Foreword 2026

We are pleased to bring you the 2026 Investigations Operations Manual (IOM). The Investigations Operations Manual (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 2026 version of the IOM reflects significant regulatory developments and operational improvements. Among the most consequential updates is the transition from the Quality System Regulation (QSR) to the Quality Management System Regulation QMSR, 21 CFR Part 820), effective February 2, 2026, which aligns FDA's medical device oversight framework with ISO 13485:2016. Cosmetics regulatory requirements have also been substantially updated in accordance with the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, under which facility registration and product listing are now mandatory. Investigators are encouraged to carefully review the changes applicable to their areas of work, including updates to import operations, inspection procedures, safety and health guidance, and organizational contacts. Additions to the IOM are highlighted in light gray. The IOM is typically published in hard copy annually; however, updates will continue to be made periodically throughout the year to the online version. The online IOM version serves as OII's official document of record and is posted on OII's Internet Website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual with all graphics included.

OII leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2027 edition including recommended changes, deletions, and additions may be submitted using the IOM Change Request (ICR) Form (FORM-000992). Suggestions are also accepted from our state and local partners, industry, and consumers and may be sent via e-mail to oii-iom@fda.hhs.gov. 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.



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Vision

Our global inspections and investigations ensure FDA regulated products are safe, trusted, and accessible.

Mission

We conduct rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.

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

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

Accountability
Commitment to Public Health Communication
Integrity and Respect Quality