SMG 2140.2

FDA Staff Manual Guides, Volume III - General Administration

Environmental Compliance and Protection Program

FDA Environmental Management System

Effective Date: 11/28/2022
Changed: 04/21/2025

1. Purpose

The Food and Drug Administration (FDA) Environmental Management System (EMS) Staff Manual Guide (SMG) confirms the Agency's commitment to developing, implementing, and maintaining a viable Environmental Compliance and Protection Program (ECPP). FDA intends to have an EMS at all appropriate levels of the organization as best practice for organizational governance for the ECPP.

FDA's EMS allows for continual improvement of all environmental safety responsibilities, quantifiable environmental aspects, and operational goals set forth by applicable federal, state, local, and tribal policies including Executive Orders and consensus standards.

2. Policy

The FDA maintains an Environmental Management System (EMS) based on an ISO 14001 Environmental Management Systems governance model to assure compliance and conformance to requirements of various Executive Orders, CFRs, and statutes. The FDA EMS is a set of processes and practices that enable the Agency to reduce its environmental impacts and increase its operating efficiency. This SMG applies to all FDA Centers/Offices/Programs that are responsible for regulatory, research and scientific activities.

3. Responsibilities

A. Office of Occupational Safety and Health (OOSH)

OOSH coordinates with various stakeholders to manage the FDA EMS and shares with FDA leadership and the Designated Agency Safety and Health Official (DASHO). The report discusses the status of EMS activities that are compliant and functional, programs that are in development, and other activities that are planned for continuous improvement. The primary responsibilities of OOSH are listed below:

- Provide leadership, oversight, and coordination of the FDA EMS.
- Implement an EMS and ensure compliance by performing audits.
- Review funding needs to support the FDA EMS.
- Ensure EMS' conformance and alignment with FDA's Environmental Initiatives.
- Assess and coordinate with the Centers/Offices/Programs for new program implementation, continual improvements, and exercise of best practices.
- Convey program successes to HHS and other Operating Divisions for potential use.

B. EMS Program Manager

The FDA EMS Program Manager will have day-to-day responsibilities for program development, improvement, and implementation. The specific responsibilities of the EMS Program Manager are listed below:

- Maintain and update all relevant EMS related documents on the SharePoint site and provide an FDA EMS template in a SharePoint site for use by the Cross Functional Teams.
- Initiate and approve internal evaluation of FDA EMS based on the most current ISO 14001 standard.

C. Cross Functional Team (CFT)

A Cross Functional Team (CFT), composed of environmental stakeholders, is established within each level of the organization that is deemed appropriate to support the FDA EMS. This measure will be based on size and complexity of the organization and as recommended by the stakeholders and approved by the Director of OOSH/DASHO. The responsibilities of the CFT include the following:

- Develop and maintain the environmental management documents required for a conforming EMS.

- Ensure appropriate training is being conducted at their respective facilities.

- Maintain the FDA EMS SharePoint site containing documents and procedures using a template provided by the EMS Program Manager.

- Review the EMS audit reports and findings and implement appropriative corrective actions with timely notification to the FDA EMS Program Manager.

- Assist in the preparation of the annual evaluation report along with the EMS Program Manager for the Director of OOSH/DASHO and take appropriate follow-up action as necessary.

D. EMS Internal Auditors

Auditors of the EMS program become qualified through experience, or attendance at an accredited internal audit training seminar or its equivalent. Qualified internal individuals will be selected by the EMS Program Manager and the CFT for the respective EMS to be audited. Responsibilities for each audit include the following:

- Review the most current ISO 14001 standard and all included clauses.

- Arrange for logistics for the audit.

- Participate in the opening and closing briefings.

- Review EMS documents and procedures using the FDA EMS checklist.

- Develop statements of conformance and nonconformance found during the audit.

- Prepare a final audit report.

- Participate in at least one internal audit per year to remain qualified.

4. Procedures

The Agency maintains an EMS that functions as the FDA-wide EMS. The standard that is to be used for all EMS within FDA conforms to the most current ISO 14001 standard. The FDA EMS will ensure that appropriate resources are requested when corrective actions are warranted.

The FDA EMS Program Manager will brief the Director of OOSH/DASHO annually or as needed on the status of all implemented FDA EMS, and ongoing efforts to develop additional EMS. FDA's EMS SharePoint site houses necessary documents for a conforming EMS.

All FDA EMS programs at the facility level will develop procedures and documents for clauses addressed in the current ISO 14001 standard that are deemed appropriate for the FDA EMS.

5. Effective Date

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

6. Document History – SMG 2140.2, "FDA Environmental Management System"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	11/03/2014	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	Throughout document to reflect reorganization structure, effective Oct. 1, 2024	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 and to reflect recent Executive Orders revoking earlier EOs	OCS/OOSH	Dr. Segaran Pillai, FDA DASHO / OOSH Director