SMG 2140.2

FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION

ENVIRONMENTAL, ENERGY, AND SUSTAINABLITY

ENVIRONMENTAL PROGRAMS

FDA ENVIRONMENTAL MANAGEMENT SYSTEM

Effective Date: 01/12/2015
Changed: 02/28/2017

1. PURPOSE.

The Food and Drug Administration (FDA) Environmental Management System Staff Manual Guide confirms the FDA's commitment to developing, implementing, and maintaining a viable environmental management system (EMS). FDA is required to have an EMS at all appropriate levels of the organization as mandated by Executive Order 14323, *Strengthening Federal Environmental, Energy, and Transportation Management*, signed 24 January 2007. FDA's EMS program will allow for continuous process improvement for all identified environmental aspects, quantified environmental impacts, and applicable sustainability goals as set forth by Executive Order 13514, *Federal Leadership in Environmental, Energy, and Economic Performance*, dated 5 October 2009.

2. POLICY

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

3. RESPONSIBILITIES.

A. Commissioner (OC) – The FDA Commissioner (OC) or the proxy will direct the Program in conjunction with the Director of the Environmental Safety and Environmental Management (ESEM) office. In this program leadership role, the OC will receive an annual update report discussing the status of the EMS programs that are complete and functioning, the programs that are in development, and those that are planned throughout FDA. The OC will also be

briefed on the overview of the annual EMS internal audit results and the status of corrective actions that have been submitted and those that have been closed out and those that are still open. The primary responsibilities of the OC are listed below:

1. Review conformance of implemented EMS;

2. Review funding needs to ensure Headquarters FDA EMS and subordinate EMS are maintained and are in conformance;

3. Assess and provide funding in coordination with the Centers for new program implementation; and

4. Convey program successes to Health and Human Services for potential agency-wide use.

B. EMS Program Manager – The FDA EMS Program Manager will have direct day-to-day responsibilities of Program development and implementation. The specific responsibilities of the EMS Program Manager are to:

1. Maintain and update EMS documents including this Manual, FDA Environmental Policy statement, and submitted corrective actions;

2. Review and address corrective actions that are submitted;

3. Maintain the library of procedures and documents on the HQ FDA EMS SharePoint page and provide an FDA EMS SharePoint page template that will be used by Cross Functional Teams (CFT) members for their respective EMS programs;

4. Periodically meet with all CFTs established throughout FDA to ensure their EMS programs are functioning based on the ISO 14001 standard and to discuss any problems they may have;

5. Initiate and approve self-certification of FDA EMS programs based on the ISO 14001 standard; and

6. Schedule and perform annual audits of the FDA HQ EMS and develop the brief to be given to the OC and shared with the Centers.

C. Cross Functional Team – The Cross Function Team (CFT) will be assembled within each level of the organization that is deemed appropriate to have its own EMS. That measure will be based on size and complexity of the organization and as recommended by FDA EMS Management (COO). The responsibilities of the CFT include:

1. Develop and maintain the environmental documents required for a conforming EMS;

2. Ensure awareness training is being conducted at their location;

3. Maintain their respective FDA EMS SharePoint page containing documents and procedures using the FDA EMS SharePoint page template provided by the EMS Manager;

4. Review and address corrective actions that are submitted; and

5. Prepare an annual conformance report to be given to the EMS Manager for appropriate follow-up action if needed.

D. EMS Internal Auditors - Auditors become qualified by experience or through attendance at an agency-accredited internal audit training seminar or its equivalent. Qualified internal auditors individuals will be selected by the EMS Manager and/or the CFT for the EMS to be audited. Their responsibilities for each audit include:

1. Reviewing the ISO 14001 standard and all included clauses;

2. Arranging for personal logistics for the audit;

3. Participating in the opening and closing conferences;

4. Reviewing all EMS documents and procedures developed and implemented, using the developed EMS checklist;

5. Developing statements of conformance and nonconformance found during the audit;

6. Preparing a final audit report; and

7. Participating in at least one internal audit per year to remain qualified.

4. PROCEDURES

In order to satisfy the requirements in Executive Orders 14323 and 13514 FDA will maintain an FDA HQ EMS that will function as the overall EMS at the agency level. The standard that will be used for all EMS programs within FDA will conform to the most current ISO 14001 standard.

The objective of this EMS is to provide a mechanism to measure the effectiveness of the subordinate EMS programs developed at FDA facilities deemed appropriate, based on size and complexity, to have their own EMS. The FDA HQ EMS will also

ensure appropriate resources are requested when corrective actions are opened and warranted. The FDA HQ EMS will brief the OC annually or as needed on the status of all implemented FDA EMS programs and the efforts on-going to develop additional EMS programs. Lastly, for those FDA locations that are deemed too small to support their own EMS as determined by ESEM, the FDA HQ EMS will serve as their supporting EMS, providing procedures and documents for use. The FDA HQ EMS SharePoint page will serve as the library of documents for a conforming EMS.

FDA facilities that are deemed appropriate to have their own EMS will establish a CFT, develop and maintain procedures and other documents, provide awareness training, and use for their document storage the FDA EMS SharePoint page template that has been developed by the EMS Manager. The list of FDA facilities requiring their own EMS will be developed as a document in the FDA HQ EMS and will be posted in the FDA HQ EMS SharePoint document library. The EMS programs developed at these facilities will be self-sufficient and stand alone, but will be subordinate to the FDA HQ EMS for purposes of self-certification (as that is the minimum level of certification) or third-party certification (should that be considered).

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

5. EFFECTIVE DATE.

The effective date of this guide is January 12, 2015.

6. 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