Objectives addressed: Clinical Laboratory Procedure Format #2-4

Introduction
The work performed in a clinical laboratory must be accomplished in an organized, efficient and consistent manner. In order to assure the quality of the work product regardless of which individual is performing the activity, Standard Operating Procedures (SOPs) must be followed. This module will list the sections commonly found within an SOP and describe the information provided within each section. It will also discuss the collection of SOPs into a procedure manual.

What is an SOP?
A Standard Operating Procedure (SOP) provides the step-by-step instructions for performing a given work activity. This activity may be the analysis of a specimen for a particular substance (analytical phase of laboratory testing), instructions for specimen collection (pre-analytical phase of testing), or how to document the reporting of a critical result (post-analytical phase of testing). Other SOPs will describe the maintenance of equipment, or how to document employee competency. There are SOPs for every work activity performed in the clinical laboratory!

SOPs must be available for use at the bench by staff performing a given work activity. This ensures that all those performing that activity have access to the same information and are using the same instructions to accomplish the task. Following the SOP assists in the detection of problems when they arise and may contain suggestions to correct the problem. SOPs used at the bench may be in an electronic format or may be on paper.

While each laboratory needs to write procedures that are specific to their work processes, the information used to write those procedures may come from several sources. Package inserts and instrument operators’ manuals are primary sources for content. Regulatory and accrediting agencies may require certain information be included within a particular procedure; they may also have guidance documents with useful suggestions. Some laboratory professional organizations, such as ASM and AABB, offer suggested procedures or procedure templates to their members. Technical manuals, textbooks and articles may be used to create a procedure outline, but details must be specific for the laboratory developing the procedure.

Each laboratory should utilize a standard format for their SOPs, in order to assist staff in quickly finding information within the SOP. The SOPs should be written using terminology that is easily understood by the staff that will be using the SOP. Clear instructions help to eliminate errors in performance. All symbols and abbreviations used within the procedure must be defined.

The procedure should be given a title that is brief but descriptive. It is recommended that the title begin with the analyte being tested and include the specimen type and method or instrument used for analysis, for example “Blood Glucose by Nova STATSTRIP® Glucose Hospital Meter” as opposed to “Procedure for Glucose Determination”. The procedure must also include the name and location of the laboratory, frequently positioned in a header or footer.

Laboratory Procedure Sections
Written procedures are organized into sections in order to simplify locating needed information. The following section headers are commonly used to organize written procedures, although a given procedure may not contain every section listed. Procedures may vary in content depending on whether the test is performed manually or on an automated instrument. A brief description of the information found under each section header is given below.
<table>
<thead>
<tr>
<th>Section Header</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle</td>
<td>States what analyte is being measured, the scientific method upon which the test is based, and how the measurement is made.</td>
</tr>
<tr>
<td>Significance of Measurement / Purpose</td>
<td>The rational for performing the test in terms of medical usefulness.</td>
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<tr>
<td>Scope</td>
<td>Who is allowed to perform this test or in which situations would this test be performed</td>
</tr>
<tr>
<td>Reagents/ media</td>
<td>List of all reagents or media required for performing the procedure. If a reagent is prepared in-house each time the procedure is performed, directions for preparing the reagent are included here.</td>
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<tr>
<td></td>
<td>Storage conditions and stability are given, along with any special handling and safety precautions (e.g., potential to transmit disease, flammability, explosion hazard, etc.)</td>
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<tr>
<td>Supplies</td>
<td>Supplies specific to performing the test are listed here. If a supply is common to the work area set up (i.e., pens, test tube racks, pipettes, etc.) they do not need to be included.</td>
</tr>
<tr>
<td>Equipment</td>
<td>A list of equipment specific to the performance of the test, such as a centrifuge, incubator, scale, etc. If the test is performed on a specific instrument, that information is included here.</td>
</tr>
<tr>
<td>Calibration and Calibration Verification Procedures</td>
<td>Explanation of how the test is standardized (calibrated), including number of calibrators and their concentrations. Must include how calibration is verified, and suggest corrective action when calibration fails. An explanation of how results are determined from the standard curve is provided.</td>
</tr>
<tr>
<td>Safety precautions</td>
<td>Required personnel protective equipment (PPE) plus any additional safety precautions such as “Wear Kevlar gloves when handling broken glass” or “Do not aim laser at the eyes”.</td>
</tr>
<tr>
<td>Specimen Collection and Handling Requirements</td>
<td>Instructions for patient preparation, such as “Must be fasting for 12 hours”. List of specimen types which can be used to perform the test (whole blood, plasma, urine, etc.)</td>
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<tr>
<td></td>
<td>Acceptable collection methods (venous, capillary, clean-catch urine, etc.), and list of anticoagulants / preservatives allowed (e.g., EDTA vs. heparinized vs. citrated plasma).</td>
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<td></td>
<td>Minimum volume required for conducting the test Specimen labelling instructions. Specimen handling instructions (e.g., specimen should be kept on ice, specimen should be protected from light, plasma must be separated from RBCs within 4 hours).</td>
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<td></td>
<td>Criteria for rejection of a specimen. Stability and specimen storage instructions (e.g., stable for 4 hours at room temperature; may be tested for up to one week following collection when held at 1-6°C).</td>
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<tr>
<td><strong>Quality Control</strong></td>
<td>Includes type of quality control performed, levels of controls tested, and frequency of testing. Expected results, criteria for accepting/rejecting patient results and steps for troubleshooting if QC fails are given. If QC material is prepared in-house, directions are included here.</td>
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<tr>
<td><strong>Procedure</strong></td>
<td>Step-by–step instructions for conducting the analysis (in the order to be performed); usually numbered. Each step begins with an action verb. Decision points state what action to take depending on results obtained up to that point (if x then y)</td>
</tr>
<tr>
<td><strong>Calculations</strong></td>
<td>Equations used within the procedure, including step by step instructions for using the equation and an example.</td>
</tr>
<tr>
<td><strong>Expected Results/ Reference Values</strong></td>
<td>Terms used for reporting results (i.e., numeric value, positive/negative, reactive/ non-reactive) “Normal” range for results Units of measure (i.e., g/dL, /µL, etc.)</td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>What the patient results mean in comparison to the expected results (i.e., what is normal vs abnormal) Additional steps to perform if results are indeterminate, or if results are outside of the acceptable range / linearity.</td>
</tr>
<tr>
<td><strong>Critical Values</strong></td>
<td>Values that indicate a patient’s life is in danger; panic values. Includes follow-up action if a critical result is obtained, and documentation that the critical value was reported to patient care staff.</td>
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<tr>
<td><strong>Reporting Results</strong></td>
<td>Directions for getting results to the patient care staff whether electronically (computer), on paper, or verbally.</td>
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<tr>
<td><strong>Method performance specifications/ Limitations</strong></td>
<td>Reportable range / linearity, including directions for preparing dilutions when reportable range exceeded. Sensitivity, specificity, accuracy and precision data Interfering substances, such as lipemia, hemolysis, drugs, etc. Other sources of error and special considerations (e.g., Reading results microscopically may result in false positive reactions)</td>
</tr>
<tr>
<td><strong>References</strong></td>
<td>Sources used to create procedure.</td>
</tr>
<tr>
<td><strong>Author(s)</strong></td>
<td>Who wrote or revised the procedure</td>
</tr>
<tr>
<td><strong>Approval Signatures and Dates</strong></td>
<td>Authorization to place the procedure into use in the workplace.</td>
</tr>
</tbody>
</table>

*Adapted from QMS02-A6, “Quality Management System: Development and Management of Laboratory Documents; Approved Guideline”. 6th ed. Clinical and Laboratory Standards Institute, 33:3 February 2013. Table 5 (page 19) and Table 6 (pages 22-24).*
These sections should be listed within the procedure in the order in which the information will be used (e.g., one would not mention that the patient must be fasting at the time of specimen collection in the limitations section… that information would be more relevant in the specimen collection section.) The use of flow charts, instrument diagrams, and computer screen prints may be used within the body of the procedure or as appendices to clarify particular steps.

Each procedure should have a unique document number, including version number and revision dates. It must be possible to trace the “life cycle” of the document (i.e., date procedure was placed into use, when revisions were made, when the procedure was retired/archived). Prior to placing a procedure into use, the procedure must be reviewed to ensure it is complete in content and clear in meaning. Procedures are reviewed by the laboratory Medical Director or designee at least once every two years.

**Organizing procedures – The procedure manual**

A procedure manual is a collection of a laboratory’s SOPs. It may be paper-based or maintained electronically, provided precautions have been taken to prevent unauthorized alterations. Frequently, each laboratory section maintains its own section-specific procedure manual.

There are several ways that procedure manuals may be organized. One common practice is to place the procedures in alphabetical order. This may be particularly useful in laboratory sections that conduct a large number of assays, such as the chemistry lab. Another organization scheme is to place procedures in the order in which they are commonly used. A similar method is to group “like” procedures together. For example, in Blood Bank all of the component preparation procedures may be in one section of the procedure manual, while another section may be dedicated to manual serological testing, and a third to tests performed on an automated instrument. Procedures may also be organized according to the instrument on which the test is performed, or the workstation where testing takes place.

In addition to the procedures, each procedure manual should have a table of contents. The manual may also contain process flow charts, job aids, and examples of properly completed forms and worksheets.

**References**


