SMG 2140.3

FDA Staff Manual Guides, Volume III - General Administration

Environmental, Energy, and Sustainability Programs

FDA Environmental Compliance Audits

Effective Date: 11/28/2022

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 environmental operations, provide a baseline measurement of compliance with federal, state, local, and tribal environmental regulations, promote prudent practices to facilitate environmental stewardship, and implement a measured and effective means of correcting the findings.

2. Scope

This SMG describes FDA's environmental compliance audit program and how FDA's inspections ensure Centers' and ORA's efforts to assure compliance through auditing, outlines the environmental auditing procedures at FDA facilities, and states the roles, responsibilities, and elements of an effective audit program. This Staff Manual Guide applies to all FDA Centers and Offices for environmental compliance requirements.

3. Responsibilities

A. Office of Laboratory Safety (OLS)/DASHO

The Director of the OLS/Designated Agency Safety and Health Official (DASHO) will direct the program through the Environmental Program Manager in coordination with the Centers and ORA environmental stakeholders. In this role, the OLS Director will receive periodic reports discussing the status of the Environmental Compliance Audit Program, a summary overview of the audit results, and compliance trends. FDA leadership (Commissioner, Center Directors

and ACRA) will be informed by the Director of OLS/DASHO of any issues identified by the Environmental Compliance Audit Program that could significantly and adversely affect the Agency. The primary responsibilities of the OLS are listed below:

- Review compliance and non-compliance trends from audit findings.
- Review funding needs to ensure Agency compliance and program implementation.
- Convey program successes to HHS for potential Agency-wide use.

B. Environmental Audit Program Manager

The Environmental Program Manager will have day-to-day responsibilities of program development and implementation. Specific responsibilities of the Program Manager are listed below:

- Maintain and update program materials including this Staff Manual, the pre-audit questionnaire, audit results, audit protocols, and a Center points-of-contact list.
- Maintain the auditor training program, including updating the qualified auditor database.
- Issue draft and final audit reports.
- Track the status of Management Action Plans (MAPs) and formally "close out" audits when all non-compliant findings are corrected or addressed.
- Provide audit teams state regulatory information as needed and conduct program evaluations.
- In accordance with FDA Environmental Audit Program Guidance Manual report on the program status to, the Director of OLS/DASHO and other environmental stakeholders, periodically.
- Communicate Environmental Compliance Audit objectives to assure regulatory compliance, minimize potential environmental risks, increase awareness, facilitate knowledge transfer of environmental technologies across FDA, and assure adequate measurable environmental performance to Director of OLS/DASHO.

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 the following actions:

- Assure that Program procedures are consistent with maintaining document confidentiality.

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

D. Environmental Auditors

Environmental auditors become qualified to provide reviews as conducted by certified environmental professionals by experience or through attendance at an Agency-approved audit training, or its equivalent. Qualified individuals within the Auditor Pool will be selected by the Environmental Program Manager and/or the Team Leader assigned to the audit. Their responsibilities for each audit include the following items:

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

- Reviewing applicable state regulatory requirements and data and implementing OLS' guidance as necessary.

- Arranging for logistics for the audit (e.g., accessibility to the facilities, coordination with the Centers, and scheduling to meet with external reviewers).

- At a minimum, participating in the opening and closing meetings.

- Conducting audits for the assigned protocols.

- Developing draft and final findings and recommendations for the assigned protocols.

- Assuring document management meets records retention policies.

- 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 detailed in the FDA Environmental Audit Program Guidance Manual. 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, and post-audit requirements.

The Manual will be used as a guide for all FDA environmental compliance audits at all FDA facilities. If needed, environmental audits at FDA international facilities will be coordinated with the FDA Office of Global Policy and Strategy.

On-site compliance monitoring and audits can involve on-site evaluations to include review of permits, data and other documentation and processes used by FDA, or include an investigation in case of an incident or possible non-compliance. Off-site compliance monitoring and audit (e.g., water and waste-water management, air quality monitoring and control, emergency response procedures) can include data collection, review, reporting, and technical support.

OLS environmental auditors will audit the FDA facilities and develop an audit report with recommendations for corrective actions. Centers and Offices will take appropriate corrective actions and report their progress through the regular reporting process. Centers and Offices are expected to participate in opening and a closing briefing with the auditors during the audit process. Audits can involve interviewing representatives at FDA facilities.

Completed audit reports will be reviewed by FDA Office of the Chief Counsel (OCC) and HHS Office of the General Counsel (OGC) as needed when a legal question arises that could impact and create risk of penalties for the Agency or personnel.

5. Effective Date

The effective date of this Staff Manual Guide is November 28, 2022.

6. Document 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. Segaran Pillai, FDA DASHO / OLS Director
Revision	11/23/2022	N/A	OCS/OLS	Dr. Segaran Pillai, FDA DASHO / OLS Director