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Safety, security and sustainability of cannabis facilities and operations —

Part 3: Good production practices (GPP)

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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.

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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.

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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).

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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;

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— 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/

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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.

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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]

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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.

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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]

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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]

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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.]

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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;

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— 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, handing 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.

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