Chapter 17

# Standard Operating Procedures (What Are They Good For ?)

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Additional information is available at the end of the chapter

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## 1. Introduction

Standardization is defined as an activity that gives rise to solutions for repetitive application to problems in various disciplines. Generally, the activity constitudes the process of establishing (determining, formulating, and issuing) and implementing standards. Thus, standards are the perfect result of a standardization activity and inside the context of quality systems consist of quality documents or documents related to the quality system. High levels of quality are important to accomplish Company business objectives. Quality, a source of competitive benefit, should stay a symbol of Company products and services. High quality is not an additional value; it is an important elemantary necessity. Each employee in all organizational units is responsible for guaranteeing that their work processes are effective and continually getting better. Top management should provide the training and an appropriate motivating environment to support teamwork both inside and across organizational units for employees to advance processes. Ultimately, everyone in an institution is responsible for the quality of its products and services. An institution in the role of a sponsor of clinical trials can best achieve its business objectives by establishing and managing robust quality systems with their integral quality documents including standard operating procedures (SOPs) (Manghani, K. 2011). The Quality Management system must evolve by trial and error, with enlarging experience, by group discussions and with changing understanding. In the beginning, attention will be focused on basic operational SOPs, afterwards moving to record keeping (as more and more SOPs are issued) and filling gaps as practice admits missing links in the chain of Quality Assurance. Essentially problems will turn up. One way to react to them is to talk with people in other laboratories who have faced similar problems. It

should not be forgotten that Quality Management is a tool rather than a goal. The goal is quality performance of the laboratory. The philosopher Kant saw autonomy as self-government originning from morality, with morality proceeding from knowledge and self-discipline. Conger & Kanungo noted that an appropriate level of authority, discretion, formalization, and rule structure is a requirement for worker empowerment, which we see as consistent with the concept of self-government. Merriam-Webster defined autonomy as 'the quality or state of being self-governing; especially: the right of self-government; self-directing freedom and especially moral independence'. Necessitated SOP use will be absolutely related to the sense of self-determination experienced by workers. Worker participation in SOP advancenment and clarification controls the affiliation between required SOP use and the sense of self-determination experienced by workers.

Standard Operating Procedures (SOP) is a process document that describes in detail the way that an operator should perform a given operation. SOPs involve the purpose of the operation, the equipment and materials required, how to perform the set-up and operations required for the process, how to perform the maintenance and shutdown operations carried out by the worker, a description of safety issues, trouble-shooting, a list of spare parts and where to find them, illustrations, and checklists. The SOP is one of many process documents which is needed for consistent operation of a given process, with other documents involving process flow charts, material specifications, and so forth.

The purpose of SOPs today is to guarantee that all workers are performing tasks in the same way, which is a needed for condition to get expected output from the process. When all workers perform their tasks constantly, it becomes possible to run controlled experiments to test the impact of changing various process parameters. When a process change is shown to improve process performance, SOPs are updated and workers are trained to the new procedures. All over the process, it is adorable to involve workers in SOP development and to praise worker ideas for the SOP improvement. For constant organizational advance, organized processes need to be constantly improved, hence necessitating ideas from those workers using those procedures. Ideas are not creative simply because they deviate from organized knowledge; ideas are creative when they are novel and suitable to the task at hand. Workers may have many ideas; nevertheless, what they choose to do with their ideas will depend on various organizational and individual-difference factors. The most important factor, however, for the advancement of creative behaviours is worker intrinsic motivation– a sine qua non of worker creative contribution. By the help of confirmatory factor analysis, the Spreitzer construct validated the four dimensions of intrinsic motivation (i.e. psychological authorization): (a) Competence (example item includes 'I am confident about my ability to do my job'); (b) Meaning (example item includes 'The work I do is very important to me'; (c) Impact (example item includes 'I have a great deal of control over what happens in my department'; (d) Self-determination (example item includes 'I can decide on my own how to go about doing my work'). Furthermore, Spreitzer argued and empirically established that an antecedent condition to innovation (i.e. creativity) and effectiveness is intrinsic motivation (De Trevil et al. 2005).

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## 2. Overview

The quality documents constitudes of Company policies, quality management plan, SOPs, working instructions, conventions, guidelines, forms, templates, logs, tags and labels. They are organized by consensus and approved by a nominated body and they provide for common and repeated use, rules, guidelines or characteristics for activities or their results with a view to promote transparency, consistency, reproducibility, interchangeability and to facilitate communication. The hierarchy and types of quality documents relevant to quality systems will depend upon Company business objectives and business model. SOPs are Level 2 quality documents and, along with other related quality documents, guarantee the efficacy and effectiveness of quality systems (Manghani, K. 2011). Standard operating procedures (SOPs) are a vital component in any quality management system (Hattamer-Apostel, R. 2001). Every good quality system is based on its Standard Operating Procedures (SOPs) (Saxena). The advancement and use of SOPs are a necessary part of a successful quality system as it supplies individuals with the information to carry out a job adequately, and aids precision in the quality and integrity of a product or end-result (United States Environmental Protection Agency, 2007). They assign all processes involved in an organization (Frank, D. 2010). A quality system is defined as the organizational structure, responsibilities, processes, procedures and resources for implementing quality management (Manghani, K. 2011).

*Standard Operating Procedures* are sets of instructions having the force of a directive, covering those features of operations which lend themselves to a definite or standardized procedure without loss of effectiveness (Saxena).

The purpose of a SOP is to reach out the operations correctly and always in the same manner. A SOP should be available at the place where the work is done". SOPs assist the progress of constant application of processes and procedures so even when there are changes in personnel, organizations avoid inconsistencies and safety risks (Frank, D. 2010). Standard operating procedures or SOPs are written step-by-step procedures that quality control (QC), quality assurance (QA), and production units use in order to assure the accuracy and precision of the quantitative experimental results and materials that they generate and provide in support of other units. SOP's are needed to guarantee the continuity of processes to obtain quality performance and quality products/preparations (Natural Resources Management and Environment Dept.). SOP's are alive documents that detail written instructions describing specific steps to follow in all activities under defined conditions (Jain, SK. 2008). They are used to accomplish standardization when performing specific functions and is used to set out the way practice and procedures necessitated to be performed. SOPs are written instructions and records of procedures agreed and adopted as standard practice (Cardiff University, 2009). SOP's are necessary to guarantee the progression of processes to accomplish quality performance and quality products/preparations (Jain, SK. 2008). A Standard Operating Procedure (SOP) document is a routine or repetitive activity followed by an organization. SOPs describe both technical and administrative operational elements of an organization that would be managed under a Quality Assurance Project Plan and under an organization's Quality Management Plan (Almeida S.L.), (United States Environmental Protection Agency 2001).

SOPs are determined to be specific to the organization whose activities are defined and assist that organization to maintain their quality control and quality assurance processes (United States Environmental Protection Agency 2001).

All organizations, businesses, etc. should have SOPs (Jain, SK. 2008). SOPs support employees with the information necessitated to perform their jobs regularly and help guarantee consistency in the quality of performance (Frank, D. 2010). SOPs are used by the governmental agencies, private industry, and academic laboratories by scientists and engineers from all of the science, technology, engineering, and mathematical disciplines. SOPs can also be intensely valuable in academic laboratories and can be employed anytime there is process that likely more than one person will use in a research group (Natural Resources Management and Environment Dept.). SOPs are mainly associated with specific documentation necessities. It should not be forgotten that "If you don't document, it didn't happen! (Jain, SK. 2008). The International Conference on Harmonization Good Clinical Practice (ICH GCP) guideline ascertaines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs must be well written in order to supply an efficacious control of good clinical practice (GCP) and prevent errors from occurring, thereby lessening waste and rework. Poorly written SOPs are a source of misinformation. To be user friendly, they should be absolute, unambiguous and must be written in plain language. SOPs are controlled documents and are best written by persons involved in the activity, process or function that is required to be specified or covered in the SOP. SOPs must be reviewed prior to their approval for release, for adequacy, completeness and compliance with Company standards and all applicable legal, ethical and regulatory requirements. They must be checked out and updated as necessitated over their life cycle and any changes made to the SOPs must be re-approved. They must bear a revision status on them and their distribution must continually be documented and controlled. When obsolete SOPs are needed to be hold for any purpose, they should be suitably identified to prevent unintended use. Only relevant SOPs in their current version must be available at points of use and must remain legible. SOPs are mandatory for the implementation of GCP and other GxPs, namely, cGMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice), within the scope of quality systems; therefore, it is well said that without SOPs there are no GxPs: no SOPs, no quality systems, and no GxPs (Manghani, K. 2011). SOPs are necessary for a clinical research organization whether it concerns a pharmaceutical company, a sponsor, a contract research organization, an investigator site, an Ethics Committee or any other party involved in clinical research to achieve maximum safety and efficiency of the performed clinical research Operatings. It is therefore a must that all people and sites involved in clinical studies (both at the sponsor and at the investigative sites) have suitable SOPs in place so as to conduct clinical research and to ensure compliance with the current regulations.

The presence of these quality documents is important when regulatory inspections (FDA, EMEA) take place since the most frequent reported deficiencies during inspections are the lack of written SOPs and/or the failure to adhere to them. The risk of GMP non-compliance is high at organizations with a poor suitability of specific SOPs and also if at all they are

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achiavable the staff or the people for whom they were written are not either following them. It therefore becomes very essential for the personnel to be trained on these SOPs so that they are absolutely aware of why and how SOPs can play important role in fulfilling the specific organizatory requirements from WHO, FDA, EMEA or other national health authorities. Health authorities world wide like the FDA or EMEA expect pharmaceutical, cosmetic and food producers to describe their manufacturing processes in written SOPs (GMP7.com). An organization's SOP manual is an important training document and provides workers with increased confidence, motivation and a sense of achievement (Frank, D. 2010). A 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. The advancement and use of *SOPs* are a basic part of a successful quality system. It supplies information to perform a job regularly, and constantly in order to access pre-determined specification and quality end-result.

*SOP* clarifies the followings; what is the objective of SOP (Purpose), what are applicability and use of SOP (Scope)?, who will perform tasks (Responsibility), who will ensure implementation of procedure (Accountability), how tasks will be performed (Procedure).

| **Responsibility** | **Responsible** |
|---|---|
| Identifying the need for development or revision of a standard operating procedure (SOP) and to convey that need to their immediate supervisor and/or the QA Manager (QAM). | Staff |
| An individual SOP to include sufficient detail that the process or procedure can be followed by another person when needed. | Author |
| Requesting peers to review the SOP to determine whether it contains sufficient detail. | Author |
| Reviewing and approving the SOP prior to its use. | Immediate supervisor and the QA Manager |
| Ensuring that the procedure or process follows the details noted in the individual SOP and to detail in writing when the SOP or a component of that SOP has not been followed. | Staff and the QAM |
| Ensuring that all routine operations and activities in their area are documented by SOPs. | Manager |
| Overseeing the appropriate preparation, numbering, retention, indexing, revision, and use of SOPs. | QAM |
| (United States Environmental Protection Agency, 2007). | |

**Table 1.** Responsibility distribution in SOP.

Procedures are not an end in themselves - they do not ensure good performance or results. More important are well-designed systems and processes, qualified employees, and a motivating company culture. Procedures provide process people – environment but do not create processes, qualified people, or a good working environment (Jain, SK. 2008). The responsibility distribution in a SOP is shown in Table 1.

## 3. Purpose

The purpose of SOP is to assign the procedures for the preparation, approval, distribution, amendment and storage of Standard Operating Procedures (Cardiff University, 2009). The purpose or objective of the procedure should express and expand well written title (Jain SK., 2008). SOPs serve as frame for organizational action – support direction and structure. They tell what, how, when, why, and who. (Iowa State University, 2010). In order to be active, SOPs need to define not only what needs to be, but who is qualified to carry it out, and under what conditions the procedure can be performed reliably (Levine D.I., 2010). They should aid constant conformance support data quality. They should be determined to be specific to the organization and assist that organization to obtain their quality control and quality assurance processes and ensure compliance (Almeida S.L.) SOPs specify the commonly recurring work processes that are to be conducted or followed inside an arrangement. They approve the way activities are to be performed to alleviate constant conformance to technical and quality system necessities and to provide data quality. They may define, for example, basic programmatic actions and technical actions such as analytical processes, and procedures for maintaining, calibrating, and using equipment. If not written appropriately, SOPs are of limited value. Additionally, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be checked out and re-enforced by management, alternatively the direct supervisor. Current copies of the SOPs also need to be readily accessible for reference in the work areas of those individuals absolutely carrying out the activity, either in hard copy or electronic format, otherwise SOPs serve little purpose (United States Environmental Protection Agency, 2007).

## 4. Benefits

The improvement and use of SOPs promotes quality through consistent implementation of a process or procedure within the organization reduced work effort, along with advanced data comparability, credibility, and legal defensibility (Almeida S.L.) The details in an SOP *standardize* the process and support step-by-step how-to instructions that enable *anyone* within your operation to perform the task in a consistent manner (Iowa State University, 2010). They abbreviate difference and advance quality through constant impact of a process or procedure inside the organization, although there are temporary or permanent personnel changes.

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SOPs can signify agreement with organizational and governmental needs and can be used as a part of a personnel training program, since they should supply detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns.

When historical data are being estimated for current use, SOPs can also be very important for reconstructing project activities when no other references are accessible. Besides, SOPs are commonly used as checklists by inspectors when auditing procedures. Eventually, the benefits of a valid SOP are decreased work effort, along with developed comparability, credibility, and legal defensibility.

The advancement and use of SOPs is a basic part of a successful quality system. It supplies individuals with the information to perform a job regularly and aids constancy in the quality and integrity of a product or end-result through constant implementation of a process or procedure inside the arrangement.

SOPs can also be used as a part of a personnel training program, hence they should support detailed work instructions. When historical data are being assessed for current use, SOPs can be beneficial for reconstructing project activities. Additionally, SOPs are commonly used as checklists by inspectors when auditing procedures. Finally, the benefits of a valid SOP are minimized work effort, together with improved data comparability, credibility, and legal defensibility. SOPs are necessary even when published methods are being administered because cited published methods may not include appropriate information for conducting the procedure in-house.

For example, if the SOP is written for a standard analytical method, the SOP should designate the procedures to be followed in greater detail than appear in the published method, detailing how, if at all, the SOP differs from the standard method and any options, changes or alterations that the organization follows (United States Environmental Protection Agency, 2007). The significance regularly set up and managed quality control and quality assurance systems with their integral well-written SOPs and other quality documents for the achievement of Company business objectives cannot be ignored. They serve as a passport to success by assisting the Company to accomplish high-quality processes, procedures, systems, and people, with eventual high-quality products and services and enhancement of the following: Customer satisfaction, and therefore, customer loyalty and repeat business and referral; timely registration of drugs by eliminating waste and the requirement for rework; operational results such as revenue, profitability, market share and export opportunities; alignment of processes with achievement of better results; understanding and motivation of employees toward the Company quality policy and business objectives, as well as participation in continuous quality improvement initiatives; and confidence of interested parties in the effectiveness and efficiency of the Company as demonstrated by the financial and social gains from Company performance and reputation (Manghani, K. 2011). Benefits of SOPs are shown in Table 2.

| Benefit | Explanation |
|---|---|
| To provide people with all the safety, health, environmental and functional information necessitated to perform a job properly. | Placing value only on production while disregarding safety, health and environment is costly finally. It is better to train employees in all aspects of doing a job than to face accidents, fines and litigation later |
| To guarantee that production operations are performed constantly to obtain quality control of processes and products. | Consumers, from individuals to companies, want products of consistent quality and specifications. SOPs specify job steps that help standardize products and consequently quality. |
| To guarantee that processes continue uninterrupted and are completed on a prescribed schedule. | By following SOPs, you help to guarantee against process shut-downs caused by equipment failure or other facility damage |
| To guarantee that no failures occur in manufacturing and other processes that would harm anyone in the surrounding community. | Following health and environmental steps in SOPs guarantees against spills and emissions that threaten plant neighbors and create community outrage |
| To guarantee that acknowledged procedures are followed in compliance with company and government regulations. | Well-written SOPs help to gurantee that government regulations are satisfied. They also show a company's good-faith intention to operate perfectly. Failure to write and use good SOPs only signals government regulators that your company is not serious about compliance. |
| To serve as a training document for teaching users about the process for which the SOP was written. | Thorough SOPs can be used as the basis for supplying standardized training for employees who are new to a particular job and for those who need re-training. |
| To serve as a checklist for co-workers who observe job performance to reinforce proper performance. | The process of actively caring about fellow workers involves one worker coaching another in all aspects of proper job performance. When the proper procedures are outlined in a good SOP, any co-worker can coach another to help improve work skills. |
| To serve as a checklist for auditors. | Auditing job performance is a process similar to observation mentioned in the previous item only it usually involves record keeping. SOPs should serve as a strong basis when detailed audit checklists are developed. |
| To serve as an historical record of the how, why and when of steps in an existing process so there is a factual basis for revising those steps when a process or equipment are changed. | As people move from job to job inside and between companies, unwritten knowledge and skills disappear from the workplace. Regularly maintained written SOPs can chronicle the best knowledge that can serve new workers when older ones move on. |
| To serve as an explanation of steps in a process so they can be reviewed in accident investigations. | Although accidents are unfortunate, view them as opportunities to learn how to improve conditions. A good SOP gives you a basis from which to being investigating accidents |
| (Jain, SK. 2008) | |

**Table 2.** Benefits Of SOPs.

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## 5. Writing style

SOPs should be written in a step-by-step, easy-to-read format by subject-matter experts who know the processes and the structure of the organization (Frank, D. 2010). They should be written by individuals aware of the activity and the organization's internal structure. These individuals are basically subject-matter experts who actually perform the work or use the process. A team accession can also be followed, particularly for multi-tasked processes where the experiences of a number of individuals are critical (United States Environmental Protection Agency, 2007).

Well-written SOPs should first shortly define the purpose of the work or process, involving any regulatory information or standards that are suitable to the SOP process, and the scope to show what is covered. Any specialized or different terms either in a separate definition section or in the suitable discussion section should be explained.

The information presented should be clear and easy to understand. The active voice and present verb tense should be used. SOP shall be simple and short. Information should be transported clearly and absolutely to remove any doubt as to what is needed. Flow charts should be used to illustrate the process being defined (Jain SK., 2008), (United States Environmental Protection Agency, 2007). (United States Environmental Protection Agency, 2001), (Almeida S.L.). It may be helpful to include additional experts to help gather information and to review, test and approve draft SOPs (Frank D., 2010).

The most commonly used method of task analysis is *Hierarchical Task Analysis (HTA)*. Operating instructions should be close to the user and kept up to date. The following issues should be considered in evaluating operating procedure documentation:

1. There should be no easier, more dangerous opportunities than following the procedure.
2. There should be an appropriate QA system in place to guarantee that the procedures can be kept up to date and that any errors are rapidly detected and corrected.
3. The procedures should not be needlessly prescriptive. The best way of guaranteeing that procedures do not become overly prescriptive is through involving the operator during the design stage.
4. Procedures should contain information on the necessities for the wearing of personal protective equipment during the task.
5. Any risks to the operator should be documented at the start of the procedure, based on a risk assessment of the task.
6. An appropriate method of coding each procedure should be used.
7. Each time a procedure is produced it should be dated.
8. There should be no uncertainty between which procedures apply to which situations.
9. Procedures do not always have to be paper based.

10. At the start of the procedure an overview of the task should be provided.
11. Prerequisites should presented clearly at the start of the procedure to guarantee that the operator can check that it is safe to proceed.
12. The most important information on the page should be defined and this should be designed to be the most prominent information.
13. Separate headings should be used to discriminate apparently between sub tasks.
14. Any warnings, cautions or notes should be placed immediately prior to the instruction step to which they refer.
15. Language should be kept as simple as possible, i.e. use nomenclature familiar to the operator.
16. The nomenclature should be consistent with that on controls or panels.
17. Symbols, colours, and shapes used for graphics should conform to industry standards (Health and Safety Executive).

## 6. Preparation of SOP

When actualizing a SOP one can choose number of different ways to organize and format them. There are some factors which determine what type of SOP to use or create: How many decisions will user need to make during process? How many steps and sub steps are there in procedure? Routine procedures that are short and necessitate few decisions can be written using simple steps format. Long procedures consisting of more than 10 steps, with few decisions should be written along with graphical format or hierarchical steps. Procedures that necessitate many decisions should be written along with flow chart. Requirement for document identification and control, accountability and traceability responsibility must be involved with every SOP; this can be obtained by supporting constant format.

The need for an SOP or the revision of an existing one should be identified by informing the appropriate supervisor. Written instructions on standardized procedures supply guidance to guarantee that activities are conducted in a constant way, hence leading to reliable product and service quality. SOPs should be prepared in full compliance with guidelines and organizations and must mirror current organizational practices (Hattamer-Apostel, R. 2001). Ideally, SOP's should be written by teams that involve some or all of the following people: Those who will perform the job, those who will perform maintenance on equipment involved in an SOP, engineers or others who design equipment and processes, technical initiator, safety personnel, environmental personnel, equipment manufacturers (Jain, SK. 2008).

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**Figure 1.** A SOP should be written by a team in that field.

## 7. Implementing SOP

The most substantial step for administering the SOP in working area, train or retrain the user. Every one should follow the procedure accurately with each and every step in detail, it is very significant to train the user otherwise individual may interpret meaning in different ways.

The trainer should share the reason WHY, SOP must performed correctly while training the user. People can follow better when they understand significance of procedure. Trainer should explain and demonstrate how each step in the SOP will be performed and should assure them this will increase Quality of product by providing safety and accuracy which will ultimately increase the confidence of the user.

The people in the writing team can write or edit parts of an SOP independently and then one person can combine the individual contributions. After combination the SOP should be circulated the draft SOP for review among the initiator before editing a final draft for review by supervisors and subsequent supervised testing by employees. Ideally a writing team should meet at least once in the beginning of a project to establish writing objectives, targets and responsibilities, but then can work semi-independently with one person serving as co-

ordinator. SOPs should be checked out by several people qualified to assess the SOP in terms of its completeness and clarity of subject matter.

SOPs should at least mention:

*a.* who can or should make which type of SOP;

*b.* to whom proposals for a SOP should be submitted, and who estimates the draft;

*c.* the procedure of approval;

*d.* who decides on the date of implementation, and who should be informed;

*e.* how revisions can be made or how a SOP can be withdrawn.

It should be organized and recorded who is responsible for the proper distribution of the documents, the filing and administration (e.g. of the original and further copies). Finally, it should be indicated how frequently a valid SOP should be periodically evaluated (usually 2 years) and by whom. Only officially issued copies may be used, only then the use of the proper instruction is guaranteed (United States Environmental Protection Agency, 2007).

## 8. SOP Review and approval

SOPs should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process (Almeida S.L.).

It is especially helpful if draft SOPs are completely tested by individuals other than the original writer before the SOPs are finalized. The completed SOPs then must be checked out and approved by peer reviewers, the QA Manager, and appropriate management prior to the use of the SOP. A set format in styling, information necessitated, and a numbering system is required, as well as biannual or annual review to ensure that the procedure is up-to-date. An archival system is needed to ensure that an historical record can be maintained and only current SOPs are available for staff use (United States Environmental Protection Agency, 2007).

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. When practical, use of electronic signatures, as well as electronic maintenance and submission, is an acceptable substitution for paper.

SOP general form defines an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item, is of the type and quality needed for the project (United States Environmental Protection Agency, 2007), (Jain, SK. 2008).

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## 9. Revising SOPS

If the SOP does not definitely describe the procedure, then the SOP must be revised. Any change in the procedure must be included into the SOP. Nevertheless, prior to any change to the SOP, management must be advised of, and approve, the change.

If there are some errors in the finalized SOPs, such as typographical errors, printing errors, e.g., wrong page numbers or misaligned sentences) or any errors that do not affect the scope of the procedure, they may be correctly immediately and reprinted. These types of errors do not require full SOP revision, thus a revision number will not be generated and management approval is not needed. If the error occurs on the signature page then the signature page will be resigned. These types of corrections will be traceable since the historical file will reflect all corrections including typographical errors. Specifically, the historical SOP file will contain both the SOP with the correct page(s) as well as the page(s) containing the error. The page with the error will not be removed from the historical file. Additions can be made to an SOP via a clarification or an addendum. Explanations and addenda must be attached to the appropriate SOP until such time that the SOP can be revised. Usually, the revision will be organized during the biannual review process. When the SOP is revised, the revision number is updated. Revisions, explanations, and addenda are prepared by appropriate personnel, but must be approved by management. An SOP can be eliminated when it is no longer applicable. Management must approve the elimination of an SOP. Two or more SOPs can be consolidated; in this case one SOP supersedes the other, but management approval is required for consolidation of procedures. The signed revised SOP must be sent to the historical file for archiving (United States Environmental Protection Agency, 2007).

## 10. Frequency of revisions & Reviews

SOPs necessitate to remain current to be useful. The review process should not be overly cumbersome to encourage timely review. Therefore, whenever procedures are changed, SOPs should be updated and re-approved. If desired, only the pertinent section of an SOP can be modified and indicate the change date/revision number for that section in the Table of Contents and the document control notation.

SOPs should also be reviewed systematically on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and suitable, or to decide whether the SOPs are even needed. The review date should be added to each SOP that has been reviewed. If an SOP defines a process that is no longer followed, it should be removed from the current file and archived (Almeida S.L.) The frequency of review should be indicated by management in the organization's Quality (Jain, SK., 2008).

## 11. Checklists

SOPs should describe how the checklist is to be prepared or on what it is to be based (Almeida S.L.)

Many activities use checklists to guarantee that steps are followed in order. Checklists are also used to document completed actions. Any checklists or forms involved as part of an activity should be referenced at the points in the procedure where they are to be used and then attached to the SOP (United States Environmental Protection Agency, 2007).

In some cases, detailed checklists are prepared specifically for a given activity. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists should be then maintained in the file with the activity results and/or with the SOP.

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## 12. Document Control

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. Usually, each page of an SOP should have control documentation notation. 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 requirement for observable records is included and when the activity is being reviewed (United States Environmental Protection Agency, 2007).

## 13. SOP Document Tracking and Archival

The organization should sustain a master list of all SOPs. This file or database should show the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. The QA Manager (or designee) is usually the individual responsible for sustaining a file listing all current quality-related SOPs used inside the organization. If an electronic database is used, automatic “Review SOP” notices can be sent. Note that this list may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

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The Quality Management Plan should indicate the individual (s) responsible for assuring that only the current version is used. That plan should also designate where, and how, outdated versions are to be maintained or archived in a manner to prevent their continued use, as well as to be available for historical data review.

Electronic storage and retrieval mechanisms are generally easier to access than a hard-copy document format. For the user, electronic access can be limited to a read-only format, thereby protecting against unauthorized changes made to the document (United States Environmental Protection Agency, 2007).

## 14. SOP General Format

This term describes an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item, is of the type and quality needed for the project (Levine, D.I. 2010).

*How should a SOP be organized?* A SOP should be organized to ensure ease and efficiency in use and to be specific to the organization which develops it. There is no one 'correct' format; and internal formatting will vary with each organization and with the type of SOP being written.

*How much detail needs to be included in a SOP?* A SOP should be written with sufficient detail so that someone with a basic understanding of the field, can successfully reproduce the activity or procedure when unsupervised (United States Environmental Protection Agency, 2007).

The QA systems in place will be covered in general by 'standard operating procedures' (SOP) and will be made up of the following essential components:

SOPs should be organized to guarantee ease and efficiency in use and to be specific to the organization which develops it. There is no one "correct" format; and internal formatting will vary with each organization and with the type of SOP being written. Where possible break the information into a series of logical steps to avoid a long list. The level of detail provided in the SOP may differ based on, e.g., whether the process is critical, the frequency of that procedure being followed, the number of people who will use the SOP, and where training is not routinely available. A generalized format is discussed next (Levine, D.I. 2010).

Organization shall have SOP on Preparation, approval, revision and control of standard Operating Procedure for more excellent control and management of SOPs. Before finalizing and distributing SOPs, organizations should get the documentation reviewed and validated by people with training and experience on the processes. If the SOP does not definitely define the procedure, then the SOP must be revised. Any change in the procedure must be included into the SOP. After all, prior to any change to the SOP, management must be advised of, and approve, the change. Finalized SOPs, containing typographical errors, printing errors, e.g., wrong page numbers or misaligned sentences) or any errors that do not act on the scope of the procedure may be corrected immediately and reprinted.

An organization's SOPs should be written in a format that is tailored to the organization type and its unique requirements. In general, administrative/programmatic SOPs will consist of five elements: Title page, Table of Contents, Purpose, Procedures, Quality Assurance/ Quality Control, and Reference (Frank, D. 2010). General SOP format is shown in Table 3.

| Element | Explanation |
|---|---|
| **Title page** | The SOP should be arranged to guarantee ease and efficiency in use and to be specific to the organization (Almeida S.L.) Each SOP produced will be issued with a unique SOP number for reference purposes. This will be located in the table on the front page and in the footer of the document. This number will state where the SOP originated, the year it was produced, the SOP number and also state the version number. The SOP reference and effective date should be included in the footer on each page of the SOP. The first page or cover page of each SOP should contain the following information: a title that clearly identifies the activity or procedure, an SOP identification (ID) number, date of issue and/or revision, the name of the applicable agency, division, and/or branch to which this SOP applies, and the signatures and signature dates of those individuals who prepared and approved the SOP. Electronic signatures are satisfactory for SOPs obtained on a computerized database. (Jain SK., 2008), (United States Environmental Protection Agency, 2001), (Almeida S.L.), (Frank D., 2010). The Author shall be the individual primarily responsible for writing the SOP.<br>**Chapter pages:** Chapter pages can help divide content by area or task type. Chapter pages serve as mini title pages introducing each section and indicate dates for the most recent revisions.<br>**Title** – a clear, brief title describing the aim of the SOP and the conditions under which it can be accurately used (Levine D.I., 2010).The title should use directive language to declare what is being done to what (United States Environmental Protection Agency, 2007). Each SOP should be given a unique name which captures the significance of the practice described (Levine D.I. ,2010). |
| **Table of Contents** | Table of contents is not required if SOP is three pages or less.<br>A table of contents may be necessitated for quick reference, particularly if the SOP is long, for locating information and to designate changes or revisions made only to certain sections of an SOP. Denotes changes or revisions made only to certain sections of a SOP (Almeida S.L.), (United States Environmental Protection Agency, 2007). |
| **Definitions** | There should be a part defining any words, phrases, or acronyms having special meaning or application (United States Environmental Protection Agency 2001). |
| **Purpose** | Each chapter should first briefly describe the purpose of the work or process, including any regulatory information or standards that are appropriate to the process (Levine, D.I. 2010). It is recommended to include criteria for the control of the described system during operation. |
| **Procedures** | In general there are four major types of procedure: Procedures that supply general operating guidance; an aid to meeting operating aims; mandatory and prescribe behaviour; and used as a training tool.<br>The key to any program striving for quality is the set of Standard Operating Procedures (SOPs) that describe how work is to be done. The procedure section will identify how the aims will be achieved.<br>This will clearly indicate a step by step description of how the procedure to be followed. Steps should include products and equipment required, possible obstacles, personnel qualifications and safety considerations. For lengthy process descriptions, a flow chart might be necessary to define processes that often involve interferences or variances. |

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**Procedures (continued)**

If calculations are involved in analyzing the data, then an example of the calculation should be provided. Figures and tables showing laboratory apparatus, representative data, etc. can be included here (Levine, D.I. 2010).

Once the necessity for a particular SOP is organized, it should be drafted immediately. SOPs are drafted by laboratory or supervisory staff qualified to perform the procedure. Next the SOP is reviewed by other staff, where possible, and then approved by the QA Manager (QAM) and management, such as immediate supervisor. Circulation to staff members for review/comment is advisable prior to acquiring management approval. The SOPs should be written to define study methods or procedures in sufficient detail so as to guarantee the quality and integrity of the data or procedure to be followed. When writing SOPs, the detail used may include both procedural requirements (exact instructions) and guidance information (general information) on the procedure. Procedural requirements must be followed accurately, while guidance information is used to help perform the procedure; it is not a mandatory requirement and, therefore, it does not have to be followed exactly. Procedural requirements can be distinguished from guidance elements, based on the context they are used. Office standard format for margins, font, and font size should be followed. Official SOPs will have a colored header and footer on each page, dated signatures on the front title page, and be printed on ivory colored paper with a watermark. An outline format should be used and include alpha and/or numeric characters are to be included to indicate levels of information (United States Environmental Protection Agency, 2007).

A SOP should be written as soon as the need for a standard written procedure for an activity is required (Cardiff University, 2009). How much someone knows about an entire process or job affects the way he or she does that job. Incorporate safety, health and environment into the traditional how-to-operate or how-to-do steps. Based on best practice/standards, the procedure should be written in specific detail to ensure that the procedure can be repeated in a reproducible fashion to include the order of steps that should be followed, the times allowed for each step (as needed) and the temperatures at which the steps are performed.

It should be kept in mind that many people do not read all the steps before starting on step one. ASOP should be written as long as necessary for a specific job. People tend to ignore long SOPs because they cannot remember more than 6 to 12 steps. If the SOP goes beyond 10 steps, the following solutions should be considered; The long SOPs should be broken into several logical sub-job SOPs, an accompanying shortened SOP should be written that lists only the steps but not detailed explanations of those steps, and the long-form SOP should be made as a training document or manual to supplement the shorter sub-job SOPs mentioned earlier (Jain, SK. 2008).

All SOPs before implementation or after revision will be approved by the management committee before implementation. Previous versions of all documentation will be stored electronically, with only the current versions available in the biorepository file.

All SOPs will be checked out on an annual basis by the management committee. Protective equipment that should be worn by staff when performing the procedure described. A list of the equipment needed to perform the procedure. All materials and supplies should be recorded. The date the procedure was first introduced as well as the date of the most recent version. The date format should be based on the ddmmyyyy system where d represents day, m represents month and y represents year.

| | |
|---|---|
| **Procedures (continued)** | Personnel Qualifications/Responsibilities (identifying any special qualifications users should have such as certification or training experience and/or any individual or positions having responsibility for the activity being described)(United States Environmental Protection Agency 2001)<br>Any related SOPs (of operations used in the present SOP); possible safety instructions should be added.<br>Generally there are four types of procedure: (Health and Safety Executive).<br>General operating guidance procedures<br>Procedures that an aid providing procedures to meeting operating aims<br>Mandatory and behaviour prescribing procedures.<br>Training tool procedures<br>**Scope and Applicability**–under what specific conditions can this protocol be used reliably; are there any known interferents or other limitations on the protocol's effective use?<br>**Introduction**–Appropriate background information on the system, methods, and instruments are used. The background section should plan the procedure and the specific aim of the SOP.<br>**Materials and Supplies**–There should be a list of any reagents involving names of suppliers used in this procedure. If the suppliers are obscure sources, a list of addresses and contact information should be supplied as well. **Cautions** – If there are some specific health and safety precautions they should be considered. For example, should gloves be worn? If so, what kind? How should spills, if they occur, be cleaned up? Are there any special procedures that should be followed in order to safely dispose of waste? (Levine, D.I. 2010). Some SOPs should be written for people who perform under different interpersonal circumstances, people who work alone, two or more people who work together as a team, for people who will control other people doing a job, for people who not familiar with rules generally understood by your employees (Jain, SK. 2008).<br>Well-written SOPs should first briefly describe the purpose of the work or process, including any regulatory information or standards that are appropriate to the SOP process, and the scope to indicate what is covered. Diagrams and flow charts should be used to help to break up long sections of text and to briefly summarize a series of steps for the reader(Almeida S.L.)<br>The age, education, knowledge, skill, experience and training, and work culture of the individuals should be considered who will be performing the SOP steps.<br>Criteria, checklists, or other standards should be applied during the procedure such as citing the document as guidance for reviewing SOPs Records Management (specifically,e.g.,as forms to be used and locations of files.<br>Once writing of an SOP have been completed, there should be several workers test it and give you feedback. |
| **Health and Safety Warnings** | Primarily for technical SOPs |
| **Cautions** | Primarily for technical SOPs |
| **Interferences** | Primarily for technical SOPs |

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|---|---|
| **Quality Assurance/ Quality Control** | The preparation of appropriate QC procedures (self-checks, such as calibrations, recounting, reidentification) and QC material (such as blanks - rinsate, trip, field, or method; replicates; splits; spikes; and performance evaluation samples) that are needed to display successful performance of the method should be defined.<br>All SOPs should be checked out annually to certify all SOPs are in line with current processes, guidelines and regulations. They should be checked out in regards with the review date assigned and recorded on the front page of each SOP. The designated individuals will approve all SOP amendments. All significant amendments will be required 2 months in advance of the annual review. Any control steps and provisions for review or oversight should be defined prior to acceptance of the product or deliverable. This can involve test plans such as verification and validation plans for software or running a "spell-check" program on the finished document (United States Environmental Protection Agency 2001).<br>Finally, next all appropriate QA and quality control (QC) activities for that procedure should be defined, and list any cited or significant references (United States Environmental Protection Agency, 2007). Before finalizing and distributing SOPs, organizations must get the documentation reviewed and validated by people with training and experience on the processes. Additionally, it is a good idea to have the SOPs tested by staff who will be asked to comply with them. By following these steps, the author can identify missing information or needed revisions. Once SOPs are approved, they should be made readily available to facility management, building occupants and cleaning employees. The SOP will require final approval and authorization. The signature on an SOP will authoise the associated forms which should show an identical issue date to the SOP. When an SOP is issued and become effective, adequate time is required for training purposes. Finally, SOPs must remain current, so they should be updated and re-approved at least annually or whenever procedures change. Though the SOP development process takes time and effort, it can provide significant improvement to a cleaning organization's operational results and workers' understanding and job performance (Frank, D. 2010).<br>All SOPs are reviewed by the applicable supervisor at least every two years in order to maintain their relevancy. Names of those individuals who have reviewed and approved the SOP for use in the laboratory. Signatures and dates should be supplied whenever possible as well. For those SOPs which do not necessitate a revision, documentation attesting to that fact must be submitted to the QAM who in turn initials and dates the table located at the bottom of the title page of the original SOP (United States Environmental Protection Agency, 2007). All SOPs require version control to ensure that individuals are using the correct verision of SOP. It is good to practice to assign a document a version number, in the format N. n where N represents a finalized document and n represents draft versions. Each new, approved and finalized document a major verison number…. should be assigned. When taking a document for revision or as draft, assign a new minor version. During the review cycle assign each new revision of the draft the next minor version, upon approval/finalization of the document assign the next major version (United States Environmental Protection Agency 2001), (Natural Resources Management and Environment Dept.). |
| **References** | References relating to the development of the SOP are required to be listed. These may include other SOPs, regulatory guidelines and published papers etc. Documents listed in the SOP must be recorded in the appendices and listed accordingly (United States Environmental Protection Agency 2001). |

| | |
|---|---|
| **Contact list** | It should involve contact details for relevant individuals such as author of document. |
| **Appendices** | This section should list appendices of other SOPs referenced in the document, or related to the procedure. |
| **Distribution** | Once approved the original paper SOP folder, it will also contain supporting documentation relating to each approved SOP for referencing purposes. An electronic copy of the SOP will be held. Approved SOPs will be distributed in hard copy to PDs and will be published. The paper version of the abandoned SOP will be filled into the archived SOP folder. All SOPs will be checked out and approved annually before it is superseded, unless a specific reason for a 6 month review can be justified. All SOPs must be kept for the duration of the project.<br>When the Sop fulfils all the necessary requirements it is printed. The author hands over the manuscript (or the floppy disk with text) to the SOP administrator who is responsible for the printing. The number of copies is decided by him/her and the author. Copying SOPs is forbidden. Extra copies can be obtained from the SOP administrator. The author (or his successor) signs all copies in the presence of the administrator before distribution. As the new copies are distributed the old ones (if there was one) are taken in. For each SOP a list of holders is made. The holder signs for receipt of a copy. The list is kept with the spare copies. Users are responsible for proper keeping of the SOPs. If necessary, copies can be protected by a cover or foil, and/or be kept in a loose-leaf binding.<br>Appropriate SOPs will be placed in green binders to be found in a designated spot in each work area, e.g., laboratory, equipment rooms, the library, etc., and shall be available to staff and managers. These binders will not be located in the supervisor's office. Removal of an individual SOP requires completion of the sign-out located on the insider of the binder. The binder must not be removed from its designated spot by anyone other than the QAM or laboratory director. It is the responsibility of the QAM to update each binder as individual SOPs are revised. The staff is required to read any revised SOP within 7 working days of issuance if the SOP is applicable to their work. Reading of the updated SOP requires signature on the SOP review sheet (United States Environmental Protection Agency, 2007). |
| **Archiving** | Proper archiving is essential for good administration of SOPs. All operating instructions should be kept up-to-date and be accesible to personnel. Good Laboratory Practice requires that all documentation pertaining to a test or investigation should be kept for a certain period. SOPs belong to this documentation. An historical file is created for each SOP that is approved by management and will be maintained in the company's archives by the QAM. The historical file will consist of the original signed SOP and all subsequent modifications thereof. Official SOPs will have both colored header and footer lines, and be printed on watermarked ivory colored paper. All copies of the original will be black and white, initialed, numbered, and placed in the appropriate binder located in each office. If a procedure is incorporated into another SOP (superseded), a copy of the superseded version is placed in the historical file of both SOPs (United States Environmental Protection Agency, 2007). |

**Table 3.** General SOP Format.

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## 15. Types of SOP

Several categories and types of SOPs can be distinguished. The name "SOP" may not always be appropriate, e.g., 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 (to avoid jotting down readings and calculations on odd pieces of paper) (Almeida S.L.)

Some of the most important SOP types:

- 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.

Generally the SOPs may be written for any repetitive technical activity, as well as for any administrative procedure (Almeida S.L.).

SOPs may be written for any repetitive technical activity, as well as for any authoritative or functional programmatic procedure, that is being followed inside an organization. General guidance for preparing both technical and administrative SOPs follows and examples of each are located in the Appendix (United States Environmental Protection Agency, 2007).

## 16. Guidelines for Technical SOP Text

Technical SOP and Administrative SOP are typical structures of SOPs. Technical and administrative SOPs need to involve 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.

A technical SOP is a standard operating procedure which involves environmental data generation, manipulation, or accumulation, e.g., an analytical process. Technical SOPs can be written for a wide variety of activities.

Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover ac-

tivities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation. Citing published methods in SOPs is not always acceptable, because cited published methods may not contain pertinent information for conducting the procedure-in-house. Technical SOPs 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 should fit within the framework presented here, but this format can be modified, reduced, or expanded as required.

## 17. Guidelines for Administrative or Fundamental Programmatic SOP

An administrative SOP is a standard operating procedure which does not include environmental data manipulation activities, e.g., how to conduct an inspection. As with the technical SOPs, these SOPs can be written for a wide variety of activities, e.g., reviewing documentation such as contracts, QA Project Plans and Quality Management Plans; inspecting (auditing) the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures.

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. For example, audit or assessment SOPs should specify the authority for the assessment, how auditees are to be selected, what will be done with the results, and who is responsible for corrective action. Administrative SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded (United States Environmental Protection Agency, 2007).

## 18. Conclusion

Eventually, SOPs serve as a fundamental means of communication for all levels of the organization. Not only do they include employees departmentally, but they also allow management and employees to gain a cross-functional view of the organization. This attitude encourages employees to think about how process change may affect other functional areas. A good system forces employee to think through processes and examine how procedure might influence product, personnel, production, and equipment. *It should not be forgotten that the "Best written SOPs will fail if they are not followed"* (Hattamer-Apostel, R. 2001), (Jain, SK. 2008).

What happens to workers' intrinsic task motivation and creativity when they are required to follow SOPs in completing their tasks? Job design and work motivation theory literatures have suggested a negative relationship; the OM literature has suggested a positive relation. We suggest that the discussion has been hindered by differences in conceptualizing required SOP use, by not explicitly incorporating the multidimensional nature of intrinsic motivation into the analysis, by an ambiguous definition of autonomy, and by ignoring important contextual moderators. When these three elements are included in the discussion, we showed that the relationship between required SOP use and intrinsic motivation could theoretically

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be positive. Finally, our model high- lights the importance of worker participation. Production pressures, high capacity utilization, and lack of management – especially supervisor – support are likely to reduce opportunities for worker participation, and hence lower intrinsic motivation and creativity (De Trevil et al. 2005).

*Example SOP*

*TITLE:* Preparation of the Perfect Cup of Coffee by the Drip Method

*Date of Preparation:* 11/29/05; *Date of Revision:* N/A; *Revision No.:* N/A

*Submitted by:* Ay Dot Student; *Approved by:* Professor Ex

*Purpose:* Provide an example of a standard operating protocol or SOP that can be appreciated by undergraduate research students from all academic disciplines.

*Scope and Applicability:* The following protocol can be used wherever quality coffee beans, good drinking water, and a drip coffee maker are available.

*Introduction:* Coffee is the beverage of choice of many college students. Properly prepared the beverage provides an invigorating and revitalizing effect. One of the most frequently used methods of preparation is the drip method. In this method, water, heated to near boiling temperatures, is slowly added to finely ground coffee beans held in a filter unit. The coffee beverage is collected below the filter unit in a glass carafe. Today this procedure is frequently accomplished using a semi-automated process in an electronic coffee maker. The procedure below outlines a reliable method for preparing drip coffee using any commercially available drip coffee maker, high quality ground coffee beans, and filtered water.

*References:* For information on coffee beans, the standard methods of preparation of coffee, and recipes see:

*Materials and Supplies:* Freshly ground Starbucks® coffee (any flavor you prefer; medium grind works best with most commercial coffee makers), commercial 4-c drip coffee maker including filter (gold mesh preferred but high quality paper filter may be used), good quality drinking water (Polar Springs®, Brita®-filtered, or similar quality source recommended), coffee cup, and additives (as desired: sugar or sugar alterative, cream or milk).

*Cautions:* Hot coffee can scald and burn. Water is an electrical conductor. If spills occur during the brewing process, wait until the brewing process is complete, turn of the electricity, and disconnect the unit from the electricity before attempting to clean up any spills. Accidental spills may be cleaned up with a kitchen sponge and dish washing detergent such as ….®. Used coffee grounds can be disposed of in the regular trash. Be sure to carefully read the directions that accompanied your coffee maker unit before attempting to use it. In particular, it is important to find out if your unit has (1) a pause feature that will allow you to remove the carafe while the coffee is brewing; and (2) an auto-off feature that turns off the heater unit located beneath the carafe at a set time after the coffee has been brewed.

*Personnel Qualifications:* No special knowledge or training is required to make coffee. However, due to the potential risk of burns, it is recommended that anyone performing this procedure who is less than ten years old be actively supervised by an adult.

*Protocol*

1. Make sure that the coffee maker is off. Locate water reservoir unit on coffee maker and carefully add 4-cups of clean drinking water to the reservoir. Note that the outside or inside of most quality coffee makers' water reservoir units are marked for the user's convenience.

2. Locate the coffee filter assembly on the coffee unit. If you are preparing the standard 4-c carafe of coffee, carefully measure one coffee measure of ground coffee into your units coffee filter assembly. Note that one standard coffee measure is equivalent to 1/8-c of coffee. Close the coffee filter assembly.

3. Plug in the coffee maker and turn the unit on. Wait until the carafe located beneath the coffee filter unit is filled with coffee. Note that some units may have a "pause" feature that will allow you to temporarily remove the carafe and pour a cup of coffee while the unit is working. If you are unfamiliar with your unit, be sure to wait until the unit is done filtering before attempting to remove the carafe.

4. If coffee spills beneath the base of the carafe unit, be sure to turn off the unit and disconnect the electricity before attempting to clean up the spill.

5. Pour yourself a cup of coffee. Most coffee units will keep the carafe warm for a set period of time before turning off automatically. Some however, do not turn off automatically. Be sure to read your coffee maker's instructions beforehand. If in doubt, be sure to turn off the electricity to your unit after the brewing process is complete. (Levine D.I et al, 2010)

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