# CANNABIS AUTHENTICITY AND PURITY STANDARD

Issue 1.1

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# Disclaimer

This document draws on principles and concepts generated either within Purity-IQ or from other sources, particularly those presented by Health Canada through its *Good Production Practices Guide for Cannabis – Requirements* under Part 5 of the Cannabis Regulations (August 29, 2019). The Cannabis Authenticity and Purity Standard is not intended to be a complete representation of that guide or any other input but is a weighted synthesis of selected ideas, experiences, and judgment from stakeholders who freely offered them.

The information in this document is not intended to be a representation of, substitute for, or supersede/limit the requirements that may apply under any government policy or legislation where cannabis is grown, handled, manufactured, or sold. In the event of discrepancy between the legislation and this document, the legislation should be considered to prevail. Client sites are advised to consult local, regional, or national legislation that may apply to them or their activities. For those sites operating within or importing into Canada, Purity-IQ highly recommends contacting Health Canada directly.

As a research, development, and standards service organization, Purity-IQ does not in any way, shape, or form engage in the production, growing, extraction, regulated analytical testing, or the sale of any cannabis-related products or paraphernalia.

This document may be supplemented from time to time through technical releases which the reader can access at **www.caps-cert.com**.

# Contributions

Purity-IQ recognizes volunteers of the CAPS Steering Committee and CAPS Technical Working Group who contributed to the Cannabis Authenticity and Purity Standard Issue 1.0, and is grateful for their professional industry contribution.

AgMedica Bioscience Inc.

American National Accreditation Board (ANAB)

Aphria Inc.

Aqualitas Inc.

Bruker Ltd

Canfolia Consulting Inc.

Cannabinerd Consulting

Canndeo Fulfillment Services

Cardiol Therapeutics Inc.

CASiGrow Cadence Agricultural Systems Inc.

CLIP Labs

Conagra Brands Inc.

Eramosa Management Services Inc.

Flowr Corp.

Folium Biosciences
Global Cannabis Applications Corp.
Gold Leaf Standard
GS1 Canada
HACCP Mentor
High North Inc.
Kannt SAS/CanBio LLC
Klair Total Quality Management Solutions
Gerald Kok
Lighthouse Genomics
Loblaw Brands Ltd
Qualium Consulting
R-Biopharm Inc.
S. Audino & Associates LLC
Safe Food En Route LLC
Safe Quality Food Institute
SCS Consulting
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Health Canada: *Good Production Practices Guide For Cannabis*
**https://www.canada.ca/content/dam/hc-sc/documents/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document/good-production-practices-guide-for-cannabis-2019-10.pdf**

Purity-IQ wishes to commend Health Canada on its leadership role in Canada and its global influence with respect to the regulation of cannabis and cannabis products. As a world leader and recognized regulatory competent authority in the cannabis sector, the tools and guidance documents provided by Health Canada, such as its *Good Production Practices Guide for Cannabis – Requirements under Part 5 of the Cannabis Regulations* (August 29, 2019), were extremely valuable in the consultative process and development of the Cannabis Authenticity and Purity Standard, Issue 1.0.

Finally, Purity-IQ thanks Bruker for kindly supplying the image on page 6.

# Contents

# Introduction

CAPS is designed to consider all GMP, GAP, and risk management requirements for cannabis and hemp, so that these products can be consistently produced, packaged, labelled, distributed, stored, sampled, and tested before being sold

# 1. Purpose

To provide the requirements for conformity to the Cannabis Authenticity and Purity Standard (CAPS), whereby applicants and holders of a licence and certificate of recognition under the auspices of Purity-IQ can develop and implement an authenticity and identity management system (AIMS), in which good manufacturing practices (GMPs), good agricultural practices (GAPs), and risk management programs are documented, verifiable, validated, and proven to be effective.

CAPS is designed to consider all GMP, GAP, and risk management requirements for cannabis and hemp, so that these products can be consistently produced, packaged, labelled, distributed, stored, sampled, and tested before being sold in any market, either domestic or foreign. These requirements shall apply to all licence holders, regardless of whether they are prescribed by regulation or self-imposed to meet internal corporate objectives.

# 2. Background

There is no global consistency with respect to the regulations (i.e. for quality, authenticity, and identity) that control the legal access to cannabis and/or its production, distribution, and sale. However, there can be a private standard, such as CAPS, that evolves from a consensus among stakeholders and includes the attributes or requirements demanded by regulatory authorities.

CAPS addresses GMPs, GAPs, and risk management programs required for site certification through **CAPS-Basic** and as a prerequisite for establishing product authenticity and purity when also applying for **CAPS-Advanced** product certification. If designed correctly and implemented diligently, CAPS certification will ensure that cannabis/hemp products leaving a site meet the safety and quality standards appropriate to their intended use and/or the declared registered cultivar or product (see Figure 1 for the levels on which CAPS is built).

These standards and other requirements may also be backed by compliance and enforcement measures delivered by the designated regulatory authorities, including unannounced inspections whereby inspectors verify adherence to specific regulations at sites where the products are produced or sold. CAPS intends to build on these requirements where they exist, and not to duplicate them. CAPS-Advanced will add authenticity and purity requirements that can be objectively measured by Purity-IQ-licensed laboratories and approved third-party auditors. This affords a greater opportunity to combine or integrate CAPS audits with those of other standards to drive operational efficiencies and lower costs to users of this standard.

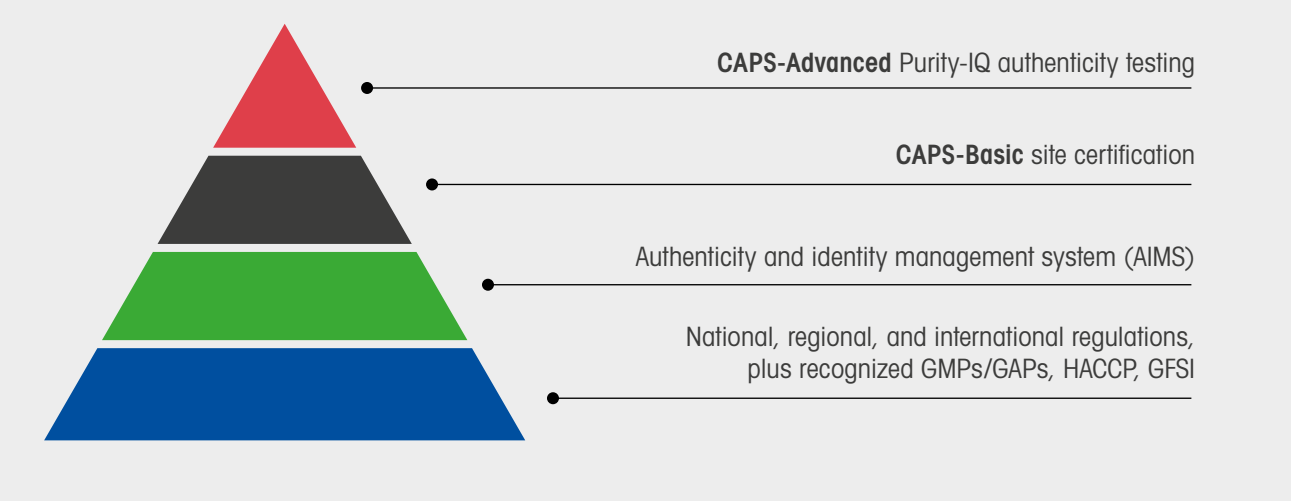



**Figure 1 Certification through CAPS**

CAPS is intended to be science- and outcome-based to allow for flexibility in approach, and not be unnecessarily prescriptive. It is also a voluntary standard and not required by legislation. However, CAPS can contribute and provide support to achieving a site's regulatory and risk-based objectives.

The knowledge and science of cannabis/hemp and the relevant testing requirements are advancing rapidly. The services rendered by Purity-IQ are intended to meet the needs of all stakeholders in the cannabis/hemp industry. They are not intended to duplicate regulators' testing needs, but to complement them. However, Purity-IQ provides an opportunity to those companies that voluntarily participate in and conform to the requirements of CAPS, not only to access its unique, leading-edge testing services, including the use of Purity-IQ-licensed laboratories, but also (through the use of the CAPS logo or "trust-mark") to market their unique cannabis/hemp products that have achieved the maximum degree of due diligence.

The advantages of CAPS-Advanced authenticity testing are that it will:

- establish genomic identity through genovar iris identification of the propagation materials (i.e. mother plants, clones) representing a cultivar
- verify that the specific clones grown in bulk genetically match the correct source material (e.g. mother plant)
- capture a unique chemical fingerprint of the metabolomic diversity for all cannabis cultivars in a standard registry
- assemble fingerprint variants within different commercial products manufactured from specific cultivars.

Breeders and growers have developed cultivars that have distinct metabolites that can be profiled like fingerprints and registered in the Purity-IQ Global Registry – Cannabis

Cannabis clones are grown in large quantities for commercial purposes. Good manufacturing and agricultural practices require the cultivars of clones to be authentic. The DNA-based genovar iris identification test method uses a sequencing and genotyping DNA chip array technology in which 40,000 single nucleotide polymorphisms (SNPs) are used to identify similarity in populations.

Cannabis metabolomic fingerprints capture the unique expression of plant metabolites produced in different conditions by specific cultivars. The metabolomic fingerprint method utilizes innovative nuclear magnetic resonance (NMR) with a cryoprobe and high-throughput sample changer. Breeders and growers have developed cultivars that have distinct metabolites that can be profiled like fingerprints and registered in the Purity-IQ Global Registry – Cannabis.

Purity-IQ's Global Registry – Cannabis includes genovar iris identifications and metabolomic fingerprints for all cultivars, providing a model for verifying cannabis cultivars throughout a supply chain. Metabolomic fingerprints can be assembled for extracts, including oils and finished products such as edibles. This provides a verification for cultivar identity and purity in support of quality assurance programs, GMPs and GAPs. Similarly, discernible metabolomic fingerprints among different batches of a cannabis crop provide assurance of consistent and efficacious products demanded by consumers.

Supply chain verification and product purity validation help to safeguard brands from adulteration and counterfeiting. Detailed assessment of metabolomic fingerprints could eventually enable brand owners to identify unwanted metabolites and screen them from their products. This enables the provision of safe and effective cannabis products for consumers seeking healthy lifestyles.

Testing requirements will be based on risk and the need for verification and validation within the AIMS, together with any extracurricular services that sites may request.

To the extent of its resources, Purity-IQ will provide technical, regulatory, and scientific support, along with guidance, to sites to help them meet the requirements of CAPS efficiently and effectively. Purity-IQ will provide consistency and transparency in its actions and consult with its stakeholders before making any significant changes to CAPS, its policies, or its operations.

# 3. Site certification process

Producers and manufacturers will be evaluated and audited by a third-party certification body (CB) licensed by Purity-IQ. Audits will evaluate conformity to CAPS and any deficiencies in the application and use of general best practices within the site's AIMS, with the expectation that conformity can be met consistently.

Upon recognition, sites and/or brand owners will be licensed to use and apply the appropriate CAPS logos.

Successful applicants to CAPS that become licensed by Purity-IQ and recognized under CAPS, as well as maintaining conformity to the CAPS requirements, will have access to all the benefits of CAPS. However, should a licence holder or duly recognized site fall out of conformity with the requirements of CAPS, Purity-IQ will fairly and responsibly implement measures to maintain the integrity and trust of its stakeholders and clients, such as:

- issuing a warning letter
- collecting and testing samples at any point in the supply chain
- directing the conduct of an unannounced audit of a site, including the assembly and review of any information or documents
- refusing, suspending, or revoking a licence and/or recognition
- taking other measures that Purity-IQ deems appropriate.

# 4. Scope

CAPS pertains to activities that include, but are not limited to, production, packaging, labelling, distribution, storage, sampling, and testing conducted by CAPS-recognized sites, and monitoring the level of conformity with the requirements as set out in CAPS.

CAPS pertains to activities that include, but are not limited to, production, packaging, labelling, distribution, storage, sampling, and testing conducted by CAPS-recognized sites

Classification of production and product scopes applicable to CAPS includes:

- propagation: cannabis plant seeds, products of micropropagation, transplants
- cultivation: cannabis plants, including mother plants and clones, to harvested products
- manufacturing: ingredients (either dry form or extracts)
- manufacturing consumer products: topicals (e.g. cosmetics), ingestibles (e.g. edible foods, extracts), devices (e.g. loaded vape pens), and dried loose or pre-rolled cannabis.

In accordance with CAPS, the requirements are broken down as follows:

- **Part I – Cannabis Authenticity and Purity Standard – Basic requirements**

  General, good manufacturing and agricultural practices, risk management, system verification, and testing requirements that must be met by the holder of a licence or certificate of recognition under CAPS for processing in order to sell, distribute, or export cannabis.


Applies to cannabis/hemp, including all classes of cannabis/hemp, and all cannabis/hemp products of those classes, including ingredients or inputs that are to be sold, distributed, or exported by a recognized site.

- **Part II – Cannabis Authenticity and Purity Standard – Advanced requirements**

  To attain and hold a certificate of recognition for CAPS-Advanced, the site must conform to Parts I and II of CAPS.

  CAPS-Basic, CAPS-Advanced risk management, and authenticity testing requirements that must be met by the holder of a licence or certificate of recognition under CAPS-Advanced for processing in order to sell, distribute, or export cannabis.

  Applies to all forms of cannabis/hemp, such as dried cannabis/hemp, fresh cannabis/hemp (including mother plants and clones), edible cannabis, cannabis extracts, and cannabis/hemp topicals.

- **Part III – Appendices**

  Additional information on added requirements outlined in other sections of CAPS.

# 5. Definitions and abbreviations

## 5.1 Definitions

Some of the following definitions may appear in regulatory statutes and are essential to understanding CAPS.

### ACCEPTABLE LEVEL

A level of a biological, chemical, or physical hazard that does not present a risk of contamination of the cannabis or any item that will be used as an ingredient or input.

### ACCREDITATION BODY

An organization that provides endorsement of a conformity assessment body's competence, credibility, independence, and integrity in carrying out its conformity assessment activities.

### ADVERSE REACTION
A noxious and unintended response to a cannabis product.

### AGRONOMIC INPUT
An input that is used in the growing of cannabis or an ingredient, and includes agricultural chemicals, biological controls, pollinators, commercial fertilizers, compost, compost tea, green manure, manure, mulch, row covers, soil amendments, and pulp sludge.

### ALLERGEN
Any protein, or modified protein, including any protein fraction or any other substance that has been identified as an allergen by a regulatory authority where the product is sold; examples of allergens include fish, peanuts, and egg.

### AUDITOR
A CAPS-certified auditor who has been appointed to verify and document evidence of conformance and non-conformance, and to write comprehensive reports on audit findings.

### AUTHENTICITY
The consistent achievement of quantitative measurements through analysis of specific compounds and genomic patterns using nuclear magnetic resonance spectroscopy and DNA extraction techniques that are unique to Purity-IQ.

### AUTHENTICITY AND IDENTITY MANAGEMENT SYSTEM (AIMS)
The documented result of a systematic approach to identifying and assessing the potential for failure to achieve specific parameters (e.g. established critical limits) and the risks associated during production; and to defining the means of their control using standard operating procedures (SOPs) for monitoring, management of deviations, testing, verification, validation, and record-keeping.

### BLENDED PRODUCTS
Cannabis products created by intentionally blending multiple cannabis sources and/or non-cannabis ingredients or inputs together.

### BRAND LICENCE AGREEMENT
The terms and conditions for the use of Purity-IQ logos, agreed between the brand owner and Purity-IQ.

### BULK CANNABIS
Any cannabis that has not yet been packaged as a cannabis product.

### CANNABINOID
Any of a group of closely related cannabis compounds, which include cannabinol and the active constituents of cannabis.

**Authenticity**

The consistent achievement of quantitative measurements through analysis of specific compounds and genomic patterns using nuclear magnetic resonance spectroscopy and DNA extraction techniques that are unique to Purity-IQ

**Cannabis product**

Cannabis of only one of the classes set out in CAPS, or a cannabis accessory if that accessory contains such cannabis after it has been packaged and labelled for sale. It may include cannabis intended for an animal, a cannabis accessory containing cannabis that is intended for an animal, or a drug containing cannabis

## CANNABIS

Cannabis can be defined as:

- any part of a cannabis plant (i.e. genus *Cannabis*), including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed
- any substance or mixture of substances that contains or has on it any part of such a plant
- any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained.

## CANNABIS EXTRACT

Cannabis extract can be:

- a substance produced by:
  - subjecting any cannabis component to an extraction process, or
  - synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant
- a substance or mixture of substances that contains a substance produced by subjecting any cannabis component to an extraction process, as referred to above.

## CANNABIS PLANT

A plant that belongs to the genus *Cannabis*.

## CANNABIS PLANT SEED

A seed of a cannabis plant.

## CANNABIS PRODUCT

Cannabis of only one of the classes set out in CAPS, or a cannabis accessory if that accessory contains such cannabis after it has been packaged and labelled for sale. It may include cannabis intended for an animal, a cannabis accessory containing cannabis that is intended for an animal, or a drug containing cannabis.

## CANNABIS PRODUCTION

Obtaining cannabis by any method or process, including by:

- manufacturing/processing
- synthesis
- altering its chemical or physical properties by any means
- cultivating, propagating, or harvesting it or any living thing from which it may be extracted or otherwise obtained.

### CANNABIS TOPICAL
A substance or mixture of natural or synthetic cannabis substances that is intended for exclusive use, directly or indirectly, on external body surfaces, including hair and nails.

### CERTIFICATE OF ANALYSIS
A summary of test results, including the test methods, specification parameters, and review and approval by authorized personnel.

### CERTIFICATE OF AUTHENTICITY
A certificate summarizing the test results of a registered product's quantitative measurement of batch-to-batch consistency through analysis of specific compounds, as established in Purity-IQ's Global Registry – Cannabis.

### CERTIFICATE OF RECOGNITION
Official recognition certificate given to a site that conforms to CAPS.

### CERTIFICATION BODY
An entity that is licensed by Purity-IQ to provide and manage auditing services and is ISO/IEC 17065-accredited by an IAF/ILAC-recognized ISO/IEC 17011 signatory.

### CHAIN OF CUSTODY
The chronological documentation or paper trail that records the sequence of custody, control, transfer, analysis, and disposition (e.g. traceability from origin to consumer).

### CLASS OF CANNABIS
Any one of the types of products, such as, but not limited to, dried cannabis, fresh cannabis, cannabis plants, cannabis plant seeds, edible cannabis, cannabis extracts, and cannabis topicals.

### CLONE
A plant that is an exact genomic reproduction of an original source plant, obtained by any method, including vegetative cuttings or tissue culture methods.

### CONFIDENCE INTERVAL
A measurement of the variation in the metabolite profile of the registered cultivar or product samples for a specific product matrix.

### CONFORMITY
The resulting assessment of the evidence found in documentation and/or employee actions at a site or brand owner that is in accordance with CAPS.

### CONSISTENCY
Reproducible achievement of quantitative results.

**Certificate of authenticity**

A certificate summarizing the test results of a registered product's quantitative measurement of batch-to-batch consistency through analysis of specific compounds, as established in Purity-IQ's Global Registry – Cannabis

**Cultivar**

An assemblage of plants selected for specific characteristics that are maintained during propagation (cultivated variety)

### CONTAMINATED
A cannabis accessory, or an ingredient or input, containing or having on it anything (including any micro-organism or physical, biological, or chemical compound) that may render it injurious to human health or unsuitable for human use, or otherwise out of intended specification or outcome as established within the GMPs/GAPs at the recognized site.

### CONTAMINATED MATERIALS
Wastes or other materials exposed to or tainted by physical, chemical, allergenic, radiological, or biological substances or agents.

### CONTROL MEASURE
A procedure or set of procedures that can be applied to prevent or eliminate:

- any biological, chemical, or physical hazard, or
- a failure in an intended outcome that creates a risk of contamination or the risk of failing to attain a specific specification of the cannabis or any item that will be used as an ingredient or input, or to reduce the hazard to an acceptable level.

### CONVEYANCE
Any item or equipment used to transport cannabis, ingredients, or inputs within the site.

### CRITICAL CONTROL POINT
A step at which it is essential to apply a control measure to prevent or eliminate the hazard or risk in question.

### CULTIVAR
An assemblage of plants selected for specific characteristics that are maintained during propagation (cultivated variety).

### DNA – DEOXYRIBONUCLEIC ACID
A molecule composed of two polynucleotide chains that coil around each other to form a double helix carrying genetic instructions for the development, functioning, growth, and reproduction of all known organisms and many viruses.

### DRIED CANNABIS
Any part of a cannabis plant that has been subjected to a drying process, other than seeds.

### DRUG
Includes any substance or mixture of substances manufactured, sold, or represented for use in any of the following:

- the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals

- restoring, correcting, or modifying organic functions in human beings or animals
- disinfection in premises in which food is manufactured, prepared, or kept.

### EDIBLE CANNABIS
A substance or mixture of substances that contains cannabis or has on it anything referred to as cannabis, and that is intended to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants, or cannabis plant seeds.

### EQUIPMENT
A set of tools or objects used to achieve a particular objective, including conveyances, utensils, pruning shears, pots, trays, extractors, beakers, forklifts, hand lifts, etc.

### EXTRANEOUS SUBSTANCES
Unintentional or dangerous solid materials that could end up in a final cannabis product and place it out of specification, such as personal objects (e.g. jewellery, parts of clothing), structural objects (e.g. glass and metal fragments), or other material from insect, animal, or plant sources, either whole or parts thereof (e.g. hair, bones, leaves, seeds).

### FINAL PRODUCT
The product that emerges at the end of a manufacturing process, ready for sale.

### FOOD
Any article manufactured, sold, or represented for use as food or drink for human beings. Also includes chewing gum, and any ingredient or input that may be mixed with food for any purpose whatsoever.

### FRESH CANNABIS
Freshly harvested cannabis buds and leaves; also could include other plant material that can be used to propagate cannabis.

### GENOMIC CULTIVAR MATCH
Genetic relatedness to the registered cultivar measured as identity by state (IBS) using the Lighthouse Genomics Cannabis 40k SNP array.

### GENOVAR IRIS IDENTIFICATION
The identification of a unique genomic pattern, whereby the authenticity and identity of cannabis propagation material produced by the site can be verified and validated.

### GLOBAL REGISTRATION CERTIFICATE
Certificate issued by Purity-IQ confirming that a product has been scientifically analyzed, fingerprinted, and deemed authentic according to the Purity-IQ genomic and/or metabolomic standard operating procedures and is officially registered in Purity-IQ's Global Registry – Cannabis.

**Genovar iris identification**

The identification of a unique genomic pattern, whereby the authenticity and identity of cannabis propagation material produced by the site can be verified and validated

**IQ rating**

A registered product's quantitative measurement of batch-to-batch consistency through analysis of specific compounds, as established in the Global Registry – Cannabis

### GOOD STANDING
Being regarded as compliant with all explicit obligations, while not being subject to any form of investigation, sanction, suspension, or disciplinary censure.

### HANDLED
When cannabis, ingredients, or inputs are produced, cultivated, grown, manufactured, packaged, labelled, stored, tested, or distributed.

### HASHISH
Also known as "hash"; this product is made by compressing and processing trichomes of the cannabis plant.

### IDENTITY
The establishment, preservation, and management of a particular chemical or set of chemicals to create a definable, measurable metabolomic fingerprint throughout the production chain to consistently achieve measurable outcomes.

### IMMEDIATE CONTAINER
The container that is in direct contact with a cannabis product or – if a wrapper is in direct contact with the cannabis – the wrapper.

### INCOMPATIBLE ACTIVITY
Tasks unsuitable or not appropriate to be performed simultaneously in proximity. CAPS identifies the co-location of cannabis and non-cannabis (e.g. conventional food) production as conflicting activities.

### INGREDIENT
Any substance or mixture of substances, including cannabis products or by-products, that when combined with a cannabis product forms an integral unit of a cannabis product that is sold as a final product.

### INPUT
Anything that is necessary for the preparation of a cannabis product but is not an ingredient or a component of an ingredient; for example:

- chemicals such as fertilizer, pesticides, water treatment chemicals, boiler treatment chemicals, chemicals for cleaning and sanitizing, and lubricants
- processing materials, including packaging, construction, and labelling materials that may have an impact on the safety, quality, or authenticity of a cannabis product.

### IQ RATING
A registered product's quantitative measurement of batch-to-batch consistency through analysis of specific compounds, as established in the Global Registry – Cannabis.

### ISO 17025
General accreditation requirements for the competence of testing and calibration laboratories.

### ISO 22000
Certification requirements for a food safety management system within an organization.

### LICENCE
An agreement held and secured between Purity-IQ and a site, brand owner, laboratory, or certification body.

### LOT OR BATCH NUMBER
A code (alphabetic and/or numeric) that can be used to identify a group of products manufactured, prepared, produced, stored, categorized/classified, packaged, and labelled under the same conditions. The code may include a harvest date, grower identification number, GPS coordinates or premises identifier, growing region, or any other data that may be used for traceability purposes.

### METABOLOMIC FINGERPRINT
The foundation by which the authenticity and identity of an individual cannabis product is established, whereby its unique molecular structures of specific compounds can be identified, verified, and validated using nuclear magnetic resonance spectroscopy techniques.

### MOTHER PLANT
The plant used as the source plant for cuttings to produce genetically identical clones of itself. (Note: This definition is specific to the cannabis industry's practice of clonal propagation, and is not to be interpreted as a mother plant of seedlings that are not genetically identical to it.)

### NON-FOOD CHEMICAL AGENTS
Chemicals at the site that are not considered to be cannabis, a food, or an ingredient, including cleaning chemicals, detergents, lubricants, petroleum products, and pest control products.

### NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY
An analytical chemistry technique that measures the absorption and emission of energy in one or more determined radio frequency range(s) of the electromagnetic spectrum by certain atomic nuclei when placed within a magnetic field.

### PEST CONTROL PRODUCT
Any substance or device that has been authorized either for use on cannabis specifically, or on crops or environments more generally; or alternatively under terms and conditions under which the regulatory authority may allow an individual to seek an authorization specific to their production.

**Metabolomic fingerprint**

The foundation by which the authenticity and identity of an individual cannabis product is established, whereby its unique molecular structures of specific compounds can be identified, verified, and validated using nuclear magnetic resonance spectroscopy techniques

**Purity-IQ cannabis registration**

List of products that have been issued a global registration certificate by Purity-IQ declaring they have been scientifically analyzed and deemed authentic

### POTABLE WATER
Water that is safe for humans to drink, is free from pollutants and harmful organisms, and conforms to local legal requirements.

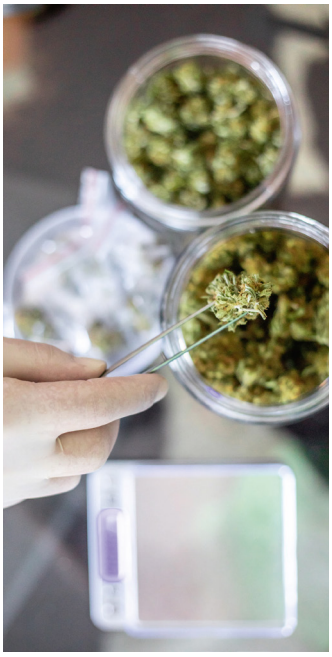
### PREMISES
Includes floors, walls, ceilings, overheads, windows and other openings, doors, pipes, light fittings, and ventilation points.

### PREVENTIVE CONTROL PLAN
A written document that describes how hazards related to the production of cannabis and cannabis products are controlled, including the ingredients or inputs used in production and how the regulatory or corporate requirements are met.

### PURITY
Being free from adulteration or contamination.

### PURITY-IQ CANNABIS REGISTRATION
List of products that have been issued a global registration certificate by Purity-IQ declaring they have been scientifically analyzed and deemed authentic.

### QUALITY ATTRIBUTES
The measurable characteristics of a cannabis product that can be determined and managed by the owner of the product in order to be acceptable to buyers, consumers, and regulators, who could consider appearance and flavour along with other attributes such as THC, CBD, and terpene levels.



### REPRESENTATIVE SAMPLE
A sample whose quantity and quality are proportional to and reflective of the total lot or batch.

### REWORK
Where cannabis, ingredients, or inputs have been removed from processing for reasons other than safety and are suitable for reprocessing, or for subsequent use or consumption.

### SANITARY CONDITION
A condition that does not present a risk of contamination, allergen cross-contamination, or introduction of an extraneous substance to the cannabis or to any item that will be used as an ingredient or input.

### SCHEDULE A
A control and tracking document, listing all cannabis products produced or processed at a site, and identifying which products are intended to display any of the CAPS logos (see Appendix 6 – Schedule A).

### SINGLE NUCLEOTIDE POLYMORPHISM
A single nucleotide polymorphism (SNP, pronounced "snip") is a DNA sequence variation occurring when a single nucleotide in the genome (or other shared sequence) differs between members of a species.

### SITE LICENCE AGREEMENT
A set of terms and conditions that form part of the annual licence agreement between the site/brand owner and Purity-IQ.

### SOURCE MATERIAL
The raw material from which a product is made.

### TECHNICAL REVIEWER
A CAPS-certified technical reviewer who is employed by a Purity-IQ licensed certification body and whose duties include the technical review of CAPS audit reports.

### VALIDATION
Establishing documented evidence that will provide a high degree of assurance that the production and testing methods will consistently, and reproducibly, lead to the predetermined specifications and quality results in tested cannabis.

### VERIFICATION
The application of methods, procedures, tests, and evaluations, in addition to monitoring, to determine whether a control measure has been implemented and is operating as intended.

### WASTE
A material, substance, or by-product eliminated or discarded as it is no longer useful or required.

**Verification**

The application of methods, procedures, tests, and evaluations, in addition to monitoring, to determine whether a control measure has been implemented and is operating as intended

## 5.2 Abbreviations

AIMS – authenticity and identity management system
CAPS – Cannabis Authenticity and Purity Standard
CB – certification body
CBD – cannabidiol
CBDA – cannabidiolic acid
CCP – critical control point
CI – confidence interval
DNA – deoxyribonucleic acid
FOCUS – Foundation of Cannabis Unified Standards
GAPs – good agricultural practices

GFSI – Global Food Safety Initiative
GMPs – good manufacturing practices
GRC – global registration certificate
HACCP – hazard analysis critical control point
ILAC – International Laboratory Accreditation Council
NMR – nuclear magnetic resonance spectroscopy
SNP – single nucleotide polymorphism
SOP – standard operating procedure
THC – delta-9-tetrahydrocannabinol
THCA – delta-9-tetrahydrocannabinolic acid

# Part I – Cannabis Authenticity and Purity Standard

## Basic requirements


The site's senior leadership shall ensure that the site's AIMS conforms to all the requirements identified in CAPS, including any prescribed by regulation where the product is produced, manufactured, or sold

# 6. General

A Purity-IQ-recognized site will only present its cannabis products as being in conformity with CAPS during sale, distribution, or export if the licensee is in good standing, there is an active certificate of recognition, and the products meet the requirements of CAPS for the activities it conducts.

The site must establish, verify, and validate an authenticity and identity management system to ensure that cannabis is produced safely and consistently within the CAPS requirements, and that all the activities it conducts with cannabis meet quality standards appropriate to its intended use of it. CAPS-Basic (a prerequisite to CAPS-Advanced) sets the overarching safety and quality limits, while CAPS-Advanced expands the requirements to include authenticity and consistency.

Licence holders and sites recognized under CAPS are responsible for understanding and complying with all requirements that apply to their licence and certificate of recognition (e.g. CAPS-Basic or CAPS-Advanced) and to their range of authorized activities. They must be able to demonstrate that cannabis has been produced, distributed, and sold in accordance with the CAPS requirements.

The CAPS requirements also apply to any activity that an individual conducts in respect of any item that will be used as an ingredient or input and must be conducted in concert with the AIMS and under the authority of a licensee. A licence holder or recognized site is responsible for ensuring that the final product, which may contain ingredients obtained from a non-licence holder, conforms with CAPS. These general requirements are outlined in further detail below.

## 6.1 Senior leadership

The site's senior leadership shall ensure that the site's AIMS conforms to all the requirements identified in CAPS, including any prescribed by regulation where the product is produced, manufactured, or sold.

### 6.1.1 Senior leadership shall ensure that:

- Financial, human, and infrastructure resources are provided to ensure conformance with the CAPS and regulatory requirements, and with the site's AIMS.
- Necessary time is allocated for the development, documenting, implementation, and effective maintenance of the AIMS.
- Personnel with defined responsibilities and the authority to initiate, implement, effectiveness-check, and record corrective actions are designated.

- The importance of meeting the requirements of the site's AIMS, including any regulatory requirements related to product safety, is communicated to all employees.
- Personnel with authority are designated to ensure that any individual entering or working within the site conforms to the product safety procedures identified in the site's AIMS.
- All information and documentation is accessible during evaluation processes and subsequent verification or audit activities.
- An AIMS team, AIMS team leader, and backup team leader are appointed.
- A member of the senior leadership attends at least one AIMS team meeting annually.

### 6.1.2 Site policy

A site policy is available that:

- confirms the senior leadership's full support for developing, implementing, and maintaining an effective AIMS
- outlines the site's commitment to producing products in conformity with all regulatory and CAPS requirements
- is signed and dated by a representative of the senior leadership who has overall responsibility for the site
- is renewed annually or when the senior leadership representative is replaced
- is communicated to all staff.

## 6.2 AIMS

The site shall develop, document, implement, monitor, and maintain an authenticity and identity management system that conforms to all the requirements identified in CAPS, including any prescribed by regulation where the product is produced, manufactured, or sold.

The site shall develop, document, implement, monitor, and maintain an authenticity and identity management system that conforms to all the requirements identified in CAPS, including any prescribed by regulation where the product is produced, manufactured, or sold

### 6.2.1 AIMS team

The AIMS shall ensure that:

- the AIMS team is multidisciplinary and includes those responsible for quality/technical, product development, sanitation and hygiene, production operations, engineering/maintenance, and other relevant functions

The AIMS shall ensure that the AIMS team leader maintains overall accountability and responsibility for the AIMS

- the AIMS team holds meetings at planned intervals, at least annually, to discuss, among other points:
  - documented timelines, action plans, and progress made from previous AIMS team meeting reviews
  - changes in the AIMS
  - results of internal, second-party (and/or third-party), regulatory, and CAPS audits
  - customer complaints and results of any customer feedback
  - incidents (including both recalls and withdrawals), corrective actions, out-of-specification results, and nonconforming materials
  - reviews of the effectiveness of the AIMS
  - resource requirements
- the frequency of AIMS team meetings is sufficient to manage the risks associated with the AIMS and may be increased depending on circumstances
- records of AIMS team meetings are maintained and include:
  - the decisions and actions agreed within the review process
  - communicating review outcomes to appropriate staff
  - implementing actions within agreed timescales.

### 6.2.2 AIMS team leader

The AIMS shall ensure that:

- the site retains the services of one individual, either salaried or contracted, as an AIMS team leader, and a backup as required
- only one individual acts as the AIMS team leader for the site at any given time
- the AIMS team leader maintains overall accountability and responsibility for the AIMS
- the AIMS team leader and their backup have:
  - successfully completed CAPS-Basic and (if relevant) CAPS-Advanced training
  - successfully completed any training sanctioned by Purity-IQ
  - the necessary qualifications, competencies, and/or skills related to:
    - » cannabis handling
    - » SOP development and implementation
    - » pest control management
    - » GMP and GAP development and implementation

- » complaint investigation and management
- » root cause analysis
- » validating and verifying process controls
- » performing risk assessments
- » HACCP principles and application
- » sample collection and retention
- » pesticide residue testing
- » quality control
- » final product labelling
- » internal auditing
- » providing training and assessment
- » record-keeping and record verification
- » managing and analyzing recalls, withdrawals, and adverse reaction reports
- » employee management

- any activity overseen by the AIMS team leader is conducted only by personnel who have the relevant knowledge, training, and experience to effectively undertake the activity
- records of AIMS team leader activities (including those of the backup) are maintained.

The AIMS team leader conducts or oversees the following:

- all quality-related complaint investigations and risk mitigation measures
- all cannabis or ingredient risk investigations and mitigation measures
- the implementation of SOPs and the requirements of the AIMS
- the assessment and recording of any circumstance requiring a deviation from an approved SOP
- the completion of the required tests outlined in section 10
- the review and assessment of all test results to confirm that they are within the specification(s) of the AIMS and in conformity with CAPS
- the maintenance, review, and verification of documentation associated with each lot or batch to ensure it has been produced in accordance with the AIMS.

The AIMS shall ensure that any activity overseen by the AIMS team leader is conducted only by personnel who have the relevant knowledge, training, and experience to effectively undertake the activity

The site shall develop, document, implement, monitor, and maintain an education and training program that supports the duties, knowledge, skills, and competency of all employees and contractors

The AIMS team leader approves or oversees the approval of the following:

- all SOPs included within the AIMS before they are implemented
- the preventive control plan before it is implemented
- cannabis safety and quality attributes prior to it being made available for sale
- specifications:
  - product release
  - labelling and packaging
  - supplier
  - laboratory testing
- every lot or batch of cannabis before it is made available for sale.

## 6.3 Training

The site shall develop, document, implement, monitor, and maintain an education and training program that supports the duties, knowledge, skills, and competency of all employees and contractors.

Education and training operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- all relevant personnel involved in the handling of cannabis, ingredients, inputs, packaging, equipment, and chemicals are:
  - appropriately trained prior to commencing work
  - demonstrably competent to carry out their duties
  - adequately trained, instructed, and supervised commensurate with their duties
- training programs are duty-appropriate and include (at a minimum):
  - standard operating procedures related to the implementation of the AIMS and CAPS

- personal hygiene requirements
- monitoring CCPs
- the principles of CAPS, including the importance of good manufacturing practices (GMPs) or good agricultural practices (GAPs)
- packaging and/or labelling operations
- handling chemicals
- handling contaminated materials or waste
- sampling and test methods for staff responsible for those activities

The AIMS shall ensure that refresher training is defined, identified, and routinely provided to support ongoing competency

- training includes a competency assessment
- training is provided before new or revised SOPs are implemented
- training is delivered by competent and skilled trainers
- refresher training is defined, identified, and routinely provided to support ongoing competency
- the effectiveness of any training activity is routinely verified
- a review of the training and education program is completed at least annually
- records associated with training activities are maintained.

## 6.4 Document management

The site shall develop, document, implement, monitor, and maintain a procedure to manage documents that form part of the AIMS.

SOPs shall include all steps necessary to conform with those specified in the AIMS

Document management operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- standard operating procedures are available for all activities related to the implementation of CAPS
- SOPs shall include all steps necessary to conform with those specified in the AIMS

The AIMS shall ensure that the method for identifying, authorizing, updating, amending, and replacing existing documents is defined

- documents are reviewed for accuracy at least annually
- documents use language that is clear, simple, and concise
- a list of controlled documents is available that indicates the document name, latest version number, and its release date
- the method for identifying, authorizing, updating, amending, and replacing existing documents is defined
- all documents are securely stored to prevent loss or damage
- reasons for any changes or amendments to documents are recorded
- where documents are in electronic form, they are backed up to prevent loss and stored securely
- records associated with the document management program are maintained.

## 6.5 Record management

The site shall develop, document, implement, monitor, and maintain a procedure to manage records that demonstrate the effective application of the AIMS.

Record management operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- records are dated, legible, accurate, in good condition, suitably and securely stored, and retrievable
- electronic records are backed up to prevent loss
- each record includes the date and time when the record was completed, and the name and/or initials of the person who completed it
- records are produced at the times when the activities occur
- alterations to records are formally authorized, with any justifications for alterations recorded

- record retention is defined with consideration given to any legal or customer requirements and the shelf life of the product
- at a minimum, records are retained for the shelf life of the product plus 12 months
- records associated with the record management program are maintained.

The AIMS shall ensure that, at a minimum, records are retained for the shelf life of the product plus 12 months

# 7. GMPs/GAPs

## 7.1 Premises

Any building or part of the building where cannabis, ingredients, or inputs are handled must be designed, constructed, located, monitored, and maintained in a manner that prevents contamination.

The premises shall be designed, constructed, located, monitored, and maintained in a manner that:

- permits it to be kept secure, clean, and orderly
- permits effective cleaning and sanitation of all its surfaces, including the repeated application of cleaning and disinfecting agents
- prevents contamination of cannabis or any item that will be used as an ingredient or input
- prevents the introduction of extraneous substances to the cannabis, ingredient, or input
- prevents the presence of holes or cracks (unless intended by design)
- prevents the entry of insects, animals, or other pests
- facilitates good waste management practices
- permits areas to be connected in a logical order and corresponding to the sequence of the operations
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- site and floor plans are available depicting the location of all cannabis-handling areas

The AIMS shall ensure that washrooms are suitably located and do not open directly to the processing or production areas

- doors that give direct access to the exterior from manufacturing and packaging areas are used for emergency purposes only and are properly sealed
- receiving and shipping areas do not allow direct access to production areas
- mechanical areas such as boiler rooms, generators, and other engineering areas are segregated from production areas
- external grounds are maintained in a suitable condition that prevents pest harbourage and waste accumulation
- the site surrounding any building is graded to allow water to drain away from the building
- adjoining land is assessed for potential sources of contamination that may drift to the site; where sources of contamination are identified, measures are taken to mitigate or eliminate the risk of contamination
- if the site is located near a source of contamination, such as a sanitary landfill, oil refinery, chemical plant, or paper or steel mill, any building air intakes are located away from those sources and the incoming air passes through filters to reduce any contaminants to acceptable levels
- washrooms are suitably located and do not open directly to the processing or production areas
- premises are equipped with drainage, sewage, and plumbing systems that function in accordance with their intended use
- the drainage, sewage, and plumbing systems can accommodate the volume and type of effluent produced at the site and are equipped with traps and vents to prevent back-flow
- brick, cement block, and other porous materials are sealed
- surface materials that shed particles are not used
- joints between walls, ceilings, and floors are sealed
- sites that choose to grow cannabis outdoors ensure that all activities with cannabis post-harvest (e.g. drying, trimming) are conducted within a building or part of a building that is in conformity with this section
- positive air pressure directs airflow from highly sensitive areas, such as aseptic rooms, to less sensitive areas, such as rooms where raw ingredients or inputs are handled
- maintenance operations meet the requirements outlined in section 7.7
- records associated with premise operations are maintained.

## 7.2 Equipment

Any equipment used to handle cannabis, ingredients, or inputs must be suitable for the intended purpose.

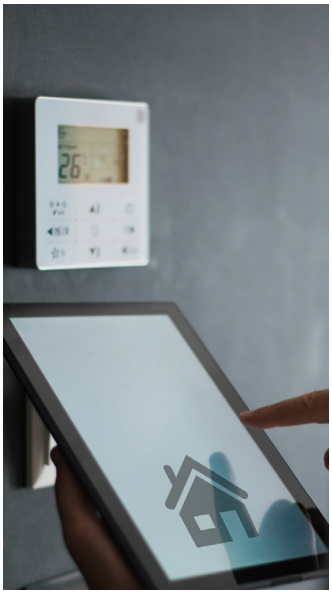
Equipment shall be designed, constructed, located, operated, monitored, and maintained in a manner that:

- permits effective cleaning and sanitation of all its surfaces
- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- permits the equipment to function in accordance with its intended use
- meets legal requirements where applicable.

The AIMS shall ensure that:

- equipment is verified to be functioning as intended by the manufacturer before use
- equipment that is used for more than one class of cannabis or ingredient is appropriate for each substance
- excessive condensation is prevented by ensuring that equipment exhausts to the outside of the building or conveyance
- where drainage is required for equipment, the equipment is connected directly to drains
- equipment is installed with sufficient space around it, is accessible, and, if necessary, can be disassembled for cleaning, inspection, and maintenance
- clean or sanitized equipment is stored separately from used or unclean equipment, and in a manner that prevents re-contamination
- defective equipment is clearly identified to prevent use and removed from production
- balances and measuring equipment are of an appropriate range, precision, and accuracy
- maintenance operations meet the requirements outlined in section 7.7
- records associated with equipment operations are maintained.

The AIMS shall ensure that clean or sanitized equipment is stored separately from used or unclean equipment, and in a manner that prevents re-contamination



Any building or part of the building where cannabis, ingredients, or inputs are handled must be equipped with adequate natural and/or artificial lighting

# 7.3 Infrastructural systems

## 7.3.1 Air filtration and ventilation

Any building or part of the building where cannabis, ingredients, or inputs are handled must be equipped with adequate air filtration and ventilation systems.

Filtration and ventilation systems shall be designed, constructed, located, monitored, and maintained in a manner that:

- provides sufficient air exchange in the appropriate direction to provide clean air, and to remove unclean air
- allows the intended air quality to be maintained within them
- permits effective cleaning and sanitation of all their surfaces as appropriate
- permits routine inspection and maintenance
- prevents the accumulation of heat, steam, condensation, and dust
- prevents contamination of cannabis or any item that will be used as an ingredient or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- maintenance operations meet the requirements outlined in section 7.7
- records associated with air filtration and ventilation operations are maintained.

## 7.3.2 Lighting

Any building or part of the building where cannabis, ingredients, or inputs are handled must be equipped with adequate natural and/or artificial lighting.

Lighting systems shall be designed, constructed, located, monitored, and maintained in a manner that:

- permits appropriate light intensity for the activity being conducted
- permits effective cleaning and sanitation of all their surfaces
- prevents contamination of cannabis or any item that will be used as an ingredient or input
- ensures that the natural colour, quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- the condition of all lighting systems is routinely inspected for intensity, damage, and breakages
- the lighting systems do not result in the production of natural toxins and microorganisms of the cannabis, ingredients, or inputs
- the lighting systems do not affect the effectiveness of chemical sanitizers being used
- all light fixtures are constructed from shatter-resistant materials and/or shielded with safety covers
- maintenance operations meet the requirements outlined in section 7.7
- records associated with lighting operations are maintained.

### 7.3.3 Water/steam/ice

Any building or part of the building where cannabis, ingredients, or inputs are handled must be equipped with a suitable supply of water.

Water systems shall be designed, constructed, located, monitored, and maintained in a manner that:

- renders the water suitable for the intended use
- delivers water in a sufficient quantity and pressure for the site's operational needs
- prevents cross-contamination between potable and non-potable water sources
- permits only potable water to be used in handwashing, cleaning, or sanitation, or as a raw material
- prevents back-flow or back-siphonage
- prevents contamination of cannabis or any item that will be used as an ingredient or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- monitoring, including the chemical and microbiological testing of water and ice, shall be conducted and reported on a scheduled basis:
    - sampling points, scope of test, and frequency of sampling are selected based on risk
    - results from any water and ice testing are reviewed and maintained

The AIMS shall ensure that monitoring, including the chemical and microbiological testing of water and ice, shall be conducted and reported on a scheduled basis

The AIMS shall ensure that water, steam, or ice does not present a risk of contamination to cannabis or any item that will be used as an ingredient or input

- water, steam, or ice does not present a risk of contamination to cannabis or any item that will be used as an ingredient or input
- non-mechanical (e.g. air gaps) and mechanical prevention devices and testing of back-flow preventers shall be visually inspected at a scheduled frequency
- procedures for monitoring, treatment, and testing the quality of water/steam/ice are documented, implemented, and maintained
- maintenance operations meet the requirements outlined in section 7.7
- records associated with water/steam/ice operations are maintained.

### 7.3.4 Temperature and humidity

Any building or part of the building where cannabis, ingredients, or inputs are handled must ensure appropriate temperature and humidity levels are maintained for the activity being conducted.

Temperature and humidity systems shall be designed, constructed, located, monitored, and maintained in a manner that:

- permits effective cleaning and sanitation of all their surfaces
- permits them to function in accordance with their intended use
- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- temperature and humidity levels and limits are specified and documented for relevant parts of the premises
- in areas supplied with a heating, cooling, or humidity control system:
  - instruments are in place to control and indicate the temperature and humidity levels
  - the system functions in accordance with its intended use
- production areas are maintained at a temperature that prevents the growth of microorganisms

- cannabis, or any item that will be used as an ingredient or input, that requires refrigeration is stored at 4°C or less
- cannabis, or any item that will be used as an ingredient or input, that requires freezing is stored at –18°C or less
- humidity is maintained at a level that is low enough to prevent condensation, where condensation would pose a risk to the safety of cannabis or any item that will be used as an ingredient or input
- temperature and humidity are checked periodically to ensure that they are maintained at a level that is appropriate to the cannabis, ingredient, or input, and to the activity being conducted
- cannabis, or any item that will be used as an ingredient or input, is placed in refrigerated or freezer storage in a manner that does not restrict airflow, which would prevent it from effectively reaching the required temperature
- a recording device, such as a thermometer, is used in the refrigerated and freezer storage area(s) to monitor and record the temperature
- the system's sensing device accurately measures the conditions in the building or part of a building; the device also activates and de-activates the system to maintain the temperature and humidity at the predetermined levels, where applicable
- maintenance operations meet the requirements outlined in section 7.7
- records associated with temperature and humidity operations are maintained.

The AIMS shall ensure that temperature and humidity are checked periodically to ensure that they are maintained at a level that is appropriate to the cannabis, ingredient, or input, and to the activity being conducted

## 7.4 Personnel hygiene

The site shall develop, document, implement, monitor, and maintain a personnel hygiene program that minimizes the risk of contamination from all individuals entering the premises.

All individuals shall perform operations in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that requirements for personnel hygiene are specified and communicated to all personnel including visitors and contractors

The AIMS shall ensure that:

- requirements for personnel hygiene are specified and communicated to all personnel including visitors and contractors
- individuals wear clothing, footwear, and protective coverings that are appropriate for the activity being conducted
- clothing, footwear, and protective coverings are stored in designated, accessible locations and in a manner that prevents contamination
- measures are taken to ensure that clothing, footwear, and protective coverings are in good condition
- hand-sanitizing and handwashing stations are provided and are:
  - appropriately equipped and adequate in number and size for the number of individuals using them
  - appropriately equipped to permit the effective cleaning and sanitizing of hands
  - located at entrances to production areas, in close proximity to the washrooms, and anywhere else deemed necessary including outdoor production areas
  - readily accessible to the individuals using them at all times
  - not used for any other purpose
  - equipped with hot and cold, or premixed potable running water
  - equipped with signage that explains proper handwashing procedures
  - durable, cleanable, and maintained in a clean and sanitary condition
- records associated with personnel hygiene operations are maintained.

## 7.5 Cleaning and sanitation

The site shall develop, document, implement, monitor, and maintain a cleaning and sanitation program to manage the cleaning and sanitation of all premises and equipment.

Cleaning and sanitation operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- procedures are available for effectively cleaning and/or sanitizing the premises and equipment
- a cleaning schedule is developed outlining:
  - the locations and/or equipment to be cleaned and/or sanitized
  - the cleaning and/or sanitizing agents to be used
  - the mixing/preparation instructions
  - the temperature controls
  - the individual(s) responsible
  - the frequency of each activity
  - the detailed procedures for cleaning and/or sanitizing
- the effectiveness of cleaning and sanitizing activities is monitored, validated, and verified
- dedicated cleaning and/or sanitation equipment is identifiable, via colour coding or other means
- records associated with cleaning and sanitation operations are maintained.

The AIMS shall ensure that the effectiveness of cleaning and sanitizing activities is monitored, validated, and verified

## 7.6 Pest control

The site shall develop, document, implement, monitor, and maintain a pest control program for the prevention and control of infestation by insects, rodents, animals, birds, and other pests.

This does not prohibit a site from using beneficial insects in the growing areas.

Pest control and prevention operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that cannabis products are only exposed to or treated with a pest control product permitted by a regulatory authority in the jurisdiction of production and sale

The AIMS shall ensure that:

- no animal is present in any building or part of the building where cannabis, ingredients, or inputs are handled
- control measures are in place to discourage pest harbourages
- a schedule for the application and frequency of pest control is documented
- cannabis products are only exposed to or treated with a pest control product permitted by a regulatory authority in the jurisdiction of production and sale
- records associated with pest control and prevention operations are maintained.

## 7.7 Maintenance

The site shall develop, document, implement, monitor, and maintain a preventive maintenance program covering the premises, equipment, services, and external areas.

Maintenance operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- oil that is used to lubricate equipment that comes into contact with cannabis, or any item that will be used as an ingredient or input, is food grade and handled appropriately
- the maintenance program includes a list of equipment requiring regular maintenance and its location
- repairs to premises and equipment are permanent and durable in nature where possible
- temporary repairs that could lead to contamination are avoided
- temporary repairs are documented with justification and an itemized plan leading to a permanent solution with a deadline for completion
- maintenance operations are performed at a prescribed frequency, or as necessary to reduce the risk of contamination

- instructions are included on:
  - how to perform preventive maintenance activities
  - the frequency of such activities
  - measures to be taken if equipment does not function as intended
  - identification of the individuals who are assigned responsibility for the maintenance procedures, and names of external companies conducting such activities, if applicable
- records associated with maintenance operations are maintained.

## 7.8 Calibration

The site shall develop, document, implement, monitor, and maintain a calibration program that ensures the accuracy of measuring, testing, and inspection devices.

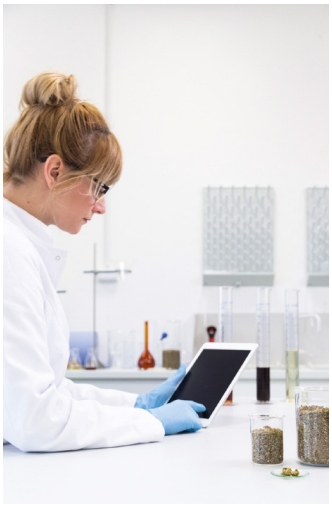
Calibration operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input is maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- all measurement, test, and inspection devices are calibrated
- calibration is performed in accordance with regulatory and/or manufacturers' requirements
- all measurement, test, and inspection devices requiring calibration are listed, with their locations specified
- methods, frequency, and responsibilities for calibration are defined
- calibration is performed by competent personnel
- calibrated measuring, testing, and inspection devices are protected from damage and unauthorized adjustment or use
- records associated with calibration operations are maintained.

The AIMS shall ensure that methods, frequency, and responsibilities for calibration are defined



The AIMS shall ensure that chemicals that are used are approved for use on cannabis or on any item that will be used as an ingredient or input, as applicable

## 7.9 Chemical management

The site shall develop, document, implement, monitor, and maintain procedures that allow for the adequate, effective, and safe management of non-food chemical agents, chemical agents, and chemical-based agronomic inputs.

Chemical use and management shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- procedures are available for effectively identifying, using, storing, and disposing of all chemicals present at the site
- chemicals are suitable for their intended use
- chemicals are clearly identified and securely stored away from cannabis-handling operations
- suppliers' instructions on use, handling, contact time, temperature, and concentration for sanitizers and non-food chemical agents are followed
- chemicals that are used are approved for use on cannabis or on any item that will be used as an ingredient or input, as applicable
- the manufacturer's instructions on the time interval and concentration for chemicals are followed
- records of chemical application include:
    - names of chemicals used
    - quantity applied (if applicable)
    - concentration used
    - date of application
    - method(s) of application
    - name of applicator
- records associated with chemical management activities are maintained.

## 7.10 Contamination control

The site shall develop, document, implement, monitor, and maintain procedures to prevent contamination of the cannabis or any item that will be used as an ingredient or input.

Contamination prevention strategies shall be implemented in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- procedures are available for effectively separating cannabis, or any item that will be used as an ingredient or input, from sources of contamination including:
  - other cannabis (e.g. of different or unknown origin)
  - any item that will be used as an ingredient or input that contains unspecified components (e.g. allergens)
  - sanitizers, agronomic inputs, and other non-food chemical agents
  - contaminated material and waste, including cannabis intended for destruction
  - co-mingling of classes of cannabis
- the site uses physical or other effective means to separate the cannabis, ingredient, or input from anything that presents a risk of contamination of it
- if two or more activities were to occur simultaneously, sequentially, or in close proximity, they would not present a risk of contamination of the cannabis, ingredient, or input
- the shipping of a cannabis product is separated from the receipt of incoming cannabis, ingredients, or inputs
- when both cannabis and non-cannabis products are handled at the same location, the site conducts these operations in separate buildings that have no direct access between them
- for sites that manufacture other non-cannabis products such as cosmetics, methods and procedures are implemented to prevent contamination or substitution errors of cannabis, ingredients, or inputs

The AIMS shall ensure that if two or more activities were to occur simultaneously, sequentially, or in close proximity, they would not present a risk of contamination of the cannabis, ingredient, or input

The AIMS shall ensure that effective procedures are implemented to prevent the cross-contamination of non-allergenic materials with allergenic materials

- any item that is found to present a risk to human health, be under investigation, or be subject to recall or withdrawal, or is deemed nonconforming is:
  - clearly identified
  - quarantined in an appropriately signed designated area
  - quantified through inventory controls
  - prevented from release or accidental use
  - not used until a decision on its disposition can be made
- site maps document personnel and material flow
- any in-house testing, such as authenticity, identity, microbiological, and pathogen testing, is conducted in a separate area from where cannabis is handled
- effective procedures are implemented to prevent the cross-contamination of non-allergenic materials with allergenic materials
- incompatible activities are prevented from occurring
- if any item that will be used as an ingredient or input is propagated, cultivated, or harvested outdoors, sources of contamination are identified and the field is not used, or the ingredients are not harvested and brought into any building, until it is certain that the ingredient will not contaminate cannabis or anything else that will be used as an ingredient
- records associated with contamination control activities are maintained.

## 7.11 Waste management

The site shall develop, document, implement, monitor, and maintain a waste management program that prevents accumulation, risk of contamination, and the attraction of pests.

Waste management operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- procedures are available outlining how waste and contaminated materials are removed, destroyed, and/or disposed of from the site
- any equipment used to handle any waste or contaminated materials is identified and is only used for that purpose
- employees are aware of the system used to identify equipment reserved for handling contaminated materials, waste, or other inedible items, via training or through the use of SOPs in the AIMS, as applicable
- waste containers are cleaned regularly or replaced as needed
- waste and contaminated materials are secured and removed using predetermined routes at a set frequency, or more often if necessary, so that they do not overflow
- waste is stored separately from cannabis-handling areas
- site maps document the movement of waste throughout the site
- records associated with waste management operations are maintained.

The AIMS shall ensure that any equipment used to handle any waste or contaminated materials is identified and is only used for that purpose

## 7.12 Site security

The site shall develop, document, implement, monitor, and maintain a site security program that complies with the requirements of the applicable regulatory authority or law enforcement.

Site security operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- site design prevents unauthorized access
- procedures for managing security emergencies and theft/loss prevention are developed
- monitoring systems are defined, and routinely inspected and tested
- records associated with the site security program are maintained.

The AIMS shall ensure that all incoming inputs and ingredients are checked for conformance against specifications, and are identifiable and traceable

# 7.13 Process control

## 7.13.1 Receival and storage

The site shall develop, document, implement, monitor, and maintain procedures that allow for the adequate, effective, and safe receival and storage of cannabis, ingredients, inputs, packaging, equipment, and chemicals.

Receival and storage operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- all incoming inputs and ingredients are checked for conformance against specifications, and are identifiable and traceable
- stored items are clearly identified
- a process for stock rotation is defined based on "first in, first out" (FIFO) or "first expiry, first out" (FEFO) principles
- allergenic and non-allergenic items are separated to prevent cross-contact
- cross-contamination between the various categories of materials and cannabis is prevented (e.g. in-process; bulk cannabis; cannabis in immediate containers and cannabis accessories; samples; material that is quarantined, approved for sale, rejected, returned, withdrawn, or recalled; and material awaiting destruction)
- a recording device, such as a thermometer, is used in the refrigerated and freezer storage area(s) to monitor temperature
- devices used to monitor storage conditions are calibrated
- records associated with receival and storage operations are maintained.

## 7.13.2 Processing

The site shall develop, document, implement, monitor, and maintain procedures that allow for the effective and safe processing and rework of cannabis, ingredients, and inputs.

Processing and rework operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- any additional processing, alterations or secondary treatments that might be done on a lot or batch of cannabis shall be justified in accordance with predetermined criteria indicating when these additional activities would be permitted
- records associated with processing and rework operations are maintained.

The AIMS shall ensure that any additional processing, alterations or secondary treatments that might be done on a lot or batch of cannabis shall be justified in accordance with predetermined criteria indicating when these additional activities would be permitted

### 7.13.3 Product release

The site shall develop, document, implement, monitor, and maintain procedures that ensure product release criteria have been met prior to a cannabis product being approved for sale or distribution.

Cannabis product release activities shall be implemented in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of cannabis or any item that will be used as an ingredient or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- a cannabis product is not released unless it meets:
  - all regulatory requirements
  - final product specifications
  - customer specifications (if applicable)
  - all testing requirements
- product release criteria are available for the cannabis product

The AIMS shall ensure that vehicles are inspected to verify that they do not impact the quality, authenticity, and identity of cannabis or any item to be used as an ingredient or input

- the release specification(s) for the cannabis product to be approved for sale or distribution is/are:
  - identified
  - documented
  - supported by adequate justification
  - where applicable, approved by the AIMS team leader or their designate before the product is released for sale
- records associated with product release activities are maintained.

### 7.13.4 Distribution

The site shall develop, document, implement, monitor, and maintain procedures that allow for the safe distribution of cannabis.

Distribution operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- vehicles are inspected to verify that they do not impact the quality, authenticity, and identity of cannabis or any item to be used as an ingredient or input
- records indicate that the cannabis, ingredient, or input, was packaged and shipped in accordance with applicable SOPs
- records track all personnel handling the product during distribution
- procedures are available ensuring the adequate security, sanitation, maintenance, and environmental conditions of the carrier
- records associated with distribution operations are maintained.

# 8. Risk management

The AIMS shall ensure that the process flow is verified for accuracy at least annually and whenever there is a change to the process

## 8.1 Preventive controls

The site shall develop, document, implement, monitor, and maintain a HACCP-based preventive controls program that identifies and controls potential hazards that may pose a risk to cannabis or any item that will be used as an ingredient or input.

### 8.1.1 Preventive controls team

The AIMS shall ensure that:

- a team is assembled to develop a preventive controls program that includes process flow(s), hazard analysis/es, and (if relevant) critical control points (CCPs).

### 8.1.2 Process flow

The AIMS shall ensure that:

- a process flow is documented showing all steps in the process (including any inputs, rework, and outputs)
- the process flow describes nominated process steps, inputs, and outputs
- the process flow is verified for accuracy at least annually and whenever there is a change to the process.

### 8.1.3 Hazard analysis

The AIMS shall ensure that:

- a hazard analysis is completed that:
  - identifies potential microbiological, chemical, physical, allergenic, regulatory, and quality hazards and their cause for each input and process step
  - evaluates each potential hazard for likelihood of occurrence and the potential to cause illness or injury if present, in the absence of control
  - allocates a suitable control measure that will prevent or eliminate the potential hazard or reduce it to an acceptable level
  - defines which hazards are "significant", i.e., their elimination or reduction to an acceptable level is necessary to control the quality, authenticity, and identity of the cannabis, ingredient, or input
- evidence is available to validate the effectiveness of allocated control measures.

The AIMS shall ensure that records associated with the preventive controls program are maintained for at least 2 years after the day on which it was approved

### 8.1.4 Critical control points (CCPs)

The AIMS shall ensure that:

- CCPs are determined for each hazard identified as significant during the risk assessment process
- each CCP includes:
  - a description of its critical limits
  - evidence to validate the effectiveness of the critical limits
  - the procedures for monitoring each CCP in relation to its critical limits
  - the corrective action to be taken when a critical limit is breached or trending towards a loss of control.

### 8.1.5 Verification and record-keeping

The AIMS shall ensure that:

- records of monitoring, corrective action, verification, and validation are maintained
- the preventive controls program has been verified to be fully implemented
- the preventive controls program is kept up to date and reviewed in the event of:
  - changes in formulations
  - new processing equipment
  - emerging information or processing data
- the preventive controls program is reviewed at least annually to ensure that any new hazards are identified and evaluated
- records associated with the preventive controls program are maintained for at least 2 years after the day on which it was approved.

## 8.2 Product development

The site shall develop, document, implement, monitor, and maintain a product development program that enables adequate control of new or modified product formulations.

Product development operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input

- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- a product development and approval process flow is available that includes steps to be followed when existing product formulations are modified
- all new and modified products are formally reviewed, approved, and accepted by the AIMS team leader
- when new or modified products are approved, changes are clearly communicated throughout the chain of production
- records associated with product development operations are maintained.

The AIMS shall ensure that when new or modified products are approved, changes are clearly communicated throughout the chain of production

## 8.3 Supply chain management

The site shall develop, document, implement, monitor, and maintain a supply chain management program that ensures all service providers, and suppliers of ingredients and inputs, including emergency providers/suppliers, effectively manage hazards and are operating effective traceability processes.

Supply chain management operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- the methods for selecting, approving, and reviewing suppliers and service providers are defined
- a register of approved suppliers and service providers is available, and includes records of inspections and audits
- the use, and conditions of use, for emergency suppliers and providers is defined
- a supplier specification is available for each service, input, ingredient, ingredient blend, and component of ingredient blends

The AIMS shall ensure that supplier and service provider audits are based on risk and conducted by salaried or contracted individuals who are knowledgeable of applicable regulatory requirements and the AIMS, as well as being trained in auditing techniques

- supplier specifications must:
  - clearly list each ingredient and, where applicable, each component of each ingredient
  - outline origin and applicable traceability information and identification
  - for service providers, outline a full description of the service provided including relevant training requirements
  - be reviewed and verified by a member of the AIMS team
  - be approved by the AIMS team leader
- documentation from the supplier indicates that the supplier shall:
  - meet the site's specifications
  - notify the site when a change is made to the supplier's service, input, ingredient, and/or ingredient blend formula
  - confirm that such changes will not be made without prior approval from the site
- the methods and frequency for monitoring the performance of suppliers and service providers are defined
- supplier and service provider audits are based on risk and conducted by salaried or contracted individuals who are knowledgeable of applicable regulatory requirements and the AIMS, as well as being trained in auditing techniques
- records associated with supply chain management operations are maintained.

## 8.4 Labelling and advertising

The site shall develop, document, implement, monitor, and maintain a labelling and advertising program that complies with applicable legal requirements and displays correct and accurate consumer information.

### 8.4.1 General requirements

Labelling and advertising operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- the correct packaging and label are applied to the correct product
- labels and packaging have traceability information that links to the manufacturer
- label and packaging design, inspection, approval, storage, handling, and rejection procedures are specified
- labelling and packaging specifications detail selection of materials and work environment controls (e.g. humidity, airflow, dust, temperature)
- a label approval process is implemented that includes a re-approval procedure following modifications to existing product formulations
- labels and printed packaging are verified for accuracy against agreed artwork and specifications prior to use
- where the label information is the responsibility of a customer or a nominated third party, the site shall provide:
  - information to enable the label to be accurately created
  - updates whenever a change occurs that may affect the label information
- records of all labelling, packaging, and advertising operations are maintained.

### 8.4.2 Purity-IQ and CAPS-certified owned and registered logos

An optional application for authorized use of the Purity-IQ and CAPS-certified owned and registered logos will be subject to the following requirements:

- The use of the Purity-IQ and CAPS-certified owned and registered logos must conform with the terms and conditions in the Purity-IQ site licence agreement, entered into directly between the site and Purity-IQ.
- The applicant must possess a current certificate of recognition issued directly from a Purity-IQ-licensed CB.
- The applicant must be in good standing with Purity-IQ concurrent to its site certification and the CAPS requirements.
- Products labelled for sale are **not** permitted to carry or display the Purity-IQ or CAPS-certified owned and registered logos.
- The company's or any agent's website, social and digital media, and/or advertising collaterals are permitted to carry or display the Purity-IQ-registered logo.
- The cannabis products must conform to all Purity-IQ requirements detailed within the CAPS Certification Brand Guidelines and be on the CAPS Schedule A (see Appendix 6).

The use of the Purity-IQ and CAPS-certified owned and registered logos must conform with the terms and conditions in the Purity-IQ site licence agreement, entered into directly between the site and Purity-IQ

The AIMS shall ensure that mitigation strategies for product defence risks are identified, implemented, and monitored

## 8.5 Product defence

The site shall develop, document, implement, monitor, and maintain a product defence program that reduces or eliminates intentional adulteration or unauthorized tampering.

Product defence operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- only authorized personnel have access to production equipment, vehicles, and processing/manufacturing and storage areas through designated access points
- sensitive processing points are protected from intentional adulteration or unauthorized tampering
- raw materials, ingredients, packaging materials, work in progress, process inputs, and final products are handled or held under secure storage and transportation conditions
- access to the premises by employees, contractors, and visitors is controlled and recorded
- mitigation strategies for product defence risks are identified, implemented, and monitored
- the product defence plan is reviewed at least annually and whenever a new risk emerges or an incident occurs
- records associated with the product defence program are maintained.

## 8.6 Product fraud

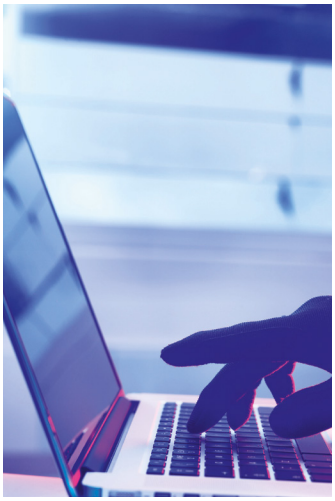
The site shall develop, document, implement, monitor, and maintain a product fraud program that reduces or eliminates identified product fraud vulnerabilities.

Operations to reduce product fraud shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- a product fraud vulnerability assessment is conducted to identify potential vulnerabilities including the site's susceptibility to product substitution, mislabelling, dilution, counterfeiting, or stolen goods that may adversely impact product integrity
- mitigation strategies for identified product fraud vulnerabilities are identified, implemented, and monitored
- the product fraud program is reviewed at least annually and whenever a new risk emerges or an incident occurs
- records associated with the product fraud program are maintained.



The AIMS shall ensure that a product fraud vulnerability assessment is conducted to identify potential vulnerabilities including the site's susceptibility to product substitution, mislabelling, dilution, counterfeiting, or stolen goods that may adversely impact product integrity

## 8.7 Corrective and preventive actions

The site shall develop, document, implement, monitor, and maintain a corrective and preventive actions program that effectively identifies, investigates, evaluates, resolves, and further prevents issues related to product safety, quality, authenticity, identity, and legality.

Nonconformity investigations and corrective action activities shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that the site reports adverse reactions or the release of out-of-specification products to Purity-IQ within 48 hours

The AIMS shall ensure that:

- procedures are available for effectively identifying, reporting, investigating, evaluating, and resolving all nonconformities and customer complaints
- all nonconformities, customer complaints, and out-of-specification results are thoroughly investigated
- complaints and other relevant information are recorded with original details
- all investigations are evaluated, and if necessary, measures are taken to immediately mitigate unacceptable risk (e.g. putting the lot or batch on hold until the investigation is completed)
- complaint records are routinely verified to ensure that all adverse reactions or failures to meet the AIMS are documented and reported
- out-of-specification products are effectively managed to prevent unauthorized release
- the site reports adverse reactions or the release of out-of-specification products to Purity-IQ within 48 hours
- records associated with the corrective and preventive actions program are maintained.

## 8.8 Traceability, recall, and withdrawal

The site shall develop, document, implement, monitor, and maintain a system that enables the effective traceability, recall, and withdrawal of ingredients, inputs, source materials, and final products.

Traceability, recall, and withdrawal operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- permits the rapid and complete recall or withdrawal of every lot or batch of product that has been sold or distributed
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- ingredients, inputs, source materials, rework, work in progress, and final products are identified and traceable at all times, e.g. using a lot/batch number
- a list of all starting materials to be used, and their cannabis source where appropriate, with details of the amount of each material used to produce each lot/batch, is available
- a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields where applicable, is available
- tracking procedures for consignees in the distribution chain are specified
- the responsibilities and methods through which a product recall or withdrawal is executed are specified
- personnel responsible for initiating, managing, and investigating a recall or withdrawal are identified
- a communication strategy to inform the appropriate consignees in the distribution chain, regulatory authorities, Purity-IQ, the CB, or any other essential body within a timeframe appropriate to the risk level of the recall is specified
- an investigation into any product recall or withdrawal is conducted to determine its root cause
- the site reviews, tests, and verifies the effectiveness of the traceability, recall, and withdrawal system at least annually
- records associated with traceability, recall, and withdrawal operations are maintained.

The AIMS shall ensure that ingredients, inputs, source materials, rework, work in progress, and final products are identified and traceable at all times, e.g. using a lot/batch number

# 9. System verification

## 9.1 External audits

The site shall develop, document, implement, monitor, and maintain an external audit program that determines conformance with CAPS via independent review.

External audit operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input

The AIMS shall ensure that a digital or hard copy of the current issue of CAPS is available on site

- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- the site is subject to an annual audit by a CAPS-approved auditor
- a digital or hard copy of the current issue of CAPS is available on site
- a current Schedule A, completed by the site or brand owner and signed by Purity-IQ, is available on site
- a self-assessment is performed to determine conformity with CAPS
- only Purity-IQ-licensed certification bodies are contracted to perform external audits
- adequate resources, information, site access, and personnel are provided as needed by the auditor and CB to prepare and conduct the audit
- any other support is provided to the auditor and CB so that the external audit is completed as efficiently and effectively as possible
- records associated with external audits are maintained.

## 9.2 Internal audits

The site shall develop, document, implement, monitor, and maintain an internal audit program that verifies the implementation of the AIMS and conformance with CAPS.

Internal audit operations shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- internal audits are scheduled
- the frequency of each internal audit is based on the risk associated with the

nominated activity and the results of previous audits

- all activities are audited at least once a year
- each internal audit addresses a defined scope
- internal audits are completed by qualified auditors who are independent of the activity being audited and present no conflict of interest
- internal audit reports identify both conformities and nonconformities and include evidence of findings
- results of internal audits are reported to applicable personnel, with corrective actions, preventive actions, and timelines for their implementation agreed upon
- implementation of corrective actions is verified and recorded
- records associated with the internal audit program are maintained.

The AIMS shall ensure that each sample used for testing must be representative of the lot or batch of cannabis, or cannabis accessory that contains cannabis, that would be sold, distributed, or exported

# 10. Testing and analysis

## 10.1 Sample collection, storage, and retention

The site shall develop, document, implement, monitor, and maintain a sample collection, storage, and retention program.

Sample collection, storage, and retention procedures shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- samples used for testing must be collected, stored, and retained according to the site's SOP(s)
- each sample used for testing must be representative of the lot or batch of

cannabis, or cannabis accessory that contains cannabis, that would be sold, distributed, or exported:

- the quantity and quality of the sample shall be proportional to and reflective of the total lot or batch

- sampling procedures are carried out under appropriate and predetermined conditions
- samples are stored under appropriate conditions that do not adversely affect their integrity:
  - samples are identifiable and stored according to the conditions set out on the label, as applicable
- a representative sample of sufficient quantity is maintained to allow any regulatory authority and/or Purity-IQ to conduct additional testing, if required:
  - for a minimum of 1 year after the "best before" or "expiry" date
  - to enable a reliable determination of whether it meets the following requirements:
    - » biological and chemical contaminants
    - » dissolution and disintegration
    - » quantities or concentrations of THC, THCA, CBD, and CBDA as per regulatory requirements and CAPS
    - » limits of quantification for pesticide active ingredients
- records associated with sample collection, storage, and retention operations are maintained.

## 10.2 Testing for phytocannabinoids

The site shall develop, document, implement, monitor, and maintain a phytocannabinoid testing program.

Phytocannabinoid testing procedures shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained

- meets legal requirements where applicable.

The AIMS shall ensure that:

- testing for the quantity or concentration of THC, THCA, CBD, and CBDA and other similar cannabinoid molecules is conducted on each lot or batch of cannabis
- the testing of manufacturing ingredients and consumer products is conducted on the final form of the cannabis, either before or after it (or the cannabis accessory that contains it) is packaged and labelled as a cannabis product
- records associated with phytocannabinoid testing are maintained.

The AIMS shall ensure that testing for the quantity or concentration of THC, THCA, CBD, and CBDA and other similar cannabinoid molecules is conducted on each lot or batch of cannabis

## 10.3 Testing for biological and chemical contaminants

### 10.3.1 Contaminant testing

The site shall develop, document, implement, monitor, and maintain a contaminant testing program.

Contaminant testing procedures shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- testing for biological and chemical contaminants (e.g. residual solvents, heavy metals, aflatoxins) – other than residues of a pest control product or its components or derivatives – is conducted on the following:
    - each lot or batch of input cannabis for all edible cannabis products (testing of this lot or batch of cannabis is conducted after the final step in the production process during which the biological and chemical contaminants, including residues of a pest control product or its components or derivatives, could have been introduced or could be concentrated, whichever is later)

The AIMS shall ensure that the site remains up to date with current contaminant testing requirements and tolerance limits

- each lot or batch of input cannabis, or final form for fresh cannabis, dried cannabis, cannabis topicals, and cannabis extracts (testing on this lot or batch is conducted after the final step in the production process or on the final form of the cannabis, either before or after it [or the cannabis accessory that contains it] is packaged and labelled as a cannabis product)

- records associated with contaminant testing procedures are maintained.

### 10.3.2 Allowable thresholds

The results of testing must enable a determination of whether the contaminants, if any, are or will be within tolerance limits.

The AIMS shall ensure that:

- accepted tolerance limits for human use are appropriate for the intended use and any reasonably foreseeable use of the cannabis product
- these limits are established considering applicable regulatory requirements where the product is produced, manufactured, or sold
- the site remains up to date with current contaminant testing requirements and tolerance limits
- records associated with allowable thresholds are maintained.

## 10.4 Laboratories

The site shall develop, document, implement, monitor, and maintain a laboratory testing program.

Laboratory testing procedures shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

The AIMS shall ensure that:

- the site uses a cannabis testing laboratory that is accredited to ISO 17025 where possible; if such a laboratory is not available, the site must maintain

documentation to validate the laboratory methods that were used

- the laboratory holds a valid licence required by any regulatory authority, if needed, and/or by Purity-IQ, for testing of its cannabis
- the laboratory uses the appropriate analytical methods that correspond to the established specifications captured in the site's approved SOP(s)
- the specification(s) against which the cannabis is to be tested is/are:
  - supported by adequate justification, including an assessment of the intended and reasonably foreseeable use as per section 10.3.2
  - approved by the AIMS team leader prior to testing
- the specifications are provided to the laboratory before any testing for phytocannabinoids, contaminants, or dissolution and disintegration testing is conducted
- procedures for submitting samples are available that include chain of custody requirements
- testing is conducted using validated methods recognized by competent authorities
- if the methods were applied as a tool for internal verification purposes, the site demonstrates that:
  - they were validated before being used
  - the results of validation studies are documented and maintained and available for review
  - procedures are available that describe testing activities and include reference standards and controls
- the site does not repeatedly test a product until the results fall within the identified specification(s) (e.g. biological and chemical contaminant testing) or until the desired result is obtained by chance (e.g. quantity or concentration of THC or CBD content)
- if the site chooses to conduct multiple tests, it must do so in accordance with procedures that outline:
  - predetermined criteria for when additional testing, including retesting, is permitted
  - the maximum number of retests that can be performed
- records associated with laboratory testing procedures are maintained.

The AIMS shall ensure that the site uses a cannabis testing laboratory that is accredited to ISO 17025 where possible; if such a laboratory is not available, the site must maintain documentation to validate the laboratory methods that were used

# Part II – Cannabis Authenticity and Purity Standard

## Advanced requirements

# 11. Risk management

The AIMS shall ensure that product certification is granted only to those products that achieve a confidence interval of at least 90%

## 11.1 Labelling and advertising

If the site chooses to use the Purity-IQ and CAPS-certified owned and registered logos, the AIMS shall ensure that:

- the site conforms to the CAPS-Basic requirement for labelling and advertising as described in section 8.4
- the applicant is in possession of and conforms with the terms and conditions in a *brand licence agreement,* agreed directly with Purity-IQ for use of the CAPS-certified registered logos
- products are registered in the Purity-IQ Global Registry – Cannabis and have an accompanying current global registration certificate issued directly from a Purity-IQ-licensed laboratory
- conformity is demonstrated through batch-to-batch registered product verification testing, accompanied by certificates of authenticity issued directly from a Purity-IQ-licensed laboratory
- product certification is granted only to those products that achieve a confidence interval of at least 90%
- final products displaying the CAPS-certified registered logos are listed and maintained as current on the CAPS Schedule A document residing at the site
- the applicant conforms to all Purity-IQ requirements detailed in the CAPS Certification Brand Guidelines.

## 11.2 Traceability, recall, and withdrawal

The AIMS shall ensure that:

- the site conforms to the CAPS-Basic requirement for traceability, recall, and withdrawal as described in section 8.8
- cannabis sources used for CAPS-certified products are those listed in the Purity-IQ Global Registry – Cannabis that are tracked throughout production to end product.

# 12. Authenticity testing

The site shall develop, document, implement, monitor, and maintain an authenticity testing program that conforms to the requirements set out in this section.

Authenticity testing procedures shall be performed in a manner that:

- prevents the introduction of extraneous substances to the cannabis, or to any item that will be used as an ingredient or input
- prevents contamination of the cannabis, ingredient, or input
- ensures that the quality, authenticity, and identity of the cannabis, ingredient, or input are maintained
- meets legal requirements where applicable.

## 12.1 Cultivar registration

The AIMS shall ensure that:

- the site submits the appropriate number of samples according to the requirements of the "Purity-IQ Global Registry – Cannabis" document for the applicable cannabis or hemp cultivar registration
- cannabis and hemp cultivar registrations achieve a genomic cultivar match meeting or exceeding 98%
- quantification of phytocannabinoids is performed at Purity-IQ licensed laboratories for registrations into the Purity-IQ Global Registry – Cannabis
- the procedures for genovar iris identification and/or metabolomic fingerprinting are conducted at Purity-IQ-licensed laboratories as outlined in Purity-IQ's licensing agreement
- records associated with cultivar registration procedures are maintained.

**Note:**
A global registration certificate will be issued to the site upon successful cultivar registration.

A certificate of analysis, containing genovar iris identification and metabolomic fingerprint data, will be issued to the site. Interpretation of results for genovar iris identification and metabolomic fingerprinting testing can be found in Appendix 3.

Genovar iris identification and metabolomic fingerprint data will be added to the Purity-IQ Global Registry – Cannabis, establishing a criterion for future batch/lot verification and authenticity testing: see section 12.3.

For further explanation, see Appendix 1.

The AIMS shall ensure that cannabis and hemp cultivar registrations achieve a genomic cultivar match meeting or exceeding 98%

A global registration certificate will be issued to the site upon successful cultivar registration

## 12.2 Product registration

The AIMS shall ensure that:

- if applicable, the site submits the appropriate number of samples according to the requirements of the "Purity-IQ Global Registry – Cannabis" document for product registration
- product registration is conducted on the final form of the cannabis product
- quantification of phytocannabinoids is performed at Purity-IQ-licensed laboratories for registrations into the Purity-IQ Global Registry – Cannabis
- the procedures for metabolomic fingerprinting are conducted at Purity-IQ-licensed laboratories as outlined in Purity-IQ's licensing agreement
- records associated with product registration procedures are maintained.

**Note:**
A global registration certificate will be issued to the site upon successful metabolomic fingerprinting.

A certificate of analysis, detailing metabolomic fingerprint data, will be issued to the site. Interpretation of results for metabolomic fingerprinting can be found in Appendix 3.

Metabolomic fingerprint data will be added to the Purity-IQ Global Registry – Cannabis, establishing a criterion for future batch/lot verification and authenticity testing: see section 12.3.

For further explanation, see Appendix 1.

The AIMS shall ensure that the procedures for metabolomic fingerprinting are conducted at Purity-IQ-licensed laboratories as outlined in Purity-IQ's licensing agreement

## 12.3 Registered cultivar and product verification

The AIMS shall ensure that:

- the site submits the appropriate number of samples and sampling methods used according to the requirements of the "Purity-IQ Global Registry – Cannabis" document for registered cultivar and product verification
- product verification is performed through metabolomic fingerprinting on each lot or batch of registered product produced that is or will become a certified cannabis product
- testing on this lot or batch of cannabis is conducted on the final registered form of the cannabis product

- the procedures for metabolomic fingerprinting are conducted at Purity-IQ-licensed laboratories as outlined in Purity-IQ's licensing agreement
- records associated with registered cultivar and product verification procedures are maintained.

**Note:**
A certificate of authenticity will be issued to the site, detailing metabolomic fingerprint data.

Metabolomic fingerprint data will be added to the Purity-IQ Global Registry – Cannabis.

Interpretation of results for metabolomic fingerprinting can be found in Appendix 3.

For further explanation, see Appendix 1.

A certificate of authenticity will be issued to the site, detailing metabolomic fingerprint data

# Part III – Appendices

# Appendix 1 Guidance for CAPS-Advanced product certification

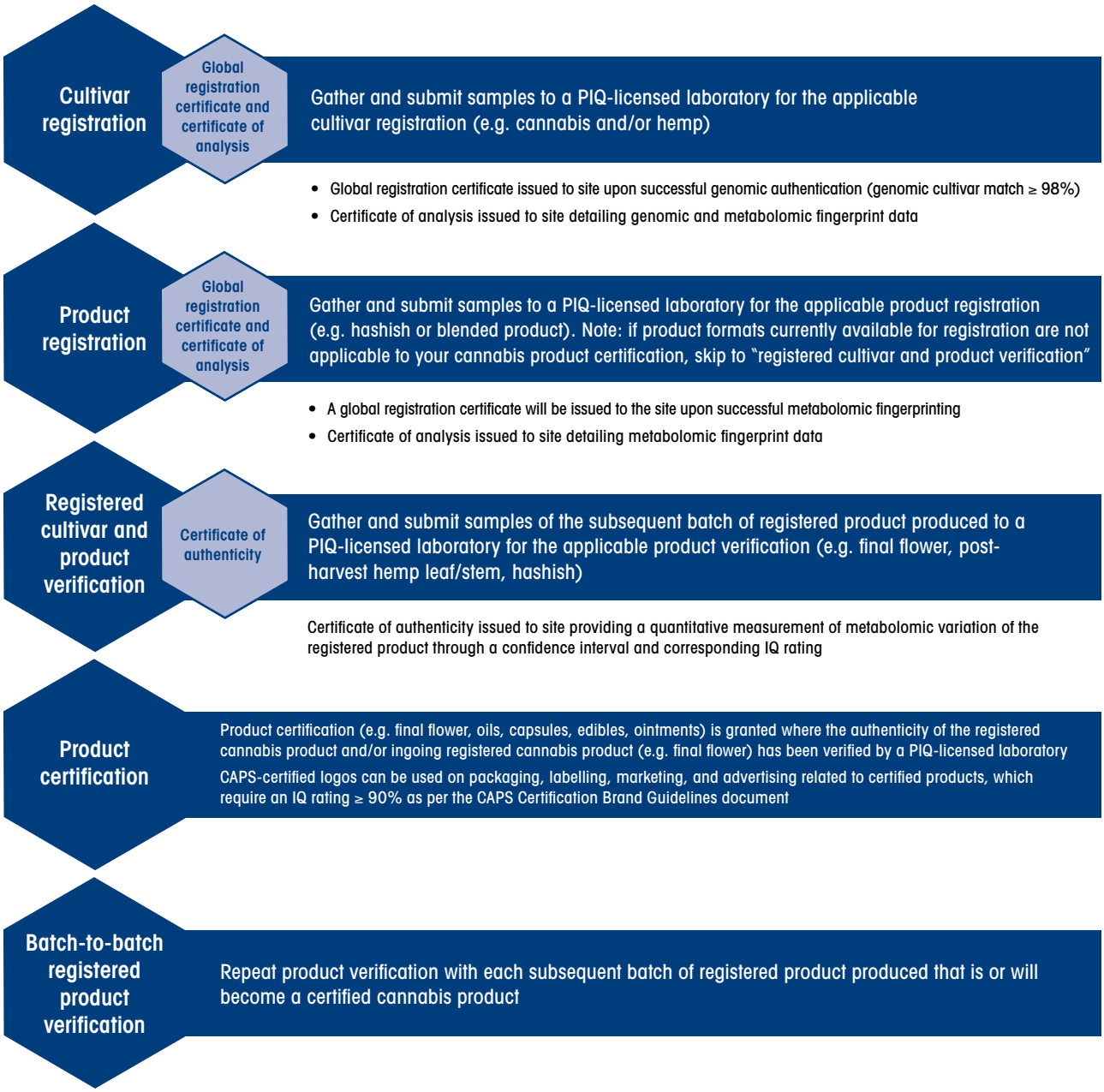



**Figure 2** Roadmap to product certification

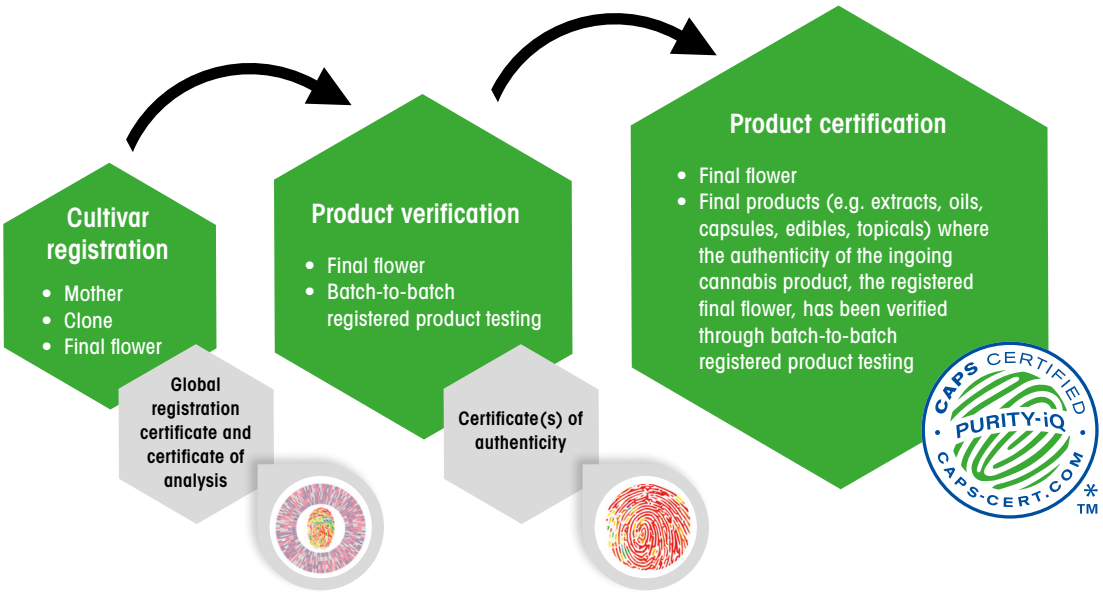



**Figure 3** Dried flower product registration and verification process example

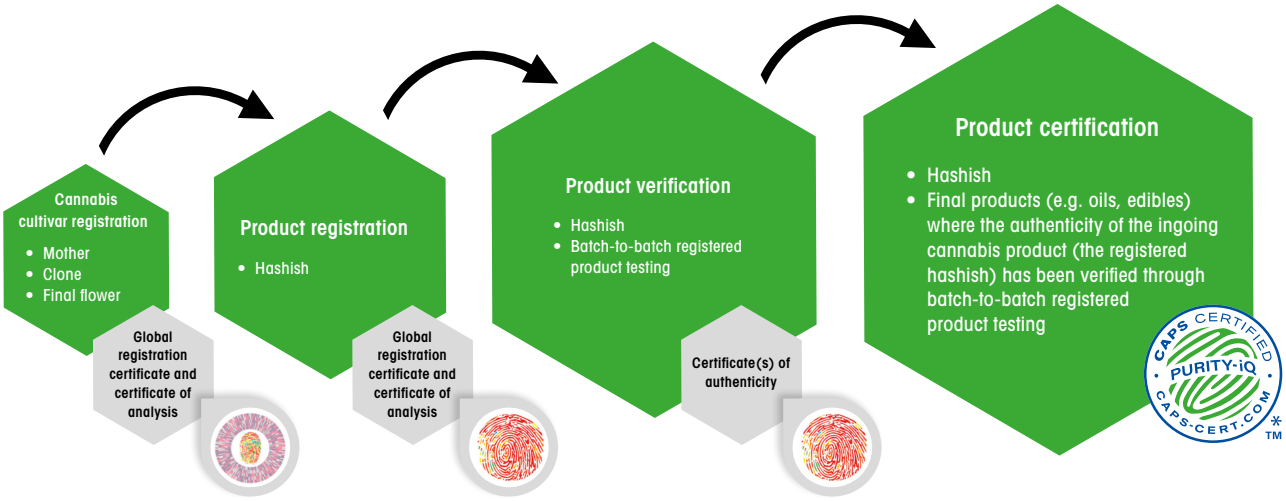



**Figure 4** Hashish product registration and verification process example

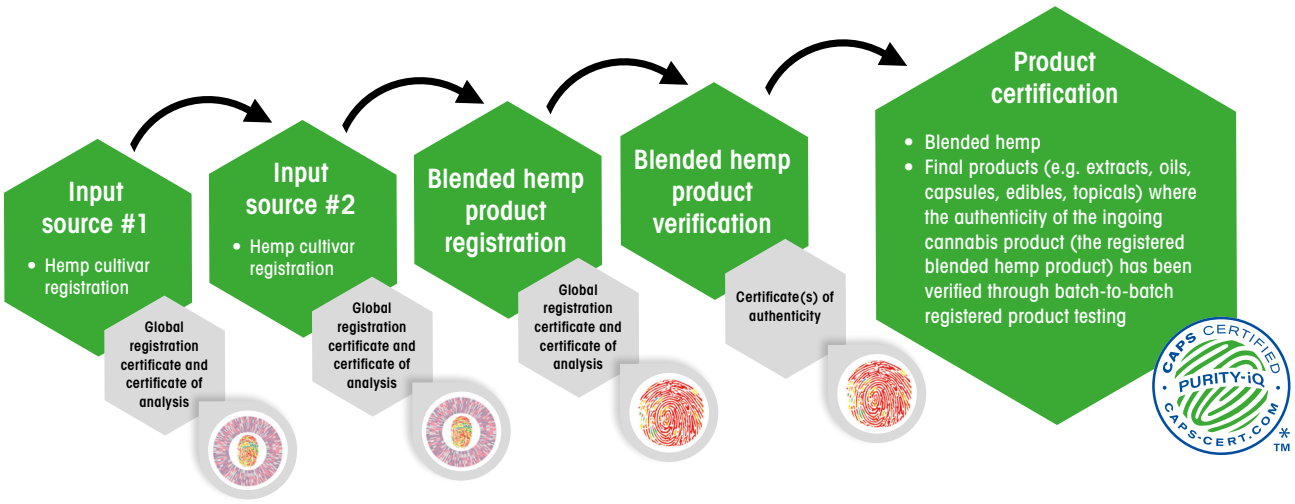



**Figure 5** Blended hemp product registration and verification process example

# Appendix 2 Global registration certificate template

The global registration certificate shall conform to the format shown below.

PIQ/GRC No: Correlates to product as registered

Purity-IQ logo

Product name

This product has been scientifically analyzed, fingerprinted, and deemed authentic according to the Purity-IQ genomic and/or metabolomic standard operating procedures and is officially registered within the Purity-IQ Global Registry – Cannabis.

Company address:
Product name:
Product type:
Date issued:

Authorized by (Director, Product Development)

*The Purity-IQ global registration certificate number correlates to laboratory certificates of analysis and has been verified by Purity-IQ*

As a research, development, and standards service organization, Purity-IQ does not in any way, shape, or form engage in the production, growing, extraction, regulated analytical testing, or sale of any cannabis-related products or paraphernalia.



**www.purity-iq.com**

# Appendix 3 Purity-IQ certificates of analysis and authenticity: Interpretation of results

## Certificates of analysis

*Genomic analysis: Genovar iris identification*

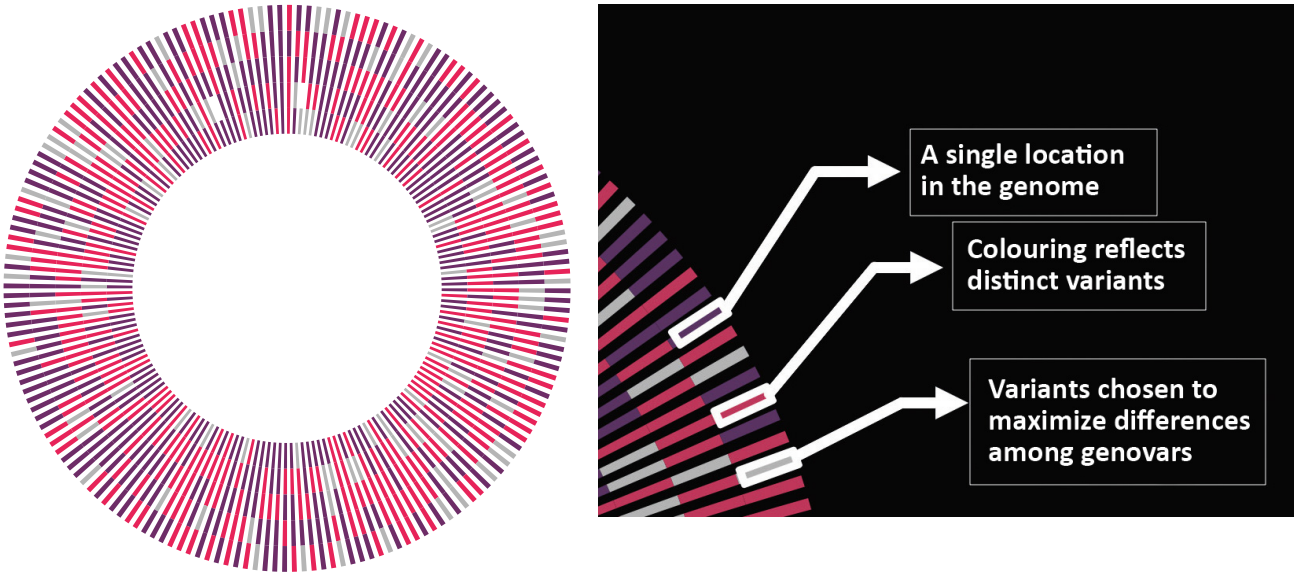



**Figure 6** Genovar iris identification

The iris represents the single nucleotide polymorphisms (SNPs) that are present for a specific cannabis cultivar (Figure 6). SNPs are the most common form of DNA sequence variation. Each SNP represents a difference in a single DNA building block, called a *nucleotide*.

**Genomic cultivar match (G)** – Genetic relatedness to the registered cultivar measured as identity by state (IBS) using the Lighthouse Genomics Cannabis 40k SNP array.

In a cannabis cultivar registration, genomic cultivar match applies to the level of genetic relatedness between mother plant, clone plant, and final flower.

In a hemp cultivar registration, genomic cultivar match applies to the level of genetic relatedness between pre- and post-harvested hemp leaf and stem.

Clones are expected to have relatedness ≥98%, siblings 85–98%, and cousins 78–90%.

## *Metabolomic analysis: Metabolomic fingerprint*

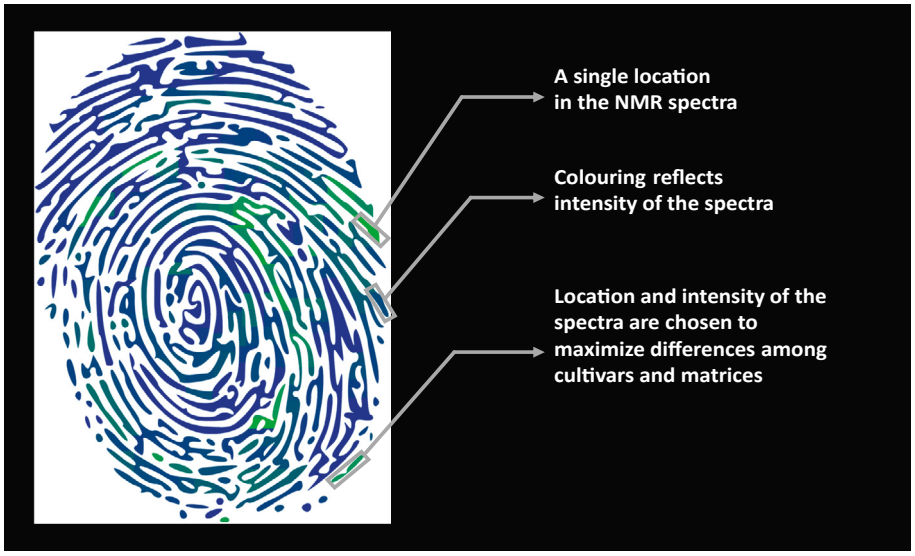



**Figure 7 Example of a metabolomic fingerprint**

The metabolomic fingerprint in Figure 7 represents the metabolites present for a specific cannabis cultivar based on the NMR metabolite profile.

The metabolomic fingerprint is quantitative, as it represents the relative molecular weight of each metabolite.

# Certificate of authenticity

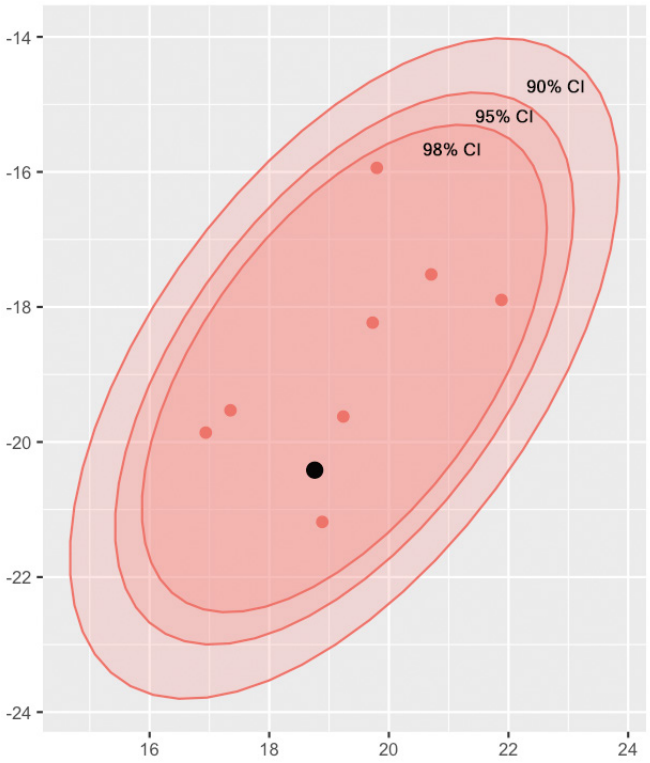
**Table 1 IQ rating matrix for verification of registered products**

| ≥98% confidence interval | ≥95% to <98% confidence interval | ≥90% to <95% confidence interval | <90% confidence interval |
|---|---|---|---|
| IQ-1 | IQ-2 | IQ-3 | Unrated |

IQ ratings for verification of registered products are shown in Table 1. The confidence interval indicates the level of variation in the metabolite profile. For example, a confidence interval of ≥95% to <98% indicates that the variation in the metabolite profile is within 2–5% of the registered product sample for a specific product matrix.

The IQ ratings apply to those products demonstrating consistent "batch-to-batch" testing evidence, which achieve confidence intervals of at least 90% as specified in the Purity-IQ CAPS requirements. Product certification will be granted only to those products contained in the Purity-IQ Global Registry – Cannabis data library.

**Confidence interval (CI)** – A measurement of the variation in the metabolite profile of the registered cultivar or product for a specific product matrix.

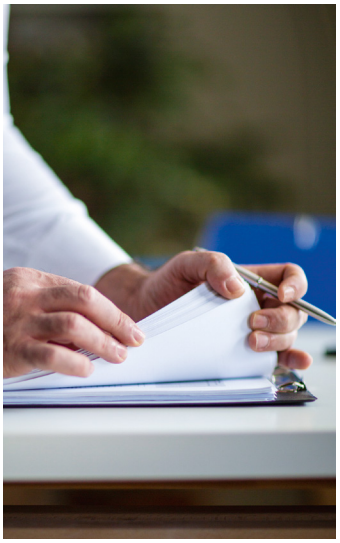



The pink circle in Figure 8 is an ordination diagram, which shows the principal components of a metabolite profile, which can then be measured using multivariate statistics.

In Figure 8, we observe the relationship between a mother plant and eight of its clone plants. In this instance, all clone plants are within a 98% confidence interval of their mother, indicating a variation in the metabolite profile of no more than 2%.

**Figure 8 Example of metabolomic ordination: mother and clone plants**

# Appendix 4 Purity-IQ certification process and audit protocol



## Schedule 1 – Conducting audit and certification functions

This section details the process for the certification of sites and licensing under the Cannabis Authenticity and Purity Standard. A roadmap of the process is provided in Figure 9.

### *1 Learn about CAPS*

Visit the CAPS website for information and resources: **www.caps-cert.com**.

Download the Cannabis Authenticity and Purity Standard (CAPS) to learn about the requirements for certification. You can also complete the free CAPS Interactive Orientation.

### *2 Apply for certification*

Apply for certification with the Cannabis Authenticity and Purity Standard (CAPS). Receive the CAPS-associated documents and coaching throughout the process. All sites must complete the online program registration form process.

### *3 Complete CAPS training*

Enhance your understanding of CAPS by completing the CAPS-Basic or CAPS-Advanced training.

### *4 Perform a GAP assessment*

Complete a self-assessment (third party or internal audit) to CAPS, to identify nonconformities and establish implementation requirements.

## *5 Develop and implement your AIMS*

Your authenticity and identity management system (AIMS) is foundational to documenting your standard operating procedures (SOPs) and preventive controls.

## *6 Select a licensed certification body*

Visit the CAPS website to select from a list of CAPS-approved CBs to conduct the CAPS-Basic or CAPS-Advanced on-site audit.

A service contract and/or audit agreement shall exist between the site and the CB in advance of an audit. The contract shall contain clauses that allow the effective management of the CAPS audit process.

The site must enter into a CAPS site licence agreement (SLA) with Purity-IQ Inc. and submit a completed Schedule A (see Appendix 6). Schedule A must capture all products that will be recognized under CAPS, and must be maintained.

A site applying for CAPS-Advanced must select a licensed laboratory and submit samples for registration into the Purity-IQ Global Registry – Cannabis, followed by verification of each lot/batch of the registered product(s). Visit the CAPS website for a list of licensed laboratories.

## *7 The audit process*

Select an audit option (standalone, combined, or unannounced combinations) and schedule your CAPS certification audit with your nominated CB. The CB will indicate an approximate duration in the audit plan.

Audits must be arranged with the CB for dates and times when production is scheduled. Sites that are newly built or "commissioned" must ensure that the systems and procedures in place conform with CAPS before an initial audit is undertaken. The site may use its own discretion in choosing when to invite a CB to carry out an audit; however, it is unlikely that full conformity can be satisfactorily demonstrated at an audit undertaken less than 3 months (90 calendar days) from implementation of the AIMS. The options and processes available for sites to demonstrate their commitment to CAPS are as follows:

- **Standalone audit** The focus of a standalone audit is on the CAPS requirements only.
- **Combined audit** The focus of a combined audit is on the CAPS requirements in conjunction with any other third-party food safety and/or good manufacturing or agricultural management practice audit.

- **Unannounced combined audit** If there is no production of any product listed in Schedule A when an unannounced combined audit takes place, the audit may still be conducted, providing the auditor(s) can walk through the process and understand the controls that operate during production. Records from previous production runs shall be made available. In this case, the next CAPS audit must be conducted while production of the Schedule A product(s) is taking place. This option (walk-through) is not permitted if it is the first CAPS audit.

## 7.1 Scope of audit

The audit shall include all the applicable requirements within CAPS and all production processes undertaken for the products listed on the site's Schedule A.

The product scope category of the audit shall be agreed between the site and the CB in advance of the audit, to ensure the allocation of one or more auditors with the correct product knowledge.

The product scope category is determined by assessing the products produced and manufacturing processes, and it must align with one of the categories listed in the CAPS product scope categories document in Schedule 4. At the time of the audit, the auditor(s) will review the scope category listed on the site's Schedule A to ensure alignment.

## 7.2 Selection of auditors

It is the responsibility of the site to ensure that adequate and accurate information is given to the CB, detailing the products it manufactures and the process technologies it uses, so that the CB can select an appropriate audit team with the required skills to undertake the audit.

The CB and auditor(s) must be aware of the need to avoid conflicts of interest when arranging for an auditor(s) to visit the site. The site may decline the services of a particular auditor offered by the CB. Ideally, the same auditor is not permitted to undertake audits on more than three consecutive occasions at the same site.

Where the audit is not being carried out by the auditor(s) in the native language of the site, an appropriate translator (supplied by the site, if needed), who has knowledge of the technical terms used during the audit, shall be provided. The final audit report must be submitted to Purity-IQ in English.

The auditor(s) may be accompanied by other personnel for training, assessment, or calibration purposes. This activity may include:

- training of new auditors by the CB
- routine shadow audit programs conducted by the CB

- witness audits conducted by accreditation bodies
- witness audits conducted by Purity-IQ.

## 7.3 Duration of the audit

Before the audit takes place, the CB shall indicate its approximate duration. The typical duration for a standalone audit is 1.5 to 2 consecutive days at the site. When a CAPS audit is being combined with another food safety and/or good manufacturing or agricultural management audit, it will take at least an extra half-day.

## 7.4 The on-site audit

A typical on-site audit consists of the following stages:

- **Opening meeting** To confirm the scope and process of the audit.
- **Document review** A review of the documented AIMS and the site's Schedule A.
- **Site inspection** To review the practical implementation of the systems, including observation of product changeover procedures and interviews with personnel.
- **Traceability challenge** Including a review of all relevant records of production (e.g. ingredients intake, production records, final product checks, and specifications).
- **Label review** Including a review of a sample of CAPS-certified product labels (if applicable, as in CAPS-Advanced) to check against specification and legislation.
- **CAPS-Advanced authenticity testing verification** Including a review of product registrations and verifications: associated global registration certificates, certificates of analysis, and certificates of authenticity.
- **Final review of findings by the auditor(s)** Preparation for the closing meeting.
- **Closing meeting** To review audit findings with the site. A draft of the nonconformity report will be left with the site (note that nonconformities are subject to subsequent technical review by the CB management).

The site shall always fully assist the auditor(s). It is expected that, at the opening and closing meetings, those attending on behalf of the site will be members of the AIMS team.

The audit process gives emphasis to the practical implementation of the AIMS procedures and general good manufacturing and agricultural practices. It is expected that the auditor(s) will spend an appropriate amount of time auditing production, interviewing staff, observing processes, and reviewing documentation in production areas with the relevant staff.

During the audit, detailed notes shall be made regarding the site's conformities and nonconformities against CAPS, and these will be used as the basis for the audit report. The auditor(s) shall document and advise the attending AIMS team representative of the number, descriptions, and extent of the nonconformities.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all nonconformities that have been identified during the audit. Information must be given on the process and timescales for the site to provide evidence to the auditor(s) of the corrective actions to close nonconformities. The auditor(s) will give the AIMS team a draft summary of the nonconformities discussed at the closing meeting.

The CB management will independently make the decision on awarding certification, following a technical review of the audit report and the closing of nonconformities in the appropriate timeframe. The site will then be informed of this decision.

## 7.5 Managing nonconformities

If the audit has identified any nonconformities, the site must undertake corrective action to remedy the immediate issues and provide an analysis of the underlying cause of each of these nonconformities, which can then be used in taking preventive action. The action plan produced shall include timelines and shall be provided to the CB.

Close-out of nonconformities can be achieved either by the site submitting objective evidence to the auditor(s) (either at or after the time of the audit) – which may include updated procedures, records, photographs, or invoices for work undertaken – or by the auditor(s) undertaking a further on-site visit, as appropriate.

If satisfactory evidence is not provided within the 28-calendar-day period allowed for submission following the closing meeting, certification will not be granted. The site may be required to have a further full audit to be considered for certification. No certificate shall be issued until the site can demonstrate that all nonconformities have been addressed. Nonconformities from the audit shall be checked during the next audit to verify effective close-out.

A site undergoing initial certification audits shall have nonconformities corrected, verified, and closed out by the auditor(s) within 90 calendar days of the completion of the site audit.

The CB will conduct a technical review of both the evidence and the completion of any corrective actions before awarding a certificate.

The CB will review nonconformities, using its independent certification process, as soon as possible after the audit. Where the review determines that a certificate cannot be awarded, the site will be required to undertake another full audit if it still wishes to pursue certification.

Occasionally, the nature and number of nonconformities make it unlikely that they can be addressed, and fully effective improvements implemented and established, within a 28-calendar-day period. In such a case, the re-audit shall not take place any earlier than 28 calendar days from the audit date. Where this occurs at a certified site, the certification must be immediately withdrawn. Some customers require that they shall be informed when their suppliers have a critical nonconformity identified or fail to gain certification. In such circumstances, the company shall immediately inform its customers and make them fully aware of the circumstances.

### 7.6 Audit reporting

Following each audit, a full written report shall be prepared in the agreed format, and in English. The audit report shall be provided to the site in a timely manner. It shall accurately reflect the findings of the auditor(s) during the audit. The report shall be prepared and issued to the site within 42 calendar days from the first day of the audit, with a copy being sent to Purity-IQ. The CB shall store the audit report and associated documentation, including auditor's notes, safely and securely for a minimum of 5 years.

## *8 Site certification*

After a review of the audit report and documentary evidence provided in relation to identified nonconformities, the designated technical reviewer shall make a certification decision. The CB shall issue the certificate of recognition, if granted, within 42 calendar days from the first day of the audit. It shall include the required information found in Schedule 2 with an expiry date that will be become permanent and thus repeat annually unless changed as per section 10 of this schedule.

CAPS logos owned or managed by Purity-IQ that are displayed on certificates of recognition shall comply with the current published CAPS Certification Brand Guidelines. While the certificate of recognition is issued to the site, it remains the property of the CB, which controls its ownership, use, and display. The CB shall inform Purity-IQ of its issuance and provide a copy.

Each site that achieves a certificate of recognition shall be entered into the registry of certified sites with its expiry date. Any fees relating directly to the site must be paid in full to Purity-IQ and/or the certifying body before the certificate of recognition is issued. Neither the certification nor the audit report shall be valid until all fees have been received, irrespective of the outcome of the certification process.

## *9 Audit frequency and recertification*

For recertification, the site must consider the necessary lead time to ensure that the audit is complete, and the next certificate of recognition can be issued before the expiry date of the existing certificate of recognition. It is expected that the site and the selected CB will make every effort to complete the necessary audit, close any

nonconformities raised, and issue a new certificate of recognition before the existing certificate expiry date has lapsed.

The window for the recertification audit must be no earlier than 75 days and no later than 42 days before the certificate expiry date.

Where combined, at the sole discretion of Purity-IQ and with a third-party management systems audit (such as GMP, HACCP, GFSI-benchmarked standards, FOCUS or ISO 22000 audit), the re-audit due date may be adjusted to conform to the protocol of the relevant scheme and, if necessary, invoke a reset in the certificate expiry date as per section 10 of this schedule.

## *10 Certificate expiry date reset or extensions*

Purity-IQ supports combining the CAPS audit with other benchmarked scheme audits. It recognizes that having a reduced number of expiry dates for site certifications increases efficiency and eases the audit burden for sites. In this situation, the CB in consultation with Purity-IQ may consider, on a case-by-case basis, resetting the expiry date of the certificate of recognition to a more convenient and expedient date.

There may be circumstances where the certificate of recognition cannot be renewed before the expiry date: for example, if the CB is unable to conduct an audit on schedule or due to other extenuating circumstances that may be out of the site's control. In this case, a temporary, administrative extension may be needed. The CB in consultation with Purity-IQ may consider deviations from this on a case-by-case basis. This does not affect the expiry date being respected going forward unless it needs to be reset as above. Justifiable circumstances can occur when the site is, for example:

- situated in a specific country, or an area within a specific country, where there is government advice not to visit and there is no suitable local auditor
- within a statutory exclusion zone that could compromise food safety or animal welfare
- in an area that has suffered a natural or unnatural disaster, rendering the site unable to produce or the auditor unable to visit
- affected by conditions that prevent access to the site or restrict travel (e.g. inclement weather)
- producing seasonal products where production is delayed by a late start to the season (e.g. because of weather or product availability).

## *11 Suspension of a certified site*

A site's certificate of recognition may be suspended if:

- the site does not comply with the CAPS requirements or any other act or regulation that may impact on the products being sold
- the operator fails to comply with the CAPS requirements, the AIMS, or any other act or regulation that may impact on the products being sold
- Purity-IQ and the CB believe that public health will be endangered, or the reputation of Purity-IQ, and the status of Purity-IQ products produced in the certified site, will be adversely affected, if the site is allowed to continue operating as a certified site
- the site is subject to a receivership or makes an assignment in bankruptcy.

If a certified site is in jeopardy of suspension, it will be notified of the existence of grounds for suspension and given evidence of any deviation from the CAPS requirements. The CB will specify corrective measures and the dates for completion. If the site has failed or is unable to take corrective measures by the specified date, a notice of suspension will be delivered to it.

The suspension of a site's certification shall remain in effect until the required corrective measures have been taken and verified as completed to the satisfaction of the CB or Purity-IQ.

If an operator fails to pay any fee specified by Purity-IQ in accordance with the conditions of payment prescribed by Purity-IQ, the certification of the site to CAPS shall also be suspended until all outstanding fees are paid.

**Note:** If a site's certification is suspended, Purity-IQ reserves the right to inform the brand owner (if different from the site) of this, and the site must cease use of all associated logos as per the site's SLA.

## *12 Withdrawal of certification*

The CB or Purity-IQ reserves the right to withdraw a site's certification if the site:

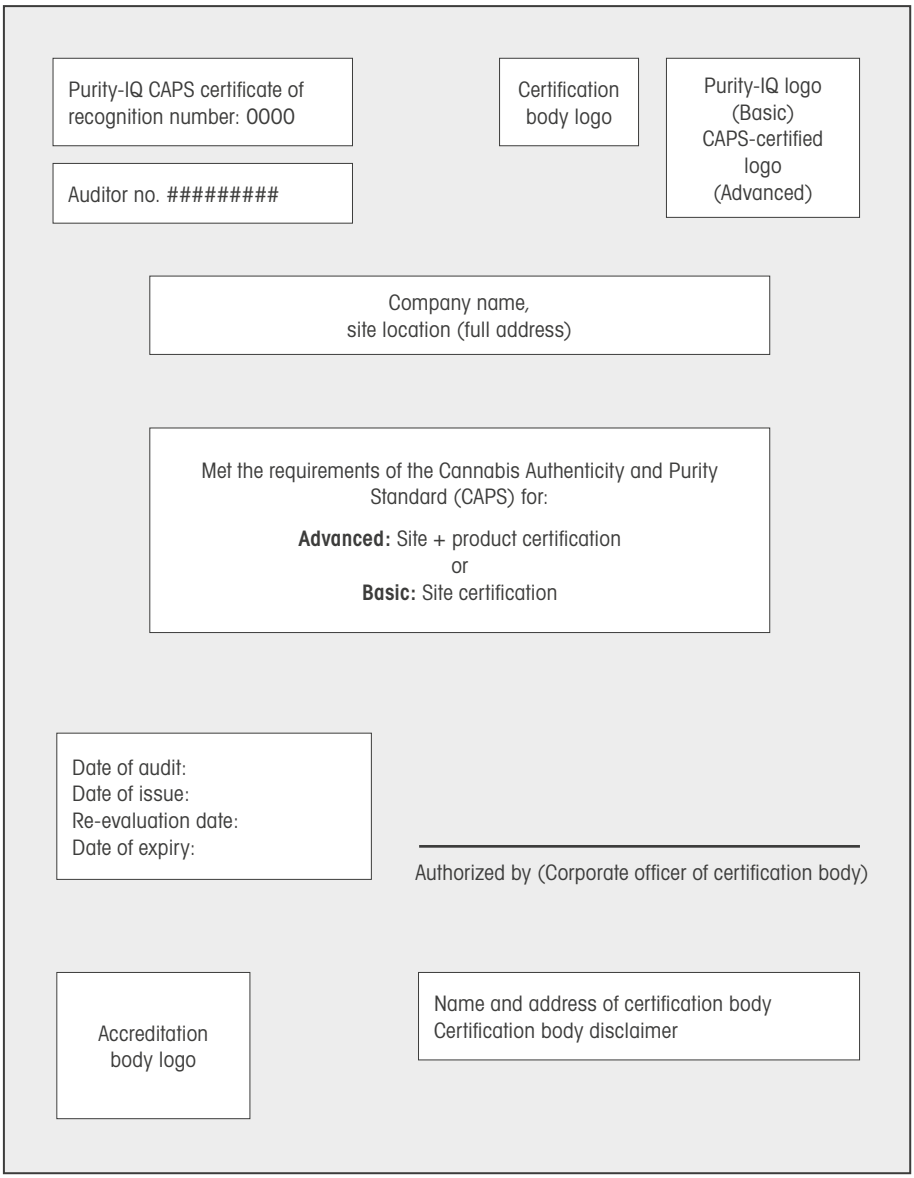
- has not implemented the required corrective measures within an agreed timeframe
- has provided false or misleading information
- gives up certification by voluntarily withdrawing from CAPS.

**Note:** If a site's certification is withdrawn, Purity-IQ reserves the right to inform the brand owner (if different from the site) of this, and the site must cease use of all associated logos as per the site's SLA.


**Figure 9** Roadmap to CAPS certification

# Schedule 2 – Purity-IQ CAPS certificate of recognition template

The certificate of recognition shall conform to the format shown below or as otherwise licensed by Purity-IQ:



The Purity-IQ CAPS certificate of recognition number indicates that the named site conforms to the requirements of CAPS and is in good standing as determined by a Purity-IQ-approved auditor under the authority of a Purity-IQ-licensed certification body.



# Schedule 3 – Management and governance

## *Requirements for certification bodies*

CAPS is a management system and product certification standard and scheme:

- Sites and products are certified upon completion of a satisfactory audit by a CAPS-approved auditor employed by a Purity-IQ-licensed independent third party – the CB.
- The CB shall have been assessed and accredited to be in conformity with ISO/IEC 17065 by an accreditation body (ISO/IEC 17011:2017) with the appropriate Mutual Recognition Agreements.
- Before signing a licence agreement with the CB to grant authority to issue certificates under CAPS, Purity-IQ will evaluate the schemes, scopes, and other information to ensure that they are complementary to good manufacturing practice audits under CAPS (e.g. HACCP, GFSI-benchmarked standards, FSEP, or ISO 22000) or good agricultural practices (e.g. GLOBALG.A.P., Primus GFS).
- The experience and qualifications of the auditors and technical reviewers are consistent with those specified by the:
    - CAPS-certified auditor requirements
    - CAPS-certified technical reviewer requirements.

## *Achieving consistency – conformity*

Maintaining a highly consistent standard of the audit and certification process, and the ability of the certified sites to maintain the standards achieved at the time of the audit and beyond, are essential to provide confidence in the scheme and enhance the value of certification.

Sites may be certified to CAPS only by CBs that are licensed and in good standing with Purity-IQ and their accreditation body. All auditors performing audits against CAPS must meet the auditor competency requirements as per the CAPS-certified auditor requirements and be certified by the Personal Certification Assessment Association (PCAA), based in Australia.

All audits performed against CAPS shall be submitted to Purity-IQ.

Purity-IQ operates a conformance monitoring program that reviews the ongoing performance of CBs, samples the quality of audit reports, assesses levels of understanding of the scheme requirements, and investigates any issues or complaints.

As part of this program, feedback on each CB's performance is provided to it through a key performance indicator (KPI) report.

As part of the conformance program, Purity-IQ may audit the offices of CBs and accompany auditors on audits at sites to observe their performance.

## *Calibrating auditors*

A key component of CAPS is the calibration of the auditors to ensure a consistent understanding and application of the requirements. All CBs are required to have processes to calibrate their own auditors. An essential element of this training and calibration is the witnessed audit program, which involves auditors being observed during an audit and provided with feedback on their performance. To ensure consistency between CBs, and for licensing purposes, an audit may be witnessed by a representative from Purity-IQ.

Guidelines apply to these activities to ensure that sites are not disadvantaged by the presence of witness or shadow auditors. This process forms an essential part of the scheme, and sites are obliged to permit witness or shadow audits as part of the conditions for certification. Auditors will be required to participate in training activities delivered through the CB or Purity-IQ, as part of their refresher training as and when required.

### *Feedback*

A site being audited against CAPS may wish to provide feedback to the CB or Purity-IQ on the performance of the auditor(s). Such feedback, when sent to Purity-IQ, will be considered in confidence. Feedback provides a valuable input to the Purity-IQ monitoring program of CB performance. All audited sites are invited to provide feedback to Purity-IQ at any time.

# Schedule 4 – CAPS product scope categories

| Category description | Product examples |
|---|---|
| Propagation materials | Seeds – regular or feminized<br>Mother plants and clones |
| Cultivated crop | Fresh or minimally processed dried flower or other plant parts |
| Manufacturing: physical extraction (e.g. mechanical pressing, heating, distillation) | Kief, dry sieve, rosin, bubble hashish, wax |
| Manufacturing: chemical extraction (e.g. solvents) | Cannabis oil, glass, shatter, wax, hashish oil, budder, isolates, live resin, extracts |
| Manufacturing: edibles | Food and drinks containing cannabis |
| Manufacturing: topicals | Creams, salves, liniments |
| Natural health products | Natural health products (NHPs) containing parts of the cannabis plant permitted under the Natural Health Products Regulations |
| Pharmaceuticals | Prescription drugs containing cannabis<br>Medical devices containing cannabis or for use with cannabis |

# Appendix 5 Purity-IQ logos for CAPS



# Appendix 6 CAPS Schedule A

## Cannabis Authenticity and Purity Standard (CAPS)

### SCHEDULE A

(NOTE: A separate Schedule A must be completed for each **individual site** and **each individual brand owner** and forms part of the on-site audit process)

Unauthorized use of any of the Purity-IQ CAPS owned or managed logos, without prior written consent, is strictly forbidden. **The Purity-IQ-licensed certification body** is responsible for reviewing only the correct use of its CAPS logos on packaging labels or advertising and is not responsible for any other printed content, including (but not limited to) ingredient listings, product claims, regulatory requirements, and/or legal obligations in any way, shape, or form.

| | | | |
|---|---|---|---|
| Date completed | Month/day/year | | |
| Site name | | Admin use only | |
| Site address | | Approved by | |
| | | Signature | |
| Submitted by | | Date | |
| Phone | | Scope category/ies | |
| E-mail | | Number of SKUs | |
| Brand owner | | Number of schedules | |
| Signed by (please print) | | | |
| **Signature** | | | |

By signing this document, the site management self-declares the listed product(s) meet(s) all management system certification requirements of CAPS.

| **Brand name** | **Product/cultivar name** | **Product description** | **Format** | **UPC/GTIN#** | **Sold as** | | PIQ Global Registry – Cannabis no. (if applicable) |
|---|---|---|---|---|---|---|---|
| | | | | (if applicable) | Retail | Non-retail | |
| Example: Joey's | Example: Pink kush | Cultivated crop | Bubble hashish | 000005368428 | X | | PIQ CN0000FL0000 |
| Example: AAA Inc. | Example: Choco brownie | Manufacturing edibles | Edible | N/A | | X | N/A |
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**IMPORTANT**

This form is part of CAPS and must be fully completed and approved by Purity-IQ prior to the third-party CAPS site audit process.

**Notes** 1. Please send the completed copy to your CAPS representative for sign-off. 2. Product certification will be granted only to those products registered in the Purity-IQ Global Registry – Cannabis demonstrating evidence of batch-to-batch verification through certificates of authenticity.

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The Cannabis Authenticity and Purity Standard (CAPS) sets the global gold standard in product safety, quality, and authentication for cannabis production, distribution, and sale.

It sets out the requirements for good manufacturing practice (GMP) and good agricultural practice (GAP), which are supplemented with detailed scientific standard operating procedures to establish product identity, authenticity, and consistency. The standard is underpinned by science and is outcome-based. It allows for flexibility in approach and is not unnecessarily prescriptive, helping organizations to achieve their regulatory and risk-based objectives.

CAPS is the first step on your journey to guaranteeing a consistently high-quality cannabis or hemp product, and differentiating yourself in the marketplace with an evidence-based stamp of quality.

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