

## **Vision**

All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

## **Mission**


Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

## **Quality Commitment**

ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

## **Values**

- *Accountability* - We take personal responsibility for meeting individual, team, and organizational commitments.
- *Commitment to Public Health* - We demonstrate our commitment to safeguarding the public health in our actions.
- *Communication* - We provide information that is accurate and clear, and in our interactions with others, we actively listen to understand other points of view.
- *Diversity & Inclusion* - We embrace each individual's uniqueness and seek out their ideas and perspectives.
- *Integrity and Respect* - We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions.
- *Quality* - We set high standards of excellence for our work and take the necessary actions to continuously improve.



Melinda K. Plaisier

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

## Foreword 2019

The *Investigations Operations Manual* (IOM) is the primary operational guide 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 guidance 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 division management must be informed and concur with any significant departures from the IOM.

In 2019, the IOM contains important changes which clarify or present new information and procedures. We are continuing to update the IOM in response to our May 15, 2017 rollout of program alignment across ORA. These program alignment updates will continue as we incorporate new and updated program-specific sections within the IOM. 2019 will also see the beginning of routine inspections under the Produce Safety Rule and the introduction of a new form, FDA 4056 Produce Farm Inspectional Observations. Information on Produce Safety Inspections is posted on FDA's Internet Website, <https://www.fda.gov/ICECI/Inspections/ucm627767.htm>. 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, [http://www.fda.gov/ora/inspect\\_ref/iom](http://www.fda.gov/ora/inspect_ref/iom), with all graphics included. The "Blue Pages" are located on FDA.gov with the IOM to allow ORA to maintain a more accurate and useful listing.

Future updates to the IOM will be performed periodically during the year to the on-line version. The hard copy is published annually. Remember, whether reviewing the "hard copy" or the "on-line" version of the IOM, the most recent version is the document of record.

We are committed to the continual improvement of the quality and usefulness of the IOM. Suggestions for the 2020 edition of the IOM or recommended changes, deletions, additions to the IOM may be sent via e-mail to [IOM@FDA.HHS.GOV](mailto:IOM@FDA.HHS.GOV). If you are recommending a change or revision, please use the IOM Change Request Form (FDA-3651) available at <http://inside.fda.gov:9003/downloads/administrative/forms/fda/ucm035205.pdf>. 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.

Thank you for your continued hard work and dedication in protecting and promoting the health and well-being of the American people.



Melinda K. Plaisier

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

NOTE: This manual is reference material for investigators and other FDA personnel. The document does not bind FDA and does not confer any rights, privileges, benefits or immunities for or on any person(s).