SMG 2140.3

FDA Staff Manual Guides, Volume III - General Administration

Environmental Compliance and Protection Program

FDA Environmental Compliance Audits

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1. Purpose

The Food and Drug Administration (FDA) Environmental Compliance Audit Staff Manual Guide (SMG) confirms the FDA's commitment to developing, implementing, and maintaining a viable environmental compliance program. The audit program allows for a systematic review of all FDA environmental operations, provides a baseline measurement of compliance with federal, state, local, and tribal environmental regulations, promotes prudent practices to facilitate environmental stewardship, and implements a measured and effective means of correcting findings.

2. Scope

This SMG describes FDA's environmental compliance audit program and the efforts necessary on the part of Centers/Offices/Programs to ensure compliance through auditing, outlines the environmental auditing procedures at FDA facilities, and states the roles, responsibilities, and elements of an effective audit program. This SMG applies to all FDA Centers/Offices/Programs subject to environmental compliance audits.

3. Responsibilities

A. Office of Occupational Safety and Health (OOSH)/Designated Agency Safety and Health Official (DASHO)

The Director of the OOSH/DASHO will direct the program through the Environmental Program Manager in coordination with the

Centers/Offices/Programs environmental stakeholders. In this role, the OOSH Director/DASHO 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, Office Directors, and the Deputy Commissioner for Human Foods Program) will be informed by the Director of OOSH/DASHO of any issues identified by the Environmental Compliance Audit Program that could significantly and adversely affect the Agency. The primary responsibilities of the OOSH 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 and other Operating Divisions for potential 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 SMG, the pre-audit questionnaire, audit results, audit protocols, and a Centers/Offices/Programs 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 the FDA Environmental Audit Program Guidance Manual, periodically report on the program status to, the Director of OOSH/DASHO and other environmental stakeholders.

- 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 the Director of OOSH/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:

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

- Review applicable state regulatory requirements and data and implement OOSH guidance as necessary.

- Arrange for logistics for the audit (e.g., access to the facilities, coordinate with the Centers/Offices/Programs, scheduling to schedule meetings with external reviewers).

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

- Conduct audits for the assigned protocols.

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

- Assure document management meets records retention policies.

- To remain qualified, participate in at least one audit per year, or be 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.

OOSH environmental auditors will audit FDA facilities and operations subject to inspections and develop an audit report with recommendations for corrective

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

Completed audit reports will be reviewed by FDA's Office of the Chief Counsel (OCC) and the HHS Office of the General Counsel (OGC) as needed when a legal question arises that could impact or 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
Change	03/14/2025	Remove OLS and insert OOSH	OCS/OOSH	Dr. Segaran Pillai, FDA DASHO / OOSH Director
Change	04/21/2025	Remove "OLS" and insert "OOSH" throughout document to reflect reorganization structure effective Oct. 1, 2024.	OCS/OOSH	Dr. Segaran Pillai, FDA DASHO / OOSH Director