

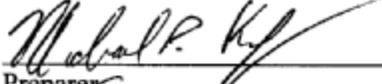
SOP NO.: QS02.3
EFFECTIVE DATE: 04 Jan

01

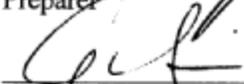
PAGE 1 OF 5
COPY #:

SOP NO.: QS02.3
EFFECTIVE DATE: 04 Jan 01
PAGE 1 OF 1
COPY #:

**U. S. Army Center for Health promotion and Preventive Medicine
Quality Assurance Team**
STANDING OPERATING PROCEDURE (SOP)
FOR
PERFORMING IN-HOUSE A2LA, ISO/IEC Guide 25,
And ISO 9001 Audits


Preparer

04 JAN 2001
Date


Supervisor Approval

1/4/2001
Date

Annual Review

Preparer

04 JAN 02
Date Due Date Comp.

Supervisor

04 JAN 02
Date Due Date Comp.

Preparer

Date Due Date Comp.

Supervisor

Date Due Date Comp.

Disclaimer: This Standing Operating Procedure has been prepared for the sole use of the

SOP NO.: QS02.3
EFFECTIVE DATE: 04 Jan

01

PAGE 2 OF 5
COPY #:

**U. S. Army Center for Health promotion and Preventive Medicine
Quality Assurance Team**

**STANDING OPERATING PROCEDURE (SOP)
FOR
PERFORMING IN-HOUSE A2LA, ISO/IEC Guide 25,
And ISO 9001 Audits**

Preparer

Date

Supervisor Approval

Date

Annual Review

Preparer

Date Due

Date Comp.

Supervisor

Date Due

Date Comp.

Preparer

Date Due

Date Comp.

Supervisor

Date Due

Date Comp.

Disclaimer: This Standing Operating Procedure has been prepared for the sole use of the U. S. Army Center For Health Promotion and Preventive Medicine (USACHPPM) and may not be specifically applicable to the activities of other organizations.

CONTENTS

PARAGRAPH	PAGE
I. PURPOSE	2
II. APPLICABILITY	2
III. DEFINITIONS	2
IV. QUALITY CONTROL.....	3
V. PROCEDURE.....	3
VI. SAFETY CONSIDERATIONS.....	4
VII. REFERENCES	4

- I. PURPOSE: This SOP is designed to provide a systematic and independent examination of a quality system and determine compliance with set standards. These standards include the, A2LA criteria, ISO/IEC-Guide 25, ISO 9001, QA plan, manuals, and SOPs.
- II. APPLICABILITY: All Strategic Initiatives Office (SIO) personnel will conduct internal assessments of DLS according to the procedures in this SOP. The original hardcopy will be maintained in the SIO, bldg. E2100, and room 1102.
- III. DEFINITIONS:
- A. Quality Control - The operational techniques and activities that are used to fulfil requirements for Quality.
 - B. Quality Assurance - The provision of objective evidence that requirements for Quality have been met.
 - C. Audit/Assessment - A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
 - D. Quality System - The collection of resources, organization, equipment, people and procedures, which implement the quality policy.
 - E. Checklist - A list of questions or items which are checked to determine compliance with the standard(s).
 - F. Audit/Assessment Team - The SIO assessor may elect to use qualified Laboratory

personnel in assisting in the audit/assessment depending on the scope of the audit/assessment.

IV. QUALITY CONTROL:

- A. The requirements must be clearly defined to the auditee. A checklist may be provided to the auditee at least one month prior to assessment. In all cases, the auditee will be notified at least one week prior to the audit.
- B. If the checklist is used, the auditee should provide the auditor with a completed checklist a least one week prior to audit.

V. PROCEDURE:

A. Audit/Assessment

- 1. If a checklist is used, it should be completed prior to the inspection by personnel involved in the areas being assessed
- 2. An In-briefing (if applicable) will take place on the first day of the audit/assessment. The purpose and procedure as well scheduling of the audit/assessment will be discussed.
- 3. The laboratory area being assessed should make all records and documentation, which are pertinent to the inspection, available to the assessor(s).
- 4. The audit will be a collection of information through interviews (verified by cross checking the same information from another source), examination of documents, and observations of activities and conditions in the relevant areas.
- 5. The audit checklist is only a guideline for conducting audits/assessments. The assessors should also conduct the audit/assessment with the following factors in mind:
 - a. Understanding - Do the operators know what is expected of them and do they show an acceptable level of competence?
 - b. Training - What special skills are required, how has the operator acquired them, and what documentation is available supporting the competency of this employee?
 - c. Methods - Do work instructions reflect current practice or are there modifications to the method that are unauthorized? Are there historical copies

of retired methods with dates of service? Are there operations performed with no work instructions?

- d. Equipment - What condition is the equipment in, and is their documentation of scheduled preventive maintenance? Has the equipment been calibrated correctly and documented (if necessary)?
- e. Documentation - Are the documents controlled? How is the distribution controlled? Are there unofficial changes, corrections, or instructions, which have never formally been incorporated into the procedure?
- f. Environment - How are specific environmental conditions identified and specified? Are operators aware of them?
- g. Records - Are the records/reports complete with the required information? Are they easily retrievable? Are analyst's notebooks, maintenance and instrument logs, temperature logs, and other laboratory record books maintained properly?
- h. Materials - Are analytical standards and reference materials prepared, labeled, used, and stored correctly?

6. When all areas have been audited an out-briefing to highlight the findings, deficiencies and observations of the audit will be presented by the Audit/Assessment Team.

B. Reporting. A final report of the findings, observations, and deficiencies will be provided to the auditee and their respective managers (usually within one month). The report will be prepared in accordance with SIO SOP 3.X.

VI. SAFETY CONSIDERATIONS: The auditor will adhere to all safety requirements of laboratory area being audited.

VII. REFERENCES:

- A. Victoria Group, Ltd., The. Internal Auditor Training Program, England: CEEM, 1992.
- B. American Association for Laboratory Accreditation. General Requirements for Accreditation. Gaithersburg, MD: ILAC, 1991.
- C. DataChem Laboratories. Quality Assurance and Environmental/Occupational Health Monitoring. Salt Lake City, Utah: Dept. of Family and Preventive Medicine, 1991.