Let’s Talk:

Remote Regulatory Assessments (RRA) In OMDRHO

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Background

- On-site domestic and foreign surveillance inspections paused in March 2020. Mission-critical (MC) inspection work and other activities continued.
- In July 2020, FDA announced resumption of domestic prioritized inspections.
- In November 2020, OMDRHO focused development of a program for remote assessments. In February 2021, OMDRHO launched RRA process- more flexible tool to continue our surveillance activities and regulatory oversight.

Presentation shares overview of OMDRHO's Remote Regulatory Assessment (RRA) program.

Voluntary Remote Regulatory Assessments

- Process is designed to allow virtual and interactive engagement between FDA Investigators and Firm Personnel.
- Remote review of records firms are required to maintain.
- Process is voluntary.
- RRA is a meaningful review of information provided electronically to remotely determine whether a firm complies with regulatory requirements.

OMDRHO RRA Statistics June 2021

Program Wide Domestic & Foreign Facilities

Launched: 02/16/2021

Firms Participating: 120

RRA Completed: 91

How Does RRA Differ from Inspections?

High Level Process Overview

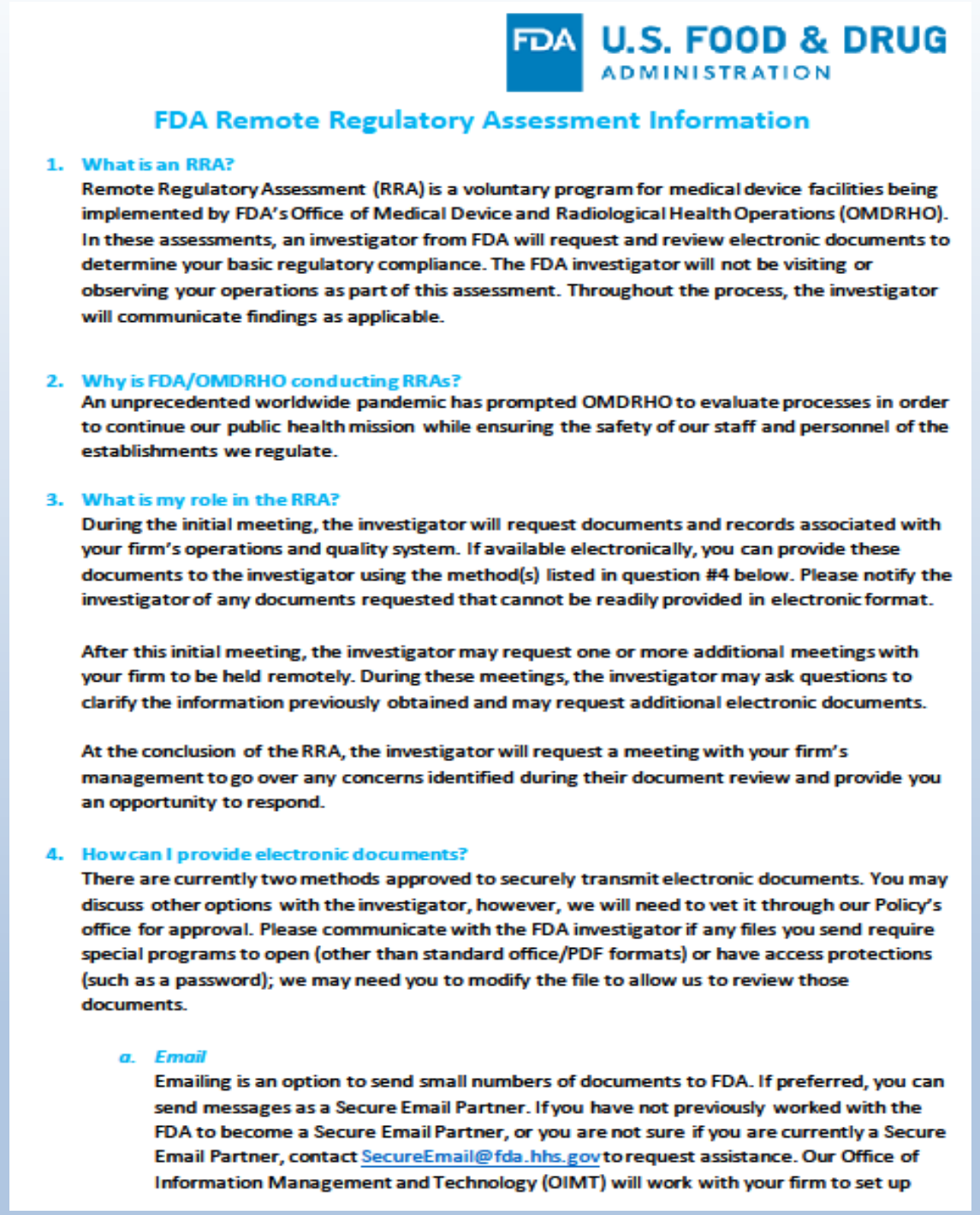
- An OMDRHO Consumer Safety Officer (CSO) contacts selected firms for **voluntary** participation.
- Contact made with firm management to provide opportunity for discussion on firm's ability and willingness to participate in process.
- Discussion held and Information will be sent for management consideration and decision to participate.
  *Email
  *Formal Invitation Letter
  *RRA Handout
- Voluntary Assessment with no penalty for non-participation.
  Firm may decline during initial contact or at any time thereafter.

If firm agrees to participate, CSO will schedule initial virtual meeting and will begin coordination of virtual logistics.

RRA Handout

- What is an RRA?
- What is my role in an RRA?
- How to provide documents electronically?
- Contacts after an RRA concluded.

Includes process for response(s), recalls, obtaining copies of report, general regulatory assistance (non-RRA questions) and OMDRHO management contact if needed.



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FDA Remote Regulatory Assessment Information

1. **What is an RRA?**
   Remote Regulatory Assessment (RRA) is a voluntary program for medical device facilities being implemented by FDA's Office of Medical Device and Radiological Health Operations (OMDRHO). In these assessments, an investigator from FDA will request and review electronic documents to determine your basic regulatory compliance. The FDA investigator will not be visiting or observing your operations as part of this assessment. Throughout the process, the investigator will communicate findings as applicable.

2. **Why is FDA/OMDRHO conducting RRAs?**
   An unprecedented worldwide pandemic has prompted OMDRHO to evaluate processes in order to continue our public health mission while ensuring the safety of our staff and personnel of the establishments we regulate.

3. **What is my role in the RRA?**
   During the initial meeting, the investigator will request documents and records associated with your firm's operations and quality system. If available electronically, you can provide these documents to the investigator using the method(s) listed in question #4 below. Please notify the investigator of any documents requested that cannot be readily provided in electronic format.

   After this initial meeting, the investigator may request one or more additional meetings with your firm to be held remotely. During these meetings, the investigator may ask questions to clarify the information previously obtained and may request additional electronic documents.

   At the conclusion of the RRA, the investigator will request a meeting with your firm's management to go over any concerns identified during their document review and provide you an opportunity to respond.

4. **How can I provide electronic documents?**
   There are currently two methods approved to securely transmit electronic documents. You may discuss other options with the investigator, however, we will need to vet it through our Policy's office for approval. Please communicate with the FDA investigator if any files you send require special programs to open (other than standard office/PDF formats) or have access protections (such as a password); we may need you to modify the file to allow us to review those documents.

   a. ***Email***
      Emailing is an option to send small numbers of documents to FDA. If preferred, you can send messages as a Secure Email Partner. If you have not previously worked with the FDA to become a Secure Email Partner, or you are not sure if you are currently a Secure Email Partner, contact SecureEmail@fda.hhs.gov to request assistance. Our Office of Information Management and Technology (OIMT) will work with your firm to set up

Process Overview

Firm MRP or designee concur to participate, CSO will then schedule initial virtual meeting.

- CSO will interview staff about processes and procedures.
- Request records to review.
- Records can be provided via e-mail (Secure Email Partner), Box.com, or WebTrader.
- Follow-up meetings will be scheduled as necessary to discuss for interactive discussion.
- Any concerns will be clearly communicated by CSO throughout RRA, as required.
- A close-out meeting will be scheduled and held.

What Types of Records?

Records reviewed will be records that are required to be maintained under Federal FD&C Act and Code of Federal Regulations

Specific records requested will vary between RRAs due to specific situation of firm

Firms will not be asked to create new record solely to support engagement in the RRA

In general, performed using a systems-based approach starting with abbreviated coverage.

Outcomes & Final Steps

- Firms should respond in writing to any concerns discussed by CSO within 15 business days of completion of RRA.
- Reviewed by Agency for any regulatory considerations and/or follow-up activities.
- RRA may be limited in scope or terminated at the discretion of the Agency.
- If you wish to obtain a copy of the RRA report, submit an FOIA request. Option for e-request at FOIA request page to submit a request online.

Benefits

For Industry

- Engagement in RRA is taken into consideration during future risk-based workplanning activities.
- Allows for identification of potential minor or easily correctable deficiencies prior to future inspections.
- Can provide information to potentially aid decisions for industry contracts, foreign governments, etc.

For FDA

- Allows FDA to continue important oversight responsibilities safely.
- Improved efficiency in use of agency resources.
- Transparent and effective communication with firms.

What Can You Do to Prepare?

Determine if your firm can provide records electronically in a timely manner and any limitations.

Familiarize yourself with platform(s) that can be used for the meetings and records submission.

Ensure key staff are available and capable of joining meetings as needed.

FAQs

What happens if I do not want to participate or to provide the information or documents?

How are FDA staff being trained for these activities?

Does FDA expect to use these tools, such as RRAs, in the future?


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