SMG 2140.3

FDA STAFF MANUAL GUIDES, VOLUME IIII – GENERAL ADMINISTRATION

ENVIRONMENTAL, ENERGY, AND SUSTAINABLITY

ENVIRONMENTAL PROGRAMS

FDA ENVIRONMENTAL COMPLIANCE AUDITS

Effective Date: 01/06/2014
Changed: 08/16/2019

1. PURPOSE.

The Food and Drug Administration (FDA) Environmental Compliance Audit Staff Manual Guide confirms the FDA's commitment to developing, implementing, and maintaining a viable environmental compliance program. The audit program will allow a systematic review of all FDA operations; provide a baseline measurement of compliance with federal, state, local, and agency environmental regulations; and implement a measured and effective means of correcting the findings.

2. POLICY

This Staff Manual Guide applies to all FDA centers and offices, both regulatory and scientific.

3. RESPONSIBILITIES.

A. **Office of the Chief Scientist (OCS)** – The FDA Chief Scientist (OCS) will direct the Program in conjunction with the Director of the Office of Laboratory Safety (OLS). In this program leadership role, the OCS will receive periodic reports discussing the status of the Environmental Audit Program, a summary overview of the audit results, and compliance trends. The FDA OCS and the Director of OLS will be apprised by the Environmental Audit Program Manager promptly of any issues identified by the Audit Program that could adversely affect the Agency in a significant way. The primary responsibilities of the OCS are listed below:

1. Review compliance trends from audit findings;

2. Review funding needs to ensure Agency compliance;

3. Provide funding for program implementation; and

4. Convey program successes to HHS for potential agency-wide use.

B. **Environmental Audit Program Manager** - The Environmental Audit Program Manager will have direct day-to-day responsibilities of Program development and implementation. The specific responsibilities of the Audit Program Manager include those listed below:

1. Maintain and update Program materials including this Manual, the pre-audit questionnaire, results, and the audit protocols;

2. Maintain the auditor training program, including updating the qualified auditor database;

3. Review draft and final audit reports;

4. Track the status of Management Action Plans (MAPs) and formally "close out" audits when all non-compliant findings are corrected;

5. Provide to the audit teams, on an as needed basis, state regulatory information Conduct Program evaluations; and

6. In accordance with FDA Environmental Audit Program Guidance Manual (currently in force), periodically report on Program status to the FDA OCS and the Director of OLS and other internal DHHS stakeholders.

C. **HHS Office of General Counsel** – The Office of General Counsel (OGC) at HHS will provide all aspects of legal review for the Program. General Counsel responsibilities include:

1. Assure that Program procedures are consistent with maintaining document confidentiality;

2. Receive and review of copies of all draft and final audit reports; and

3. Provide legal advice on issues identified by the audit teams.

D. **Environmental Auditors** - Auditors become qualified by experience or through attendance at an agency-accredited audit training seminar or its equivalent. Qualified individuals within the Auditor Pool will be selected by the Audit Program Manager and/or the Team Leader assigned to the audit. Their responsibilities (for each audit) will include:

1. Reviewing assigned audit protocols and the completed pre-audit questionnaire;

2. Reviewing applicable state regulatory data;

3. Arranging for personal logistics for the audit;

4. At a minimum, participating in the opening and closing conferences;

5. Conducting audits for the assigned protocols;

6. Developing draft and final findings and recommendations for the assigned protocols;

7. Assuring document management meets records retention policies; and

8. To remain qualified, participating in at least one audit per year, or being authorized by the Program Manager to participate in an audit.

4. PROCEDURES

The process for planning and conducting environmental compliance audits for FDA facilities is spelled out in the latest effective FDA Environmental Audit Program Guidance Manual signed and effective September 16, 2013. The Manual describes in detail the objectives of the program, scope and coverage of the audits, and the audit procedures which include pre-audit, on-site audit activities, and post-audit requirements.

Completed audit reports will be reviewed by the HHS OGC on an as needed basis when a legal question arises that could impact and create risk for FDA in the form of administrative penalties and/or civil or criminal actions.

The manual will be used for all FDA environmental compliance audits at all FDA facilities within the Continental United States (CONUS.). International environmental audits will be governed by a separate manual and SMG, if and when the program is developed.

5. EFFECTIVE DATE.

The effective date of this guide is January 6, 2014.

6. HISTORY – SMG 2140.3, FDA Environmental Compliance Audits

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/03/2013	N/a	OO/ESEM	Kristine Leiphart, Deputy Chief Operating Officer
Change	02/13/2017	Remove COO; insert OC	OO/ESEM	Matthew Amann, ESEM Director
Change	08/16/2019	Remove OC and insert OCS; remove ESEM and insert OLS	OCS/OLS	Dr. Sigaran Pillai, OLS Director

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