

# Guidance on Standard Operating Procedures (SOPs)

Quality Management Systems Subcommittee  
Science & Policy Workgroup

NOTE: This guidance is not legal advice. It is intended to assist licensed marijuana businesses with establishing Standard Operating Procedures (SOPs). Please consult an attorney or quality management professional if you have any questions regarding the requirements that apply to licensed marijuana businesses.

## What Are SOPs?

A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations.

Companies should have an SOP for each process or product they make. SOPs play a big part in ensuring consistency throughout a facility and among products by providing instruction and documentation on how things are done. There are many benefits to developing and maintaining SOPs, including:

- Using an SOP as a training tool so that employees are trained consistently.
- Ensuring jobs, tasks, operations, processes are performed properly.
- Ensuring processes are completed on a prescribed schedule.
- Minimizing or mitigating risk by preventing potential failures, errors, or mistakes.
- Ensuring processes, operations, etc. are followed in compliance with applicable regulations.

There are different types of SOP(s) and each organization's SOPs may look different. Formatting, content, detail, and structure may vary. The following list provides examples of different SOPs:

- **Operational SOP:** Outline the standard accepted procedures for operating standard equipment or performing a repetitive technical activity.
- **Administrative SOP:** Explain the typical function or programmatic responsibilities within a specific job.
- **Analytical SOP:** Document the exact steps and method in performing a recurring process.
- **Methodic SOP:** Describe a complete testing system or method of investigation.
- **Safety SOP:** Detail all the precautions that ensure a safe working environment.
- **Infection Control SOP:** Dictate the precise protocol to ensure devices, equipment, and facilities are cleaned according to best practices.
- **Change Control SOP:** Provide guidance on implementing and ensuring required organizational changes.
- **Quality Assurance SOP:** Detail the steps to maintain and control quality.
- **Complaint Management SOP:** Explain how to deal with complaints, from receiving to addressing to archiving.

## What should be included in an SOP?

While there are different types of SOPs, the structure and basic components of an SOP are the same. Typical SOPs include the following elements:

- **Purpose** - The purpose of this procedure is to...(what is the procedure intended to do?)
- **Scope** - This procedure applies to...
- **Responsibilities** - include employers and employees
- **Personal Safety** - Potential dangers or hazards associated with the job; Personal protective equipment required; Company requirements
- **Safety** - If applicable\*\*
- **References** - State, local regulatory agencies and applicable regulations and requirements
- **Equipment Required**
- **Raw Materials**
- **Procedure** - Start to finish
- **Definitions/Acronyms** - Used in the SOP
- **Forms** - Records or other documents generated in the performance of procedure
- **Approval Block** - Who the SOP was prepared by, reviewed by and approved by; Should include signatures; The person with approval authority should be the owner of the SOP.
- **Revision Log** - Date of revision, description of revision, version number, and the individual making the revisions
- **Training Log** - Employees who are trained shall sign and date

There are other things to consider that can assist in making SOPs stronger and more effective. These include:

- Adding specifics/details
- Adding diagrams, pictures, etc.
- Obtaining employee input on process performance
- Ensuring employees fully understand the SOP before implementing
- Storing in a location (physically or electronically) where all employees can access
- Reviewing SOPs frequently and update when necessary
- Training all relevant employees on SOPs or changes to SOPs

## When should an SOP be reviewed and/or updated?

At a minimum, SOPs should be reviewed annually to verify they are still necessary, accurate, effective, and are meeting the organization's needs. There are other situations that may trigger the need for SOP review and/or revision. These include:

- SOPs should be reviewed and/or revised as processes change or are updated.
- SOPs may also need to be reviewed and/or revised when a discrepancy or failure (nonconformance or noncompliance) occurs.

## **What aspects should be considered related to updating an SOP and change management?**

It is important that SOPs be continuously updated to reflect any changes that are made to a procedure and to ensure the SOP is up-to-date. Out-of-date SOPs are of no use to an organization and can create unnecessary risk. It is important to have an SOP that defines change control procedures.

When making revisions to an SOP, the changes should be recorded and tracked so the operator can refer back to older versions of the SOP, if needed. This is a key component and definition of 'change management'. The Revision Log associated with the SOP should state the date of the revision, a description of the revision(s), version number, and who made the revision. It can also include information relative to why the revision(s) is being made.

Change management applies to any change to the SOP, procedures, instrumentation, equipment, raw material, process, or product specification. It should also include a process for the method(s) that will be used to track changes and their outcomes.

It is important to establish responsibilities and ownership associated with the SOP. Generally speaking, most employees will not be responsible for or have the ability to change, alter, or update an SOP. This is to ensure that procedural and other changes have the proper level of review and approval and that the changes are tracked. Employees should have a method for discussing suggestions, necessary changes, etc. with upper management and/or the owner of the process or SOP.

While employees may not have the ability to edit or revise an SOP, they should be made available to employees as a reference. Outdated versions of the SOP should be archived so that only the current version is accessible. It should be clearly communicated where the 'official version' of the SOP(s) are located, whether that be electronically or in a physical format. It is important that employees do not print off and post or store SOPs as they can become outdated and controlled copies are the only ones that get updated. If an employee is working to an outdated SOP, it can introduce potential risk to the process, product, etc.

## **Training associated with SOPs**

Employee training is a key element of having accurate and effective SOPs. Employees should be trained on all SOPs that are relevant to their everyday job duties. This training should occur initially when an employee is hired. Additionally, training should occur if an employee's job responsibilities change and/or if the content of the SOP changes. It is also worthwhile to consider performing periodic, recurring training on SOPs, especially those considered to be key to risk mitigation, product safety, etc. In some aspects, such as pesticide management and worker safety, regulatory agencies require recurring training and typically provide a requirement associated with the frequency.

When training is performed, a training log should be created and maintained that includes the name of the trainer, date, and location of the training, as well as the employee name/signature. The SOP or other documentation that demonstrates the training content should also be retained with the training log to create a complete record.

## **Marijuana Enforcement Division (MED) Business Record Requirements**

There are specific record requirements that are specified by the Marijuana Enforcement Division (MED). The following list summarizes MED requirements for business records:

### **3-905 – Business Records Required**

#### **A. General Requirements**

- *Each Regulated Marijuana Business shall retain all books and records necessary to fully account for the business transactions conducted under its license for the current year and three preceding calendar years.*
- *On premises records: **six months** (or complete copies of such records) must be maintained on the Licensed Premises at all times.*
- *On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.*

#### **The books and records must include:**

- Current Employee List – full name and Employee License number; update its list within 10 days of an employment
- Secure Facility Information – business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
- Advertising Records – All records related to Advertising and marketing
- Licensed Premises – Diagram of all approved Limited Access Areas, Restricted Access Areas, and any permitted off-premises storage facilities.
- Visitor Log
- All records normally retained for tax purposes.
- Waste Log
- Surveillance Logs
- Every Licensee shall maintain a record of its identity statement and Standardized Graphic Symbol
- Testing Records
- Sampling Unit Records/Sample Plan
- License Application Records
- **Standard Operating Procedures.**
- Audited Product and/or Alternative Use Product Records
- All records for Transfers of Marijuana Consumer Waste.
- Corrective Action and Preventive Action – Jan 2021
- Recall Plan
- Certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer
- Records required to be maintained by Delivery Permit holders.
- Records required to be maintained by Licensed Hospitality Businesses.
- All other records required by these Rules.