SMG 2010.21

FDA Staff Manual Guides, Volume III – General Administration

FDA Official Councils and Committees

FDA Enterprise Risk Management Council

Effective Date: 09/13/2022

1. Purpose.

This charter describes the duties and responsibilities of the Food and Drug Administration (FDA) Enterprise Risk Management Council (ERM Council), the organization of its membership, and its operating procedures. The Council oversees FDA ERM Program activities and make decisions pertaining to the oversight and management of the FDA's Risk Profile.

2. Scope.

The ERM Council bears executive responsibility for presiding over agency-wide risk management at FDA. The Council ensures that ERM goals align to the priorities of the Agency and makes recommendations and decisions on the following topics:

A. Finalization of the Annual Agency Risk Profile.

B. Recognition of and Monitoring for New and Emerging Risks.

C. Development and Implementation of ERM Policy, including on the Agency's Risk Appetite and Tolerance.

D. Recommendations for Resourcing Enterprise-level Risks.

E. Escalation of Concerns Regarding Significant Challenges Managing Specific Risks to the Executive Committee and Commissioner.

F. Monitoring of Top Priority Risk Response Plan Implementation.

The ERM Council is a decisional and recommending body that oversees agency-wide risk management activities across the FDA, unless it is determined by Council Members that a decision needs further input from the FDA Executive Committee.

3. Responsibilities.

The ERM Council bears executive responsibility for governing over agency-wide risk management process at FDA. The ERM Council's considerations, recommendations, and decisions inform and complement decisions across program areas and business operations, so that risk-related deliberations and data are integrated into FDA's broader management processes. Engagement occurs at least annually with Center and Office leaders on enterprise-level risks, as well as emerging Center-level risks with potentially significant impact. These risks are shared with the Council so that all benefit from other Center and Office Member awareness and input. This includes overseeing the management and monitoring of FDA's Enterprise Risk Profile; advancing a risk-informed culture; ensuring integration of ERM with agency-wide processes such as strategic planning, budget formulation, and management controls; and formalizing FDA's approach to risk appetite and tolerance and determining the Agency's capacity to bear risk. In addition, each year the ERM Council selects an ERM Award recipient who has made a major difference to the Agency in how FDA manages key enterprise risks.

4. Organizational Structure.

The ERM Council reports to the Executive Committee and is established by this charter. The ERM Council may receive guidance and strategic direction directly from the FDA's Executive Committee relative to direction on Top Priority risks and the ERM Program's alignment to strategic objectives. The ERM Council advises the Executive Committee and other Center and Office level bodies on a variety of risk and risk management topics, including through making funding priority recommendations and ensuring accountability for sufficient management of the agency's enterprise risks. The Chief Operating Officer (COO)/Deputy Commissioner for Operations serves as the Chairperson and a rotating Center Director or Deputy Director serves as the Co-Chairperson of the ERM Council. The Co-Chairpersonship is a two-year term with the ability to serve an additional term.

5. ERMC Council Membership.

A. Voting Member Entities

The ERM Council's Voting Members are Deputy Commissioners or Center Directors, with some members designated as official proxies who are Center Deputy Directors, Associate Commissioners, or other Senior Executives.

1. Center for Biologics Evaluation and Research
2. Center for Drug Evaluation and Research
3. Center for Devices and Radiological Health
4. Center for Food Safety and Applied Nutrition
5. Center for Tobacco Products
6. Center for Veterinary Medicine
7. Office of the Chief Counsel
8. Office of the Chief Scientist
9. Office of Operations
10. Office of Policy, Legislation, and International Affairs
11. Office of Regulatory Affairs

B. Non-Voting Member Entities

The ERM Council's Non-Voting Members are primarily leadership in headquarters offices, or offices with direct roles in the administration of the Council's activities.

1. Office of Food Policy and Response

2. Office of Clinical Policy and Programs

3. Office of Operations, Office of Finance, Budget, Acquisitions, and Planning (OFBAP), Office of Planning, Evaluation, and Risk Management (OPERM); also Executive Secretariat

C. By Invitation

The Council regularly invites Enterprise Risk Owners to present, and other participants are by invitation and/or hold specific roles, such as FDA Chief of Staff; Deputy Commissioner; or Directors of OFBAP's Office of Budget, and Office of Fiscal Services and Operations.

6. Roles.

A. Council Roles

<u>Chair, Co-Chair, and Executive Pro Tempore</u>

The FDA COO/Deputy Commissioner for Operations serves as the Chairperson and a Center Director serves as the Co-Chairperson; they are voting members for their organizations. The Chairperson and Co-Chairperson are responsible for:

1. Establishing areas of priority for Council consideration, in alignment with the FDA budget cycle and Strategic Priorities.

2. Annually submitting the Agency Risk Profile to the Agency head.

3. Directing the appropriate individuals and teams to implement decisions/actions agreed upon by the Council.

4. Overseeing implementation of Council-approved decisions and recommendations.

5. Bringing new risks to the Council's attention.

6. Submitting Council recommendations to the Executive Committee or Commissioner.

In the absence of the Chairperson and Co-Chairperson, the FDA CFO serves as the Executive Pro Tempore and assumes the responsibilities of the Chairperson and Co-Chairperson. As with the Chairperson and Co-Chairperson, the CFO is a member of the ERM Council leadership.

Voting Members

Voting members are responsible for the following activities:

1. Serving as lead senior representative for his/her Center or Office.

2. Finalizing the annual Agency Risk Profile.

3. Promoting resourcing of enterprise risks owned by their respective Center or Office as well as cross-cutting risks.

4. Recognizing and monitoring emerging and continuing enterprise risks; and ensuring their sound management through planning, implementation, and monitoring approaches, either as, or with, Risk Owners in their organizations.

5. Formalizing FDA risk appetite and tolerance statements and determining the Agency's capacity to bear risk over time.

6. Resolving questions regarding selection of Risk Owners and contributors from their respective organizations to cross-cutting risk management and coordination needs, as necessary.

Non-Voting Members

Non-voting members are responsible for the following activities:

1. Serving as lead senior representative who champions and manages ERM within his/her office and/or across FDA.

2. The same responsibilities as Voting Members in items 3 to 6 above.

Executive Secretariat

OPERM's Division of Enterprise Risk Management is responsible for the following activities:

1. Managing the Agency Risk Profile cycle, including advising and supporting Risk Owners on identifying, updating, and reporting on risks to the Council; bringing new proposed risks to the Council's attention; and facilitating appropriate alignment with budget, strategic planning, performance, and other related activities for Council consideration.

2. Developing and compiling all materials for Council meetings and proposing agendas.

3. Facilitating follow through on decisions, actions, and recommendations agreed upon by the Council.

7. Policy.

A. ERM Council Voting and Decisions

Decisions are made when a quorum is achieved. In addition to the Chairperson, a quorum requires the attendance of a majority of voting members. Decisions are held by vote and by simple majority. In the event of a tie, the Chairperson will have the tie breaking vote.

B. ERM Council Meetings

1. Regular meetings are held quarterly, and more frequently/ad hoc as needed.

2. Proposed agenda items may be submitted by an ERM Council member to the ERM Program two months in advance of a meeting. All pre-read materials are due to the ERM Program one month in advance of a meeting for distribution to ERM Council members at least 48 hours in advance of meeting.

3. The Chairperson and Co-Chairperson determine the agenda.

4. The Council coordinates with other Councils of Committees within the FDA as appropriate.

5. If a voting member cannot attend, s/he should provide sufficient advance notice of an executive designee who has decision-making authority.

8. ERM Council Charter Approval.

This ERM Council is hereby ratified by the ERM Council Chairperson and Co-Chairperson:

_____ _____

Jim Sigg, COO and Deputy Commissioner for Operations
ERM Council Chairperson

Date

_____ _____

Steve Solomon, CVM Center Director
ERM Council Co-Chairperson

Date

9. Charter Updates.

Amendments to the ERM Council charter can be proposed by Members or the Executive Secretariat at any time. Adoption of amendments to the charter will be in accordance with the decision procedure described above. This charter along with Council member's roles and responsibilities will be evaluated on an annual basis.

10. Effective Date.

The effective date of this SMG is September 13, 2022.

11. Document History - SMG 2010.21 “FDA Enterprise Risk Management Council”

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	2/25/2022	N/A	OC/OO/OFBAP/ OPERM/DERM	Sarah Lynch, Director, DERM

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