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Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry¹

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1. Scope

1.1 This guide applies to all entities that cultivate, process, manufacture, test, and distribute cannabis products.

1.2 This guide defines corrective action and preventive action (CAPA) and the significance of an effective CAPA process and CAPA subsystem.

1.3 This guide defines instruction on the establishment of adequate processes and procedures for the identification, analysis, measurement, and correction of quality issues.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Terminology

2.1 Definitions:

2.1.1 *aberrant results, n*—aberrant results

2.1.2 *active failure, n*—errors made by frontline workers such as manufacturing technicians, machine operators, drivers, and so forth.

2.1.3 *adverse trend, n*—trend of deficiencies (issues) that may negatively impact quality if not corrected.

2.1.4 *change management system, n*—formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner.

2.1.5 *closed-loop system, n*—system that an operation, process, or mechanism is regulated by feedback.

2.1.6 *consumer, n*—person or organization that receives a product or service anywhere within a product's life cycle.

2.1.7 *consumer product, n*—any tangible product for sale that is used for personal, family, household, or non-business purposes.

2.1.8 *correction, n*—immediate action to eliminate a detected nonconformity.

2.1.8.1 *Discussion*—Corrections are typically one-time fixes. Corrections are also known as remedial or containment actions.

2.1.9 *corrective action, n*—action to eliminate the causes of a detected nonconformity or other undesirable situation.

2.1.9.1 *Discussion*—Corrective action is taken to prevent recurrence of the issue.

2.1.10 *corrective action and preventive action, CAPA, n*—systematic approach that includes actions needed to correct, avoid occurrence, and eliminate the cause of potential nonconforming product and other quality problems.

2.1.11 *corrective action and preventive action (CAPA) plan, n*—encompasses the identification of corrective or preventive actions or both, the verification and validation of corrective or preventive actions or both, and the evaluation of the plan's effectiveness.

2.1.12 *data analysis, n*—analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems.

2.1.12.1 *Discussion*—Appropriate statistical methodology should be used when necessary to detect recurring quality problems.

2.1.13 *data sources, n*—processes within a quality management system (QMS) that provide quality information that could be used to identify nonconformities or potential nonconformities.

2.1.14 *deviation, n*—departure from an approved instruction, procedure, specification, or standard.

2.1.15 *harm, n*—physical injury or damage to the health of people or damage to property or the environment.

2.1.16 *hazard, n*—potential source of harm.

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2.1.17 *human error*, *n*—departure from acceptable or desirable practices on the part of an individual resulting in an unacceptable or undesirable result.

2.1.18 *human factor*, *n*—discipline concerned with designing machines, operations, and work environments to match human capabilities, limitations, and needs.

2.1.19 *in-conformance data*, *n*—data that meet the established acceptance criteria.

2.1.20 *initial impact assessment*, *n*—preliminary evaluation of the impact of a detected situation/event based on the initial data and evidence available.

2.1.21 *latent failure*, *n*—errors made by individuals, including managers and engineers, who are involved in the development and modification of the daily processes performed by frontline workers.

2.1.22 *metrics*, *n*—quantitative measurement that is collected, recorded, and analyzed to determine whether quality goals and objectives have been met, exceeded, or failed specified requirements.

2.1.23 *nonconformance*, *n*—nonfulfillment of a requirement.

2.1.24 *nonconformity*, *n*—deficiency in a characteristic, product specification, process parameter, record, or procedure that renders the quality of a product unacceptable, indeterminate, or not according to required specifications.

2.1.25 *objective evidence*, *n*—data that demonstrate something exists or is true.

2.1.25.1 *Discussion*—Objective evidence can be collected by means of observations, measurements, tests, or any other suitable method.

2.1.26 *preventive action*, *n*—action taken to eliminate the cause of a potential nonconformity or other undesirable condition.

2.1.26.1 *Discussion*—Preventive action is taken to prevent occurrence of a potential issue.

2.1.27 *product life cycle*, *n*—sequence or stages a new product progresses through from the birth of the product until its final withdrawal from the market.

2.1.28 *quality*, *n*—degree to which a set of inherent characteristics fulfills requirements.

2.1.29 *quality issue*, *n*—any issue that may negatively impact product quality.

2.1.30 *quality management*, *n*—coordinated activities to direct and control an organization in regard to quality.

2.1.31 *risk*, *n*—combination of the probability of occurrence of harm and the severity of that harm.

2.1.32 *risk analysis*, *n*—systematic use of available information to identify hazards and estimate the risk.

2.1.33 *risk assessment*, *n*—overall process comprising a risk analysis and a risk evaluation.

2.1.34 *risk evaluation*, *n*—process of comparing the estimated risk against given risk criteria to determine the acceptability of risk.

2.1.35 *root cause*, *n*—gap in a process input or supporting business system that is responsible or partially responsible for an issue.

2.1.36 *root cause analysis*, *RCA*, *n*—analysis necessary to determine the original or true cause of a system, product, or process nonconformity.

2.1.37 *root cause analysis tools*, *n*—tools used to conduct root cause analysis for a problem or situation.

2.1.37.1 *Discussion*—RCA tools identify many possible causes for an effect or problem and sort ideas into useful categories.

2.1.38 *scope creep*, *n*—changes, continuous, or uncontrolled growth in a project's scope at any point after the project begins.

2.1.39 *severity*, *n*—measure of the possible consequences of a hazard.

2.1.40 *symptom*, *n*—sign or the existence of something, especially of an undesired situation.

2.1.41 *timeliness*, *n*—time frame commensurate with the risk and magnitude of the issue.

2.1.42 *trend*, *n*—sequence or pattern of data.

2.1.43 *trending*, *v*—monitoring data over time.

2.1.44 *validation*, *n*—confirmation through provision of objective evidence that the requirements for a specified intended use or application have been fulfilled.

2.1.45 *verification*, *n*—confirmation through the provision of objective evidence that specified requirements have been fulfilled.

3. Significance and Use

3.1 The ability to identify and respond to opportunities before issues become systemic or are a risk to consumer health and safety is vital to maintaining compliance and achieving consumer expectations. The CAPA process is a systematic approach for documenting, identifying, and correcting existing and potential quality issues from various data sources. The CAPA subsystem analyzes and trends data inputs from quality systems and processes to identify if a quality issue is recurring, systemic in nature, or impacts consumer health and safety (see Fig. 1).

4. CAPA Process

4.1 Organizations should establish a process and procedure to routinely analyze internal and external data generated to identify and address quality issues.

4.2 Organizations should decide what terms best describe quality issues within their operation.

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4.4 Quality issues can occur in any process involved in the product life cycle. Key data sources of quality issues are:

- 4.4.1 Product complaints,
- 4.4.2 Laboratory controls,
- 4.4.3 Audits (internal and external),
- 4.4.4 Supply chain, and
- 4.4.5 Nonconforming product.

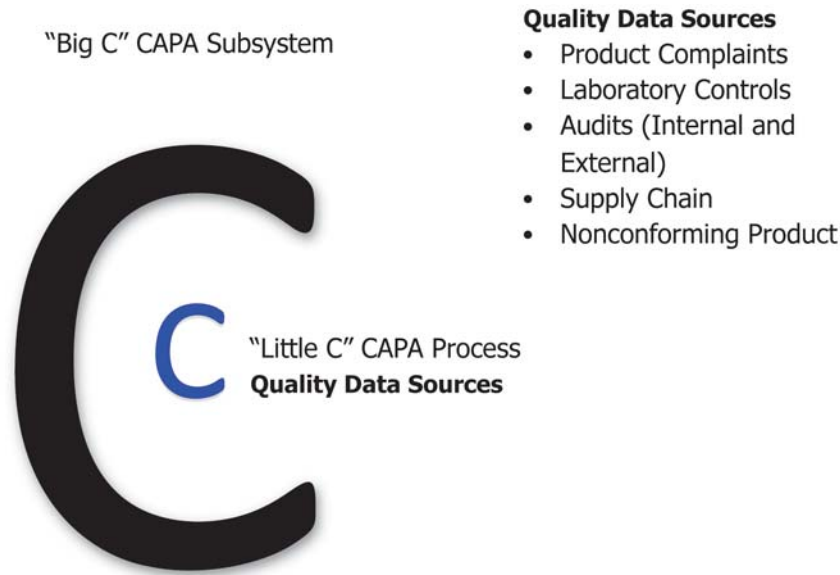


FIG. 1 CAPA Process versus CAPA Subsystem

4.5 The same workflow should be followed no matter when or where a quality issue occurs. Any CAPA process involves, at minimum, five basic steps:

- 4.5.1 Define the quality issue,
- 4.5.2 Assess risk/impact,
- 4.5.3 Investigate the cause of the quality issue,
- 4.5.4 Correct the quality issue, and
- 4.5.5 Trend/monitor.

4.6 All quality related issues should be defined, investigated, and corrected with a documented plan to prevent recurrence of the quality issue. The extent of the investigation into the cause of a quality issue is determined by the initial impact assessment and the level of risk identified. Implemented actions may include a correction, corrective action, or a preventive action.

4.7 Quality issues may be classified as minor, major, or critical.

4.8 Minor issues typically do not affect any quality attribute, a critical process parameter, or an equipment or instrument critical for process or control. Minor issues do not necessarily require an investigation aimed at identifying the root cause and are typically resolved by implementing corrections.

4.9 Major issues affect a quality attribute, a critical process parameter, or an equipment or instrument critical for process or control. The risk to consumers is moderately high. Major issues may result from recurring minor issues. Major issues require a root cause investigation and the identification and implementation of appropriate corrective action(s) or preventive action(s).

4.10 Critical issues affect a quality attribute, a critical process parameter, or an equipment or instrument critical for process or control. The risk to consumers is very high. Critical issues require a root cause investigation and the identification and implementation of appropriate corrective action(s) or preventive action(s).

4.11 Unplanned events, or incidents, may also occur within quality processes. Incidents are errors or occurrences during execution of an activity that do not impact product quality. Incidents should be documented as data may be retrieved and used as part of a larger investigation.

5. CAPA Subsystem

5.1 The CAPA subsystem is a critical component of any quality management system (QMS). It is one of the most important improvement activities within the QMS and it is vital to the success and sustainability of an effective QMS.

5.2 CAPA subsystems shall be data driven. It is difficult to draw conclusions about systems, processes, or product quality issues without sufficient, relevant data.

5.3 The CAPA subsystem collects, trends, and monitors information and data from quality systems and processes to detect recurring or systemic product and quality problems (see Fig. 2). Corrective or preventive actions should be used when issues are identified as recurring, systemic, or as a serious risk to consumers. Corrections or containment actions often accompany corrective or preventive action implementation.

5.4 The effectiveness of implemented corrective or preventive actions is monitored through a change management system. The change management system is used to: validate corrective and preventive actions before implementation; properly disseminate information regarding corrective and preventive actions; and document all CAPA-related activities essential to ensuring the CAPA subsystem is effective.

6. Trending and Monitoring

6.1 Trending detects shifts in data that may indicate a loss of process control effectiveness. These shifts may require further investigation to determine necessary process changes, additional training requirements, and other changes required to maintain or regain process control. Nonconforming Product