STANDARD OPERATING PROCEDURES (SOPs)

Standard Operating Procedures (SOPs) are set of written instructions that document a routine or repetitive activity followed by an organization. In today's business environment, SOPs must make bottom-line economic sense, especially if invest the time and energy to develop and implement effective SOPs. SOPs describe both technical and fundamental programmatic operational elements of an organization that would be managed under a work plan or a Quality Assurance (QA) project plan such as analytical processes, and processes for maintaining, calibrating, and using equipment.

SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result. SOPs can indicate compliance with organizational and governmental requirements and can be used as a part of a personnel training program, since they should provide detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns. So SOPs have positive impact on business performance as directly or indirectly. Those are;

- Reduce system variation, which is the enemy of production efficiency and quality control.
- Having complete step-by-step instructions helps trainers ensure that nothing is missed and provides a reference resource for trainees.

- A SOP can be an excellent reference document on how a task is done for employees filling in on jobs they do not perform on a regular basis.
- Involving employees in developing SOPs can help assure the final product is more complete, useful and accepted.
- SOPs can help in conducting performance evaluations. They provide a common understanding for what needs to be done and shared expectations for how tasks are completed.
- Employees can coach and support each other if there is documentation available on exactly how various tasks must be done and everyone knows what their co-workers are supposed to be doing. This can also help generate a more cooperative team approach to getting all the daily tasks done correctly.
- Having well defined SOPs, using them in training and insisting that they be followed can help keep employees safe at work and may provide some legal protection if an injury occurs.
- Well thought out and implemented SOPs can greatly reduce biosecurity risks in the operation.
- Developing and following SOPs for tasks where there is environmental risk, such as manure, chemical or waste handling, help to protect the environment and may provide some legal protection if an environmental mishap occurs.
- Having SOPs can encourage regular evaluation of work activity and continuous improvement in how things are done.

Several categories and types of SOPs can be distinguished. The name "SOP" may not always be appropriate. It may be the description of situations or other matters may better

designated protocols, instructions or simply registration forms. Also worksheets belonging to an analytical procedure have to be standardized. A number of important SOP types are:

- Fundamental SOPs (These give instructions how to make SOPs of the other categories)
- Methodic SOPs (These describe a complete testing system or method of investigation)
- SOPs for safety precautions
- Standard procedures for operating instruments, apparatus and other equipment
- SOPs for analytical methods
- SOPs for the preparation of reagents
- SOPs for receiving and registration of samples
- SOPs for Quality Assurance
- SOPs for archiving and how to deal with complaints

SOPs implemented within an operational environment that incorporates many internal and external components as laws, plans, agreements, etc. All of these elements must be considered when formulating or amending SOPs. If SOPs are created without adequate consideration of these internal and external factors, the resulting guideline will be incomplete, ineffective, and possibly even dangerous to the personnel who use them.

Development of a SOP

Developing a complete set of SOPs for a business can be a time consuming process. But a little time spent in the beginning to organize the effort can help reduce frustration with the process and make the effort more efficient and effective. Using the following five steps will aid in organizing efforts.

1. Identify the key areas of concern in the operation where SOPs might be useful.

2. From the key areas identify the top one or two priority areas for attention as in which areas are more controls desired or required, in which areas will economic returns or impact on the operation be greatest and which areas are likely to yield some good successes early in the process.
3. Focusing on the selected top priority areas, identify all the processes, functions or operations that involve in these areas.
4. Group together and combine or subdivide further all of those important processes, functions or operations within each area and then prioritize them for SOP development.
5. Identify the best individual to lead the development effort for each SOP and assign a development team of employees, managers, agribusiness representatives, consultants and anyone else who can bring relevant expertise to the effort.

SOPs may develop for any repetitive technical activity, as well as for any administrative or functional programmatic procedure, that is being followed within an organization. Technical SOPs can be written for a wide variety of activities need to include the specific steps aimed at initiating, coordinating, and recording and/or reporting the results of the activity, and should be tailored only to that activity. Technical SOPs are also needed to cover activities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation. As with the technical SOPs administrative or fundamental programmatic SOPs can be written for a wide variety of activities as reviewing documentation such as contracts, QA project plans and quality management plans. Administrative SOPs need to include a number of specific steps aimed at initiating the activity, coordinating the activity, and recording and/or reporting the results of the activity, tailored to that activity.

The SOP development process is critical to successful implementation of SOPs. It should be an inclusive process that considers the input of everyone with an interest in the procedure's success. The organization should have a procedure in place for determining what procedures or processes need to be documented. SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised. The experience requirement for performing an activity should be noted in the section on personnel qualifications.

SOP for the same task will differ from organization to organization. There are also a number of different approaches to developing SOPs depending on the business, complexity of the SOP and the number of people involved in the development. In most of the situations following six-step procedure is effective.

1. Name the SOP using descriptive action words.
2. Write a scope for the SOP.
3. Develop an overall task description.
4. Describe each task in detail.
5. Get everyone on board.
6. Set up a system to monitor the SOP regularly.

It is important to realize that developing useful and effective SOPs requires time and commitment from all management and employee levels. Once the development task is complete three important steps still remain are;

- ✓ Educate employees about the new SOP.
- ✓ Control "procedural drift" by ensuring that the SOP is followed consistently over time.

- ✓ Establish an evaluation and review system to be certain that over time all the steps of an SOP are still correct and appropriate for the production system.

Format of SOP

SOPs should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and conveyed clearly as explicitly to remove any doubt as to what is required. Also, use a flow chart to illustrate the process being described. There are different formats exist to present SOP.

Checklists

These are easy to write and follow and work well for short, simple, straightforward tasks.

Hierarchical steps

It is an extension of the checklist format. this format works better for tasks that require additional detail or sub-steps within each primary step.

Linear flow chart

This is a graphic version of the previous two formats. It works well for tasks where activities must be done in a specific order and where an easy to- follow reminder at the job site is useful.

Annotated pictures

This format works well where a language barrier exists and helps to shorten complex and detailed SOPs.

Branching flowchart

This format makes complex SOPs, especially those with a number of decisions that affect subsequent steps, easier to follow.

The best SOP format is one that, given the situation, does the best job of accurately transmitting the necessary information and facilitating consistent implementation of the SOP. The primary considerations for choosing the best SOP formats are;

The SOP

Consider the SOPs' scope and complexity, the number of steps involved, the amount of detail necessary within each step, and how many decisions, if any, must be made that will influence subsequent steps.

The people who will use the SOP

How do they learn? If they visual learners or auditory learners. What employee levels and can they read and understand it? Can they read and understand another language if the information were translated?

How the SOP will be used

Any individual can do a job correctly, on time and every time using a SOP which give detailed directions. At the same time, any of SOP may have a number of different uses. Depending on the intended use at the time, the SOP may be written or presented differently to be more effective.

Review and Approval of SOP

SOPs are of limited value if they not written correctly. In addition, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be reviewed and re-enforced by management. Current copies of the SOPs also need to be readily accessible for

reference. When historical data are being evaluated for current use, SOPs can also be valuable for reconstructing project activities when no other references are available. Also the SOPs are frequently used as checklists by inspectors when auditing procedures.

SOPs need to remain current to be useful. Therefore, whenever procedures are changed, SOPs should be updated and re-approved. SOPs should be also systematically reviewed on a periodic basis, as every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed. The review date should be added to each SOP that has been reviewed. If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.

The review process should not be overly cumbersome to encourage timely review. The frequency of review should be indicated by management in the organization's Quality Management Plan. That plan should also indicate the individual(s) responsible for ensuring that SOPs are current. SOPs should be reviewed by one or more individuals with appropriate training and experience with the process. It is especially helpful if draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalized.

The finalized SOPs should be approved as described in the organization's Quality Management Plan or its own SOP for preparation of SOPs. Generally the immediate supervisor, such as a section or branch chief, and the organization's quality assurance officer review and approve each SOP. Signature approval indicates that an SOP has been both reviewed and approved by management. As per the Government Paperwork Elimination Act of 1998, use of electronic signatures, as well as electronic maintenance and submission, is an acceptable substitution for paper, when practical.

Each organization should develop a numbering system to systematically identify and label their SOPs, and the document control should be described in its Quality Management Plan. A short title and identification (ID) number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed. The organization should maintain a master list of all SOPs. This database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. This database may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

SOP is a compulsory instruction. If deviations from this instruction are allowed, the conditions for these should be documented including who can give permission for this and what exactly the complete procedure will be. The original should rest at a secure place while working copies should be authenticated with stamps and/or signatures of authorized persons. Ultimately a valid SOP reduces work effort, along with improved comparability, credibility, and legal defensibility.