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Standard Operating Procedures (SOPs) in HHS-Certified Workplace Drug Testing Laboratories

Standard operating procedures (SOPs) are a detailed set of instructions that outline the steps, methods, and protocols required to complete a task or process consistently and efficiently.[1-3] A variety of industries use SOPs to ensure quality, safety, and compliance with regulations. SOPs are critical for forensic toxicology laboratories, including the laboratories and instrumented initial test facilities certified by the Department of Health and Human Services (HHS) to perform federally regulated workplace drug testing in compliance with the HHS *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG)* and HHS *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG)*.[4-6]

SOPs play a crucial role in forensic toxicology by outlining procedures for receiving specimens, maintaining chain of custody, carrying out tests, examining data, reporting drug test results, and following quality control requirements. They also govern sample disposal and provide guidelines for the use and security of electronic programs, ensuring integrity and confidentiality in sensitive cases.[7] Furthermore, by standardizing procedures to ensure different staff members perform tasks consistently, SOPs improve the laboratory's capacity to provide consistent, trustworthy results—a crucial capability in legal settings where the accuracy and precision of toxicological data can have far-reaching consequences.[7]

Effectively developing and implementing SOPs requires a thorough grasp of the laboratory's existing conditions, strategic goals, and objectives alongside a clear understanding of customer, stakeholder, and regulatory agency requirements and expectations. Understanding these will help laboratories tailor SOPs to meet specific departmental needs, ensuring that they align with comprehensive laboratory standards and contribute to the laboratory's efficacy and reliability in delivering high-quality results.

Developing an SOP begins with an understanding of the laboratory's framework and requirements of suitable standards.[1-3] The development process should align with the laboratory workflow to promote accurate data and a culture of responsibility and safety.[8] Effective SOPs are comprehensive, with thoroughly described laboratory procedures.

Key Components of SOPs

Many sources describe key components of an SOP. In particular, the Standard for the Minimum Content Requirements of Forensic Toxicology Procedures (ANI/ASB Standard 152, 1st Ed. 2021)[1] and the Mandatory Guidelines published by the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) Division of Workplace Programs, which mandate the requirements for testing specimens that fall under the Drug Free Workplace Program, are relevant for forensic toxicology. Section 11.1 of the UrMG[4] notes that the following must be included in an HHS-certified laboratory's SOP manual:

(a) An HHS-certified laboratory must have an SOP manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include, at a minimum, a detailed description of the following:

- Chain of custody procedures
- Accessioning
- Security
- Quality control/quality assurance programs
- Analytical methods and procedures
- Equipment and maintenance programs
- Personnel training
- Reporting procedures
- Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

General components of an SOP include the following:

- Title and Purpose: Clearly explain the purpose and state what the SOP is for and why it is important.
- Scope: Clearly define boundaries of the procedure, including what it encompasses and any limitations.
- Responsibilities: Specify who is responsible for carrying out each step of the procedure.
- Materials and Equipment: List all materials, tools, and equipment needed to perform the procedure.
- Procedure: Provide a detailed step-by-step description of how to perform the task or process.
- Safety Precautions: Outline necessary safety precautions and risk assessments. Highlight any safety hazards associated with the procedure and detail the necessary precautions.
- Quality Control Measures: Outline any quality checks or verification steps to ensure accuracy and reliability.
- Troubleshooting: Include instructions for addressing common issues or problems that may arise during the procedure.
- References: Cite any relevant standards, regulations, or guidelines that the SOP is based on.
- Revision History: Document any revisions or updates made to the SOP over time including dates and reasons for changes.
- Document Control: Include the unique name/number, indication of approval, and page numbering.

SOPs may provide a list of related documents, such as quality control charts and forms, for practical guidance, alongside a glossary of definitions and abbreviations for clarity. References may not always be included in the SOP depending on the topic; however, their inclusion establishes SOPs within scientific literature and practices, ensuring that they are grounded in current, reliable sources.[9] Manufacturer's inserts or manuals provide valuable information and may be used as reference material for procedures but may not be used to replace the formal procedures in the laboratory SOP manual.

Standard operating procedures (SOPs) in drug testing labs are the backbone of consistency and reliability; they ensure every step is meticulously followed, transforming complex processes into repeatable, validated results that uphold the integrityof scientific inquiry and safeguard public health.

Availability and Accessibility

SOPs may exist in paper (hardcopy) format or electronic format. SOPs must be readily available to all laboratory staff. It is important to ensure that procedures described in the SOPs are consistent with laboratory practice and that staff are following the written procedures. Staff may choose to have printed copies of the SOPs (e.g., sections, pages) at their workstations; however, the copies must be clearly annotated to document that they are current and must be replaced concurrently with the implementation of any new procedures and procedural changes. Also see *Document Control* below.

Reviewing and Updating

Regularly reviewing and updating SOPs is essential to ensure their relevance and accuracy, keep pace with evolving technological advancements, expand scientific knowledge, and shift regulatory landscapes. In addition, this ongoing process of assessment and comparison enables the laboratory to edit procedures for clarity and completeness as needed to facilitate staff understanding, thereby standardizing practices and reducing errors. Staff compliance with the SOP is essential in a field where the stakes are high and the margin for error is minimal.

HHS-certified laboratories must have procedures for making changes to SOPs. The Responsible Person (RP) must review and approve all SOP changes. All changes must be documented in an itemized list of changes on a Summary of Changes sheet for each SOP section.

Document Control

Each SOP should be identified by a unique name or number. A version number and implementation date should appear on each page of the SOP. SOP pages should be numbered (e.g., 1 of 3, 2 of 3). It is important to archive the retired older versions of the SOP in a secured and organized location. These document control measures facilitate laboratory staff's compliance with the correct SOP and also allow identification of the procedure used at any given time for future reference. Many laboratories use a laboratory quality management system or laboratory information management system for document control. This process involves version control, approval procedures, access control, maintaining document security, document storage, and distribution methods to ensure consistency and compliance with regulations or organizational standards. Security is a critical aspect of document control. Access control should ensure that only authorized individuals have access to the documents. This practice may be done by ensuring that staff have read-only access and obsolete versions are removed and archived to prevent use. Access to editable versions of SOPs should be restricted.

Implementation

SOPs are critical components of a staff training program. The importance of following SOPs must be communicated to staff. When changes are made to the SOPs, staff must be notified and training on the new/revised procedures must be completed and documented before implementation.

HHS-certified Laboratories/National Laboratory Certification Program Requirements

As discussed previously, the current UrMG4 and OFMG5 (i.e., Section 11.1[b]) provide a list of the topics that, at a minimum, must be included in an HHS-certified laboratory's SOP. A laboratory must have an SOP addressing these topics prior to applying for HHS certification under the National Laboratory Certification Program (NLCP). NLCP inspectors review the SOP and its implementation during the initial inspection and then at each maintenance inspection after the laboratory becomes certified. All procedures must be consistent with requirements in the UrMG, OFMG, and other program guidance provided by HHS.

HHS-certified laboratories are required to have clear and concise documentation to enable the inspector to verify the contents, history of each section, and what version of an SOP was in effect at the time a specimen was tested. An itemized list of all changes must be documented on a Summary of Changes sheet for each section. Each SOP section page must contain a version number and implementation date.

HHS-certified laboratories must have complete and current SOPs that describe, in detail, all laboratory operations. A detailed SOP manual is required for laboratories to be eligible to apply for accreditation under the NLCP, and it must be completed before the laboratory is eligible to receive NLCP performance testing samples.

During NLCP inspections, laboratories may provide the inspection team with a paper or electronic copy of the SOP manual, whichever format laboratory staff use at the time of the inspection. The SOP manual should serve as an accurate guide to laboratory operations and must thoroughly describe laboratory procedures. During NLCP inspections, inspectors verify the following items regarding the SOP:

- All procedures are appropriately described.
- All procedures or information are consistent between different sections of the SOP manual.
- The SOP manual is consistent with the actual laboratory practices observed during the inspection.
- All sections and procedures are properly indexed and cross-referenced in the SOP manual.
- Complete copies or appropriate sections of the SOP manual initialed and dated by the RP(s) are available in the work areas.
- The SOP manual is complete, current, well-maintained, and reviewed periodically by the RP(s).
- The SOP manual includes a Summary of Changes page for each section.
- The SOP manual contains a Signature Page by which the full signatures and initials of all laboratory personnel can be verified.
- Obsolete versions of the SOP manual are archived.

In conclusion, SOPs are the foundation of quality, integrity, and productivity in drug testing laboratories and ensure consistent treatment of all specimens, thereby providing forensically defensible and scientifically accurate drug test results. Developing, implementing, and continuously improving SOPs is essential for maintaining high standards in forensic toxicology and other laboratory settings. Integrating well-structured SOPs ensures that laboratories not only meet current challenges but are also prepared for future advancements and public health emergencies.

References

1. American National Standards Institute/American Academy of Forensic Sciences Standards Board (2021). Standard for the Minimum Content Requirements of Forensic Toxicology Procedures (ANSI/ASB Standard 152:2021). https://www.aafs.org/sites/default/files/media/documents/152_Std_e1.pdf. Accessed May 15, 2024.
2. International Organization for Standardization. (2017) General requirements for the competence of testing and calibration laboratories (ISO/EIC Standard No. 17025: 2017). ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories
3. International Organization for Standardization. (2015). Quality management systems – requirements (ISO/EIC Standard No. 9001: 2015). ISO 9001:2015 - Quality management systems
4. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (2023). *Federal Register, 88,* 70768 – 811. U.S. Department of Health and Human Services.
5. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (2023). *Federal Register, 88,* 70814 – 850. U.S. Department of Health and Human Services.
6. RTI International, Center for Forensic Sciences. Manual for Urine Laboratories, National Laboratory Certification Program (NLCP). Research Triangle Park, NC: RTI International, Center for Forensic Sciences.
7. Issa, SY (2019). Forensic Toxicology. IntechOpen.doi:10.5772/intechopen.82869 https://www.intechopen.com/chapters/65005
8. Pillai SP, Calvert J, Fox E. Practical considerations for laboratories: Implementing a holistic quality management system. Frontiers in Bioengineering and Biotechnology, 2022:10:1040103. https://doi.org/10.3389/fbioe.2022.1040103.
9. Gumba H, Musyoki J, Mosobo M, Lowe B. Implementation of good clinical laboratory practice in an immunology basic research laboratory. American Journal of Clinical Pathology, 2019:151(3):270–4. https://doi.org/10.1093/ajcp/aqy138.

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STANDARD OPERATING PROCEDURE

FOR

Developing SOPs for Federally Regulated Drug Testing Laboratories *MOCK*

(ABC-DE-001)

Authored By:

4/6/23

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1.0 PURPOSE

Clearly explain the purpose and state what the SOP will be used for and why it is important.

2.0 SCOPE

Define the boundaries of the procedure, including what it encompasses and any limitations.

3.0 RESPONSIBILITIES

Specify who is responsible for carrying out each step of the procedure.

4.0 MATERIALS AND EQUIPMENT

List all materials, tools, and equipment needed to perform the procedure.

5.0 PROCEDURE

Provide a detailed step-by-step description of how to perform the task or process.