SMG 2140.2

FDA Staff Manual Guides, Volume III - General Administration

Environmental, Energy, and Sustainability Programs

FDA Environmental Management System

Effective Date: 11/28/2022

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 Protection Program (EPP). FDA intends to have an EMS at all appropriate levels of the organization as best practice for organizational governance for the EPP.

FDA's EMS allows for continuous improvements for all environmental responsibilities, quantifiable environmental impacts, and applicable sustainability and climate change goals set forth by federal, state, local, and tribal policies, Executive Orders, and statues, including but not limited to the following Executive Orders:

- Executive Order 14057, Catalyzing America's Clean Energy Industries and Jobs through Federal Sustainability (December 8, 2021)
- Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (January 27, 2021)
- Executive Order 14030, Climate-Related Financial Risk (May 20, 2021)
- Executive Order 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis (January 20, 2021).

2. Policy

The FDA maintains an EMS based on ISO 14001 Environmental Management Systems governance model to assure compliance and conformance to requirements

of various Executive Orders, CFR's and statutes. The FDA Environmental Management System (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 and Offices that are responsible for regulatory, research and scientific activities.

3. Responsibilities

A. Office of Laboratory Safety (OLS)

OLS coordinates with various stakeholders to manage the FDA EMS and shares with the FDA leadership and the Commissioner of the EMS annual review report. The report discusses the status of the EMS activities that are compliant and functional, programs that are in development, and those that are planned for continuous improvement. The primary responsibilities of OLS 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 needs.
- Ensure EMS' conformance and alignment with FDA's Green Initiatives.
- Assess and coordinate with the Centers and Offices for new program implementation, continuous improvements, and exercise of best practices.
- Convey program successes to Health and Human Services for potential department-wide 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 (CFT).
- Initiate and approve internal evaluation of FDA EMS based on the most current ISO 14001 standard.

C. Cross Functional Team (CFT)

The Cross Function Team, 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 OLS/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 locations.
- Maintain the FDA EMS SharePoint site containing documents and procedures using a template provided by the EMS Program Manager.
- Review the 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 OLS/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 OLS/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