

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA ENVIRONMENTAL SAFETY AND HEALTH COUNCIL

Effective Date: August 13, 2015

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1. PURPOSE

This charter describes the duties and responsibilities of the U.S. Food and Drug Administration (FDA or Agency) Environmental Safety and Health Council (ESHC), its membership, and its operating procedures. The Council will serve in an advisory capacity for the Employee Safety and Environmental Management office (ESEM).

2. OWNERSHIP

Process and Document Owners

This document will be maintained by the following parties:

- Change Management Process Owners: Chairperson
- Document Owner: Chairperson
- Key Partners: Office of Operations, Executive Secretariat

Review Schedule and Sign-Off Procedure

This document will be reviewed for content and accuracy semi-annually by the Office of Operations Executive Secretariat and/or Chairperson.

Version Control

Initial approval by the Commissioner will result in the creation of version 1.0. Future approvals will always be whole numbers (version 2.0, 3.0, etc.). Any changes will result in a change of version number as well. For example, should a new objective/process be added after initial approval, this would result in draft version 1.1. Once this change is approved by the Commissioner, the document would become version 2.0.

| Version # | Date | Modified by | Description of Modification |
|-----------|------------|-------------|-------------------------------------|
| 1.0 | 03/10/2015 | E. Mitchell | Version 0.4 submitted for signature |

3. SCOPE

In partnership with the Management Council (MC), the ESHC supports ESEM's commitment to providing enterprise level environmental and occupational safety and health (ESH) oversight of Agency operations, by allowing FDA programs a forum to communicate and agree to FDA-wide requirements for efficiently and effectively delivering ESH programs to customers and stakeholders while maintaining an Agency perspective. The ESHC ensures issues and policies are addressed and resolved in a manner that enhances operational processes and performance standards.

The ESHC will provide its members the opportunity for a meaningful exchange of information and collaborative approaches to meeting common challenges related to providing a safe and healthful place of employment. In doing so, the ESHC will serve as a bi-directional body for operational performance, while enhancing communications and outreach efforts of ESEM and the Center Safety Programs. Specifically, the ESHC will support ESEM mission to:

- Manage and support safety programs to enhance the effectiveness of the Agency in accomplishing its mission.
- Create the expertise, information and tools needed to provide the highest practical degree of safety, health and environmental compliance for all FDA employees
- Minimize risks of accident, injury or illnesses to human resources and minimizing losses in property damage, in compliance with applicable federal, state and local regulations.

By performing the following activities:

- Deliver sustained review of agency performance against established metrics
- Provide accountability for implementation of ESEM enterprise initiatives

- Consider specific standing topics which merit attention by leadership team and require customer or stakeholder input

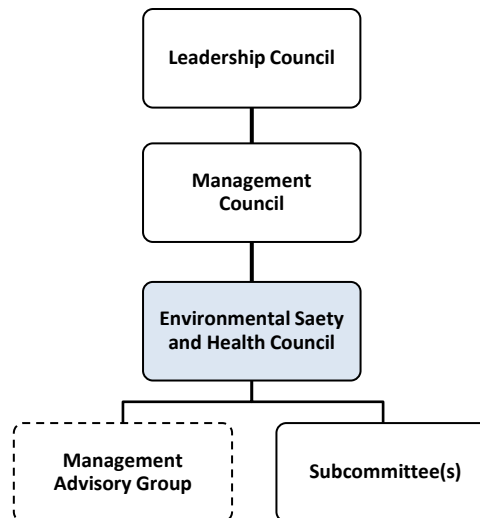
The scope of the activities may be expanded by ESHC recommendation, with the concurrence of the MC.

4. ORGANIZATIONAL STRUCTURE

The ESHC is a component of the Operations Management Councils (OMC). Each OMC is subordinate to the MC.

Subordinate to the ESHC are any created subcommittees, in addition to the Management Advisory Group (MAG). The MAG is an ad-hoc group of the OMC, formed as needed to address cross-functional issues affecting one or more Councils.

A diagram of the organizational structure is provided below.



5. RESPONSIBILITIES

In fulfilling the requirements of the scope, the ESHC will:

- Identify, clarify, and recommend the activities of the ESHC
- Provide agency-wide governance and oversight of ESH priorities and performance measures
- Advise on strategic priorities affecting employee safety and health

- Increase accountability and transparency of ESEM activities and operations
- Clarify roles and responsibilities for internal and external customers and stakeholders
- Provide input as necessary to address challenges in operational success ESH programs

In performing these responsibilities the ESHC will:

- Communicate recommendations, decisions, and actions on the Agency's ESH policies, plans and strategies to the MC as appropriate
- Maintain records of ESHC recommendations, decision, and actions
- Provide input to and work with other Agency components as necessary to achieve FDA goals and missions
- Establish and oversee subcommittees and MAGs for the purpose of fulfilling the ESHC's responsibilities
- Review work products of the subcommittees and MAGs appointed by the ESHC to develop recommendations/options for cross-Agency implementation

Membership

Members of the ESHC will serve as long as they are in the below-mentioned positions.

Chairperson

The ESHC will be chaired by the Director, Employee Safety and Environmental Management. The Chairperson will be responsible for the following activities:

- Establishing areas of priority for ESHC consideration, in alignment with FDA strategic planning
- Arranging and organizing meetings
- Distributing documents to Council members
- Maintaining records of Council activities and actions/decisions
- Ensuring accuracy of Council documents

- Gathering details/additional information from appropriate staff across the agency to support ongoing Council activities, meetings, and initiatives
- Preparing and maintaining minutes of Council meetings

ESHC Membership

- The following voting members have been established:
- Director, Employee Safety and Environmental Health or their designated representative
- Center/Office Safety Managers as appointed by Executive Officers
- FDA Designated Agency Safety and Health Officer (DASHO)
- ESEM Leadership
 - FDA Radiation Safety Officer
 - FDA Biosafety Officer
 - FDA Occupational Medical Director
- Other members, as decided by the ESHC

Principals are expected to make every effort to personally attend ESHC meetings.

Other participants, observers, and consultants from within the agency and from other federal government organizations may participate and attend as decided by the ESHC.

6. PROCEDURES

ESHC Meetings

- Will be held monthly or as otherwise decided by the Chairperson or ESHC
- Meetings can only be made when quorum is achieved. Quorum requires attendance of two-thirds of the Centers and one-half of the ESEM Program Offices.
- Will have minutes prepared in writing within two weeks after they are held
- At a minimum, meeting minutes should record attendees, issues presented, decisions made, and any outstanding action items

Meeting Agenda

- Proposed agenda items may be submitted by any ESHC member to the Chairperson
- Agenda items should be submitted and posted at least one week in advance of each meeting
- Agenda items and all supporting documents will be distributed by the Chairperson to all ESHC members a minimum of two days prior to the meeting
- Meeting minutes will be sent out two days before the next meeting

Decision Making

- Decisions are reached through consensus. When a vote is required, the Chair will poll the members to establish unanimous consent and the vote will be recorded
- If consensus cannot be reached, voting is conducted by roll call vote with a simple majority needed for approval. In situations where there is a tie, the ESEM Director will serve as the tie-breaker.
- Once approved by the ESHC, decisions will be referred to the MC for final approval, as appropriate

Records and Reporting

- Chairperson will ensure ESHC activities including recommendations, decisions, issues, action items, meeting summaries and other pertinent materials attributable to the ESHC are documented and communicated to senior management via MC meetings and affected staff, as appropriate, in a timely manner
- Documents approved by the MC will be made available to agency staff as appropriate
- Chairperson will provide an operations report to the MC quarterly, consisting of ESEM operations as well as ESHC accomplishments, issues and quarterly forecasts
- Chairperson will provide the Office of Operations, Executive Secretariat a schedule/timeline of ESHC activities, to be updated semi-annually

Subcommittees

- ESHC will have four standing subcommittees
 - WO Safety Subcommittee will meet to discuss White Oak specific safety issues. This may include occupant emergency plans, emergency response teams, emergency notification events and other issues that affect all of the centers at WO.
 - Safety Training Subcommittee will cover safety training for safety officers, industrial hygienists and employees. This may include hazardous communication, respiratory protection, occupant emergency and ergonomics training.
 - Laboratory Safety Subcommittee will cover laboratory specific items such as chemical hygiene plans, chemical fume hoods, bio safety cabinets, chemical usage and chemical storage.
 - Office Safety Subcommittee will discuss ways to prevent hazards in the office setting. Areas of consideration are ergonomics, electrical safety, indoor air quality, slips, trips and falls and proper storage.
- ESHC shall decide on and record in writing the specific responsibilities and operating procedures each subcommittee
- Subcommittees will consist of appropriate FDA personnel, as decided by the ESHC

Charter Updates

- Amendments to the ESHC Charter can be proposed by any ESHC member at any time. Adoption of amendments to the ESHC Charter will be by decision of the ESHC, with the concurrence of the MC.

7. EFFECTIVE DATE

The effective date of this guide is August 13, 2015.

8. Document History – SMG 2010.11, FDA Environmental Safety and Health Council

| VERSION | STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|---------|------------------|---------------|----------------------------|---------|---|
| 1.0 | Initial | 05/14/2015 | N/a | OO/PEO | Walter S. Harris, FDA Chief Operating Officer |