuse in any cannabis product and meets any statutory and regulatory requirements.

A.9.2.2 The segregated system shall include containers (see A.9.3), waste management, including storage, and removal (see A.9.4) and drains and drainage (see A.2.4).

A.9.2.3 Cannabis waste materials shall be included in the organization's traceability system (see 6.10) and be accounted for through reconciliation (see 6.10.6).

A.9.3 Containers for waste or hazardous substances

Containers for waste or hazardous substances shall be:

a) clearly identified for their intended purpose;

b) located in a designated area;

c) constructed of impervious material which can be readily cleaned and sanitized;

d) closed when not in immediate use;

e) locked where the waste can pose a risk to the product.

A.9.4 Waste management and removal

A.9.4.1 Provision shall be made for the segregation, storage and removal of waste.

A.9.4.2 Accumulation of waste shall not be allowed in product-handling or storage areas.

A.9.4.3 Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal.

A.9.4.4 Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused.

A.9.4.5 Removal and destruction shall be carried out by approved disposal contractors.

A.9.4.6 The organization shall retain documented information regarding destruction.

A.10 Pest control

A.10.1 General requirements

Hygiene, cleaning, incoming materials inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.

A.10.2 Pest control programmes

A.10.2.1 The organization shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.

A.10.2.2 Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements.

A.10.2.3 Programmes shall include a list of chemicals which are approved for use in specified areas of the establishment.

A.10.3 Preventing access

A.10.3.1 Buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.

A.10.3.2 External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

A.10.4 Harbourage and infestations

A.10.4.1 Storage practices shall be designed to minimize the availability of food and water to pests.

A.10.4.2 Material found to be infested shall be handled in such a way as to prevent contamination of other materials, products or the establishment.

A.10.4.3 Potential pest harbourage (e.g. burrows, undergrowth, stored items) shall be removed.

A.10.4.4 Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).

A.10.5 Monitoring and detection

A.10.5.1 Pest-monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

A.10.5.2 Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.

A.10.5.3 The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analysed to identify trends.

A.10.6 Eradication

A.10.6.1 Eradication measures shall be put in place immediately after evidence of infestation is reported.

A.10.6.2 Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product quality or product safety hazards.

A.10.6.3 Documented information of pesticide use shall be maintained to show the type, quantity and concentrations used, where, when and how applied, and the target pest.

A.11 Management of purchased materials

A.11.1 General requirements

Purchasing of materials which impact product safety or quality shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified and documented information maintained.

A.11.2 Selection and management of suppliers

A.11.2.1 There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include:

a) assessment of the supplier's ability to meet quality and product safety expectations, requirements and specifications;

NOTE 1 Organizations can encourage suppliers of cannabis or cannabis derivatives or cannabis products to have in place a CQP developed using this document or equivalent.

b) description of how suppliers are assessed;

EXAMPLE Examples of a description of how suppliers are assessed include auditing the supplying site prior to accepting materials for production, and appropriate third-party certification.

c) monitoring the performance of the supplier to ensure continued approval status;

NOTE 2 Monitoring includes conformity with material or product specifications, fulfilment of Certification of Approval (COA) requirements, satisfactory audit outcomes.

d) determination of the validity of the supplier's licence(s), if required, for the production of cannabis or cannabis derivatives or cannabis products.

A.11.2.2 There shall be a defined process for the selection, approval and monitoring of suppliers during an emergency.

A.11.2.3 The organization shall establish, implement, and maintain a review process for product specifications to ensure continued compliance with product quality, product safety and legal and customer requirements.

A.11.3 Incoming material requirements (raw/ingredients/packaging)

A.11.3.1 Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. integrity of seals, freedom from infestation, existence of temperature documented information).

A.11.3.2 Materials shall be covered by a COA or documentation demonstrating conformity with specified requirements prior to acceptance or use.

A.11.3.3 There shall be a programme for collecting representative samples from each batch of materials (ingredients, packaging, labels) to determine if the materials meet specifications established. The method of verification shall be documented.

NOTE The inspection frequency and scope can be based on the hazard presented by the material and the risk assessment of the specific suppliers.

Materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use.

A.11.3.4 Stored materials such as ingredients, packaging and packaging containers shall be retested or re-examined after a specified time in storage or after exposure to adverse conditions to ensure the components continue to meet their established specifications.

A.11.3.5 Access points to bulk material receiving lines shall be identified, capped and locked. Discharge into such systems shall take place only after approval and verification of the material to be received.

A.12 Warehousing

A.12.1 General requirements

Materials and products shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

NOTE Additional information on the secure handling of cannabis, cannabis derivatives and cannabis edibles can be found in IWA 37-2.

A.12.2 Warehousing requirements

A.12.2.1 Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by product or storage specifications.

A.12.2.2 Ingredients that present a risk of injury to human health are identified as such and are stored in a designated area within the facility. Where products are stacked, measures should be taken to protect the lower layers.

A.12.2.3 Waste materials and chemicals (e.g. cleaning products, lubricants, and pesticides) shall be stored separately.

A.12.2.4 A separate area or other means of segregating materials identified as non-conforming shall be provided.

A.12.2.5 Specified stock rotation systems "first in, first out" (FIFO) and "first to expire, first out" (FEFO) shall be observed.

A.12.2.6 Gasoline- or diesel-powered fork-lift trucks shall not be used in ingredient or product storage areas.

A.12.2.7 The organization responsible for processing shall ensure that anything that will be, or was intended to be, used as an ingredient that presents a risk of injury to human health is identified as such, and is stored in a designated area within the facility.

A.12.3 Vehicles, conveyances, and containers

A.12.3.1 Vehicles, conveyances, and containers shall be maintained in a state of repair, cleanliness, and condition consistent with requirements given in relevant specifications.

A.12.3.2 Vehicles, conveyances, and containers shall provide protection against damage or contamination of the product.

A.12.3.3 Control of temperature and humidity shall be applied and recorded where required by the organization.

A.12.3.4 Where the same vehicles, conveyances, and containers are used, cleaning shall be carried out between loads.

A.12.3.5 Bulk containers shall be dedicated to product use only. Where required by the organization, bulk containers shall be dedicated to a specified material.

A.12.4 Cannabis warehousing requirements

A.12.4.1 Incoming cannabis and cannabis derivatives shall be stored separately from other incoming ingredients and access to the storage area shall be controlled.

A.12.4.2 Cannabis products shall be stored separately from other end products and access to the storage area shall be controlled.

A.12.4.3 Incoming cannabis and cannabis derivatives and outgoing cannabis products shall be transported by authorized parties in a manner that maintains their quality prior to and during transportation.

NOTE 1 Statutory and regulatory requirements can apply.

NOTE 2 Additional information on the secure handling of cannabis, cannabis derivatives and cannabis edibles can be found in IWA 37-2.

A.13 Measures for prevention of cross contamination

A.13.1 General requirements

Programmes shall be in place to prevent, control and detect contamination. Measures to prevent physical, chemical, allergen and microbiological contamination shall be included.

A.13.2 Microbiological cross-contamination

Areas where potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented. A hazard assessment shall be carried out to determine potential contamination sources, susceptibility of the product and control measures suitable for these areas as follows:

a) separation of raw from in-process and finished products;

b) structural segregation — physical barriers, walls or separate buildings;

c) access controls with requirements to change into required workwear;

d) traffic patterns or equipment segregation — people, materials, equipment and tools (including use of dedicated tools);

e) air pressure differentials.

A.13.3 Allergen management

A.13.3.1 Allergens present in the product, either by design or by potential manufacturing cross-contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.

A.13.3.2 Products shall be protected from unintended allergen cross-contact by cleaning and line change-over practices and/or product sequencing.

NOTE Manufacturing cross-contact can arise from either:

— traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations, or

— when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

A.13.3.3 Rework containing allergen(s) shall be used only:

a) in products which contain the same allergen(s) by design, or

b) through a process which is demonstrated to remove or destroy the allergenic material.

NOTE Additional information regarding rework requirements is given in A.14.

A.13.3.4 Employees handling product should receive specific training in allergen awareness and associated manufacturing practices.

A.13.4 Physical contamination

A.13.4.1 Where brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.

A.13.4.2 Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible.

A.13.4.3 Glass breakage documented information shall be maintained.

A.13.4.4 Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.

NOTE 1 Examples of such measures include:

— adequate covers over equipment or containers for exposed materials or products;

— use of screens, magnets, sieves or filters; or

— use of detection or rejection devices such as metal detectors or X-ray.

NOTE 2 Sources of potential contamination include wooden pallets and tools, rubber seals, and personal protective clothing and equipment.

A.13.5 Chemical contamination

A.13.5.1 Chemicals, including cleaning materials and lubricants, shall be evaluated and controlled to prevent product/material contamination.

A.13.5.2 Additional methods for controlling chemical contamination include:

a) controlled and authorized access to approved chemicals;

b) concentration of cleaning and disinfection materials;

c) chemicals suitable for the use.

A.13.6 Cannabis management (contamination)

A.13.6.1 Products shall be protected from unintended cross-contact with cannabis or cannabis derivatives, or cannabis products.

NOTE Manufacturing cross-contact can arise from either:

— traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations, or

— when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

A.13.6.2 Areas where potential for cross-contamination by cannabis or cannabis derivatives or cannabis products exists shall be identified.

A.13.6.3 A hazard assessment shall be carried out to determine potential contamination sources, susceptibility of the product and control measures suitable for these areas as follows:

a) separation of cannabis production from other production;

b) structural segregation — physical barriers, walls or separate buildings;

c) access controls with requirements to change into required workwear;

d) traffic patterns or equipment segregation — people, materials, equipment and tools (including use of dedicated tools);

e) cleaning and line change-over practices and/or product sequencing;

f) air pressure differentials;

g) rework containing cannabis, cannabis derivatives or cannabis products shall be used only:

   1) in products which contain the same cannabis derivatives or cannabis products by design, or

   2) through a process which is demonstrated to remove or destroy the cannabis material.

A.13.6.4 Cannabis derivatives present in the product, either by design or by potential manufacturing cross-contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.

A.14 Rework

A.14.1 General requirements

Rework shall be stored, handled and used in such a way that product safety, quality and traceability are maintained.

NOTE Regulatory requirements can apply.

A.14.2 Storage, identification and traceability

A.14.2.1 Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination.

A.14.2.2 Segregation requirements for rework (e.g. allergen) shall be documented and met.

A.14.2.3 Rework shall be clearly identified and/or labelled to allow traceability. Traceability documented information for rework shall be maintained.

A.14.2.4 The rework classification or the reason for rework designation shall be documented (e.g. product name, production date, shift, line of origin, shelf-life).

A.14.3 Rework usage

A.14.3.1 Where rework is incorporated into a product as an "in-process" step, the acceptable quantity, type and conditions of rework use shall be specified. The process step and method of addition, including any necessary pre-processing stages, shall be defined.

A.14.3.2 Where rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

A.15 Product defence, biovigilance and bioterrorism

A.15.1 General requirements

The organization shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

A.15.2 Access controls

A.15.2.1 Potentially sensitive areas within the establishment shall be identified, mapped, and subjected to access control.

A.15.2.2 Where feasible, access should be physically restricted by use of locks, electronic card key or alternative systems.

NOTE Additional guidance on access controls related to cannabis and cannabis product operations is given in IWA 37-2.

A.16 Product fraud and intentional adulteration

A.16.1 The organization shall undertake a product fraud vulnerability assessment to identify potential vulnerability, including economically motivated adulteration and to identify and prioritise product fraud mitigation measures.

A.16.2 The organization shall establish, implement and maintain a product fraud plan to mitigate the product and public health and any organizational risks from the identified product fraud vulnerabilities.

A.16.3 The organization shall retain appropriate documented information.

A.17 Selection and management of customers

A.17.1 There shall be a defined process for the selection, approval and monitoring of customers.

A.17.2 The process used shall be justified by a risk assessment and shall include:

a) an assessment of the customers' ability to meet statutory and regulatory requirements (including licensing if required) and the organization's security, quality and product safety expectations;

b) a description of how customers are assessed.