SMG 2350.1

FDA Staff Manual Guides, Volume III - General Administration

Financial Management - Financial Integrity

Guidance for the Implementation of the Federal Managers' Financial Integrity Act of 1982 (FMFIA)

Effective Date: 10/20/2021

1. Purpose

This guide sets forth the Food and Drug Administration's (FDA) policy, responsibilities, and guidelines for complying with Section 2 and Section 4 of the Federal Managers' Financial Integrity Act of 1982 (FMFIA) and Office of Management and Budget (OMB) Circular A-123, Management's Responsibility for Enterprise Risk Management (ERM) and Internal Control (OMB Circular A-123), dated July 15, 2016.

2. Background

FMFIA requires federal agencies to annually evaluate and assert on the effectiveness and efficiency of their internal controls and financial management systems. The Department of Health and Human Services (HHS) Secretary must provide a statement in the Agency Financial Report (AFR) on whether there is reasonable assurance that HHS' internal controls are achieving their intended objectives and the financial management systems conform to government-wide requirements.

In support of this requirement, the HHS Risk Management and Financial Oversight Board (RMFOB) requires each Operating Division (OpDiv), including FDA, to submit an Assurance Statement and to recommend to the HHS Secretary if any reported findings are deemed **"material weaknesses."**

In preparation for submission of the FDA Assurance Statement to HHS, FDA conducts its own Assurance Statement process. During this process, in

conjunction with the completion of an ERM/FMFIA Risk Tool, the Office of Operations (OO), Office of Finance, Budget, Acquisitions, and Planning (OFBAP), Office of Planning, Evaluation, and Risk Management (OFBAP/OPERM) engages with FDA Centers and the Office of the Commissioner (OC) Offices to obtain a Preliminary and Final Individual Assurance Statement (IAS). The Preliminary and Final IAS provides reasonable assurance, at the Center and OC Office-levels, that information is accurate, reliable, timely, and properly maintained to support management reporting and decision-making and to protect resources from fraud, waste, and abuse. Reasonable assurance also includes periodically evaluating programs to ensure assurance of compliance with applicable laws and regulations, and that Center or OC Office activities are managed in an effective and efficient manner.

3. Reference/Authority

FDA policy is consistent with guidance set forth by the following policies regarding FMFIA:

"Federal Managers' Financial Integrity Act of 1982" (FMFIA) (PL 97-255, 8 September 1982) (https://obamawhitehouse.archives.gov/omb/financial_fmfia1982)

"Federal Financial Management Improvement Act of 1996" (FFMIA) (https://www.congress.gov/bill/104th-congress/house-bill/4319)

"Chief Financial Officers (CFO) Act of 1990" (https://www.congress.gov/bill/101st-congress/house-bill/5687/text)

Government Accountability Office (GAO) "Standards for Internal Control in the Federal Government" (https://www.gao.gov/assets/670/665712.pdf)

OMB Circular No. A-123 "Management's Responsibility for Enterprise Risk Management and Internal Controls" (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2016/m-16-17.pdf)

OMB Circular No. A-123 Appendix A "Management of Reporting and Data Integrity Risk" (https://www.whitehouse.gov/wp-content/uploads/2018/06/M-18-16.pdf)

OMB Circular No. A-123 Appendix B "A Risk Management Framework for Government Charge Card Programs" (https://www.whitehouse.gov/wp-content/uploads/2019/08/Issuance-of-Revised-Appendix-B-to-OMB-Circular-A-123.pdf)

OMB Circular No. A-123 Appendix C "Requirements for Payment Integrity Improvement" (https://www.whitehouse.gov/wp-content/uploads/2021/03/M-21-19.pdf)

OMB Circular No. A-123 Appendix D “Compliance with the Federal Financial Management Improvement Act (FFMIA)” (https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2013/m-13-23.pdf)

4. Definitions

Assurance Statement – Statement required by FMFIA that an Agency has evaluated its internal controls and financial management systems to determine that the FMFIA objectives to ensure (1) effective and efficient operations, (2) compliance with applicable laws and regulations, and (3) reliable reporting are met.

Agency Financial Report (AFR) – Annual report by each of the CFO Act agencies, including HHS, that provides fiscal and high-level performance results that enable the President, Congress, and American people to assess accomplishments.

Enterprise Risk Assessment (ERA) – The ERA is conducted to identify risks across the FDA’s Centers/Offices and is used to achieve ERM and FMFIA requirements and objectives. To facilitate this assessment, OPERM distributes risk tools to each Center/Office to record identified risks. These assessments are recorded in the Agency’s Annual Risk Register, as well as analyzed, and used as inputs to the Agency’s Annual Risk Profile each year.

Enterprise Risk Management (ERM) – A discipline that addresses the full spectrum of an organization’s risks, including challenges and opportunities, and integrates them into an enterprise-wide, strategically-aligned portfolio view. ERM contributes to improved decision-making and supports the achievement of an organization’s mission, goals, and objectives.

Enterprise Risk Management Council (ERMC) – Governance body over FDA’s Enterprise Risk Management Program responsible for providing Agency-wide risk management and providing leadership decision-making support on addressing enterprise-wide risks within and across program areas and business operations. In addition to programmatic and operational risks, top fraud, waste, and abuse risks are included in FDA’s Annual Risk Profile and monitored accordingly.

Individual Assurance Statement – Statement completed by the Centers and OC Offices to provide reasonable assurance that: resources are protected from fraud, waste, and abuse; programs were evaluated periodically to provide assurance over compliance with applicable laws and regulations; and Center or OC Office activities are being managed in an effective and efficient manner.

Internal Controls – Process used by management to help an entity achieve its objectives needed to run its operations efficiently and effectively, to report reliable information about its operations, and to comply with applicable laws and regulations.

Material Non-Conformance – A weakness or combination of weaknesses in financial system internal controls that would significantly impair the fulfillment of FDA's mission; deprive the public of needed services; violate statutory or regulatory requirements; significantly weaken safeguards against waste, loss, unauthorized use or misappropriation of funds, property or other assets; or result in a conflict of interest.

Material Weakness – A weakness or combination of weaknesses in non-financial system internal controls that would significantly impair the fulfillment of the FDA's mission; deprive the public of needed services; violate statutory or regulatory requirements; significantly weaken safeguards against waste, loss, unauthorized use or misappropriation of funds, property or other assets; or result in a conflict of interest.

Non-Material Weakness – A weakness or combination of weaknesses that represents a less significant deficiency, does not rise to the level of a material weakness, and should be reported internally, corrected, and monitored.

Organizational Risk Reviews (ORRs) – ORRs are conducted as part of the FMFIA process to review high-risk business processes and identify areas to strengthen FDA's financial and non-financial management processes and controls. In addition to traditional internal control assessments, an ORR is used to assess FDA's internal controls and includes a performance review over process areas of potential risks. ORR topics can be qualitative or quantitative in nature, and complement but do not duplicate, the work Centers and Offices conduct for the ERA.

Risk Management and Financial Oversight Board – HHS governance body over internal controls that evaluates the OpDivs' Assurance Statements and recommends a Department assurance for the HHS Secretary's consideration and approval, resulting in the Secretary's Annual Assurance Statement.

Senior Assessment Team – Governance body over FDA's Internal Controls Program responsible for providing oversight and accountability for internal controls over reporting and fostering an environment that promotes strong internal controls.

5. Policy

Through FDA's FMFIA Program, FDA seeks to establish, maintain, and report on internal controls to:

- Reduce the risk of fraud, waste, and abuse of assets and resources, and misappropriation of funds,
- Promote reliable internal and external reporting,
- Enforce compliance with applicable laws and regulations, and

- Facilitate effective and efficient operations.

FDA managers should incorporate the requirements, standards, and timelines contained within the Reference/Authority section of this document for compliance with FMFIA.

6. Responsibilities

The Office of Planning, Evaluation, and Risk Management (OPERM) (Pathname: HHS/FDA/OC/OO/OFBAP/OPERM) is responsible for leading FDA's overall ERM and Internal Controls Programs, including the day-to-day activities of the FDA FMFIA Program. OPERM also facilitates oversight activities by the FDA Senior Assessment Team (SAT). SAT is responsible for overseeing internal controls over reporting and compliance with FMFIA, OMB Circular A-123, and HHS guidance. OPERM further leads and facilitates ERM governance activities as related to OMB Circular A-11, OMB Circular A-123, HHS guidance, FMFIA, and other external guidance sources.

A. FDA Program Management.

1. The Commissioner of the FDA is responsible for reviewing and signing the Annual Assurance Statement, which certifies FDA is meeting the requirements under FMFIA. This statement and accompanying Summary of Management Assurances must include a summary of identified **"material weaknesses"** and **"non-conformances"** and a plan for corrective action.

   Deficiencies identified in Center or OC Office IAS that the Commissioner or other senior-level managers determine are significant and reportable outside the agency (e.g., included in the Agency's Annual Assurance Statement) are considered a "**material weakness**". If a deficiency is directly related to the Agency's financial management systems, it is considered a "**material non-conformance."**

   The designation of **"material weakness"** requires a judgment by the Commissioner or other senior-level managers that the relative risk and significance of the deficiency merits the attention of the HHS Secretary.

   Likewise, the designation of **"material non-conformance"** requires a judgment by the Commissioner or other senior-level managers that the relative risk and significance of financial management systems deficiencies merit the attention of the HHS Secretary.

   Additionally, the Government Accounting Office (GAO) and the HHS Office of Inspector General (OIG) can make **"material weakness"** and/or **"material non-conformance"** recommendations based on results of

audits they conduct of Agency programs and activities.

All **"non-material weaknesses"** (e.g., less significant deficiencies) are to be reported internally, corrected, and monitored at the Center or OC Office program-level.

2. **OPERM** is responsible for the overall FMFIA program management and administration. Responsibilities include:

   a. Develop FDA's FMFIA Preliminary and Final IAS and coordinate the annual FMFIA process;

   b. Develop and issue FMFIA-related guidance to Agency components, and coordinate directly with Centers and OC Offices to promote improved FMFIA processes and operations,

   c. Coordinate with Centers and OC Offices to develop and monitor corrective action plans for deficiencies, including **"material weaknesses,"**

   d. Schedule and hold SAT meetings,

   e. Collaborate and share FMFIA program information with SAT,

   f. Provide training and orientation, as needed, to Center or OC Office Risk Champions and to FDA program managers,

   g. Review and provide comments on guidance issued by organizations, including HHS and OMB,

   h. Facilitate FMFIA ERAs by FDA Centers and OC Offices and provide advisory services on risk management, and

   i. Perform ORRs as requested by SAT.

B. Financial Management Systems (FMFIA Section 4).

1. **Financial Management System Owners** submit, through OPERM, under Section 4 of FMFIA, the results of the FFMIA assessments over the applicable financial management systems.

   The FFMIA assessment evaluates financial management system compliance with FFMIA and OMB requirements, as stated in OMB Circular No. A-123 Appendix D. FFMIA requires agencies to have financial management systems that substantially comply with federal financial management systems requirements, standards promulgated by the

Federal Accounting Standards Advisory Board (FASAB), and the United States Standard General Ledger (USSGL) at the transaction-level.

Further, FFMIA requires that Agency financial management systems have general and application controls in place to support management decisions by providing timely and reliable data. The Agency head must determine annually if the Agency's financial management systems substantially comply with FFMIA.

If the financial management systems are non-compliant, management is required to develop a remediation plan to bring those systems into substantial compliance. Management must determine whether non-compliance with FFMIA should also be reported as a non-conformance under Section 4 of FMFIA.

C. Component Organization Program Management.

1. **Center Directors, Associate Commissioner for Regulatory Affairs, and designated OC Office Directors.** Responsibilities are to:

   a. Plan, manage, and coordinate internal control activities for their respective organizations,

   b. Submit, to OPERM, Preliminary and Final IAS to provide reasonable assurance that resources are protected from fraud, waste, and abuse, that programs have been evaluated periodically to provide assurance over compliance with applicable laws and regulations, and that Center or OC Office activities are managed in an effective and efficient manner,

   c. Report **"material weaknesses"** to OPERM as soon as identified, submit a corrective action plan for approval, and prepare status reports for inclusion in the Preliminary and Final IAS,

   d. Review and approve Center or OC Office ERA and submit to OPERM, and

   e. Assist in administrative and programmatic reviews as required by SAT.

2. **FDA Managers (at all levels)**. Responsibilities are to:

   a. Provide quality assurance over program performance,

   b. Perform program operations timely,

   c. Track effectiveness and efficiency of program and administrative

activities,

d. Control costs and mitigate adverse aspects of agency operations,

e. Manage programs with integrity and in compliance with applicable laws and regulations,

f. Establish and maintain adequate controls over resources entrusted to them,

g. Identify and escalate potential risks to leadership and relevant stakeholders in OPERM for further analysis, support, and management, and

h. Monitor and improve the effectiveness of risk mitigations and internal controls associated with their programs and operations.

3. **Risk Champions** (also known as Liaisons, Lead Practitioners, or Points of Contact). Risk Champions have responsibilities related to Agency-wide ERM, as well as specific to FMFIA, and are vital to managing the intersection of sound risk management and internal controls programs within their organizations.[1] Responsibilities specific to FMFIA are to:

   a. Provide internal direction and guidance to their respective Center or OC Office on FMFIA policies and procedures,

   b. Coordinate the IAS within their respective Center or OC Office,

   c. Direct or conduct FMFIA activities within their respective Center or OC Office, including developing, obtaining approval for, and submitting the ERA,

   d. Monitor and track corrective actions to ensure **"material weaknesses"** are corrected, and

   e. Maintain communication with OPERM on matters relating to FMFIA.

7. Effective Date

The effective date of this guide is October 20, 2021.

[1]For more information related to ERM responsibilities, contact FDAERM@fda.hhs.gov.

8. Document History - SMG 2350.1, "Guidance for the Implementation of the Federal Managers' Financial Integrity Act of 1982 (FMFIA)"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/16/2009	N/A	OC/OO/ OM/OFM	William C. Collinson, Acting Director, OFM
Revision	07/03/2014	N/A	OFBA/OFO/ OFM	William C. Collinson, Director, OFM
Revision	12/22/2014	N/A	OC/OO/ OFBA/OFM	William C. Collinson, Director, OFM
Revision	09/29/2021	N/A	OC/OO/ OFBAP/ OPERM	Sahra Torres-Rivera, Deputy Chief Financial Officer, Office of Finance, Budget, and Acquisitions