

Foreword 2024

We are excited to bring you the 2024 *Investigations Operations Manual* (IOM). The IOM is the primary operational reference for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instruction supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your management must be informed and concur with any significant departures from the IOM.

The 2024 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray.

The IOM is also posted on ORA's Internet Website <https://www.fda.gov/inspections-compliance-enforcementand-criminal-investigations/inspection-references/investigations-operations-manual>, with all graphics included.

In 2023, the IOM Refresh Project continued its cover to cover, all-inclusive review of the IOM to ensure the manual presents information in a clear and useful manner for field and operational staff. Elizabeth Miller, Dan Solis, and I, as the Executive Sponsors for the IOM Refresh Project, are particularly proud of the effort and engagements of the team to implement these most recent updates. The 2024 IOM includes the update to two of the IOM's core chapters: Chapter 5 – Inspections and Chapter 6 – Imports. Chapter 5 was reorganized to provide a General Section that is applicable to all programs and program specific sections, including a section on combination products. Chapter 6 is better organized and now contains all information related to imports for exports and inspections of food importers from the Foreign Supplier Verification Program.

The IOM is published in hard copy annually, though updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2025 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the agency, our state and local partners, industry, and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

As the professionals across ORA continue to advance our mission every day, I am reminded how grateful I am to be a part of this dedicated and incredibly talented group of people. As we look forward to the potential of a new field organization, we can further focus our expert capabilities on the core frontline operations that protect public health - Inspections, Investigations, and Imports.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.



Michael C. Rogers, MS
Associate Commissioner for Regulatory Affairs
U.S. Food and Drug Administration, Office of Regulatory Affairs

Vision

Public health is protected, promoted, and advanced.

Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

Ultimate Outcome

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

Core Values

ORA's core values define the organization's "character" and inform its actions and decisions.

Accountability

Commitment to Public Health

Communication

Inclusion, Diversity, Equity, and Accessibility

Integrity and Respect

Quality