

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 several 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



secure communications. Please notify the investigator of any delays due to this encryption being set up.

You can send files requested via email to the FDA investigator directly via one or more emails. Your email subject line should include at least the words "Remote Regulatory Assessment" and your firm's name. Due to email limitations, attachments may not be more than 100 megabytes per email. If you send more than one email due to this limitation, please indicate the number of emails expected (e.g. "1 of 3") in the subject line.

b. Electronic Submission Gateway (ESG) Webtrader

The Gateway is an agency-wide and central transmission point for accepting secure electronic submissions over the Internet. The FDA ESG (also referred to as the ESG or the Gateway): enables automatic submissions processing, functions as a single point of entry for the receipt and processing, serves as a conduit to reach final FDA destination, and automatically routes submissions to the appropriate FDA Center or Office.

The electronic submission process through the ESG encompasses the receipt, acknowledgement of receipt (to the sender), routing, and notification (to a receiving FDA Center or Office) of the delivery of an electronic submission.

Please visit [Setting up a WebTrader Account Checklist | FDA](#) to access the checklist for setting up a WebTrader Account with the FDA ESG.

c. Cloud file sharing (CFS)

CFS through box.com can securely transfer and store document uploaded as large as 15 gigabytes per file and no limit on the number of files. Due to limited availability, OMDRHO has assigned one support staff member in each division to be an Account holder. The Account holder will facilitate the file sharing. You will need to set up an account via the free account option BOX offers or fund your own paid account. If you would like to use box.com during the RRA, please notify the Investigator.

Once a secure URL is provided, you will be able to visit and upload documents to this service, which will then be made available remotely to the Investigator.

5. What happens if I do not want to participate or provide information/documents?

Your participation in this RRA is voluntary. You may decline to participate in the RRA at any time, and non-participation will not result in regulatory action. Refusal to provide information requested during an RRA is not a refusal under FDA's inspection authority found in Section 704 of the Food Drug and Cosmetic Act (21 USC 374).

6. What are the outcomes of an RRA?

These RRA findings will be considered by management during future routine FDA workplans and will be a factor in deciding the need for an onsite inspection.

If significant concerns are found during the RRA, they may be considered violations of the FD&C Act, an on-site inspection of your firm may be scheduled, or further communication and/or action with Compliance Branch may be considered.

7. Who are my contacts during the RRA?

While the RRA is ongoing, your first point of contact for any questions or concerns is the FDA Investigator assigned to your RRA.

If you cannot resolve the concern with the Investigator, you may contact the Director of Investigations Branch, who is responsible for overseeing medical device investigations conducted in your area:

James Hildreth, DIB for OMDRHO Division 2 can be reached at:

James.Hildreth@ora.fda.hhs

(949) 608-2919

8. Who are my contacts after the RRA has concluded?

a. *Response to the RRA*

If your firm wishes to submit a response to any concerns identified by the Investigator during your RRA, you may email RRA related correspondence to the following email address: ORADevices2FirmResponse@fda.hhs.gov. Your response should include in the subject line the words “**Remote Regulatory Assessment**” and provide your **firm’s name**. If any attachments are provided, you should clearly label/identify them for ease of review. Due to email limitations, attachments may not be more than 100MB per email. If you send more than one email due to this limitation, please indicate the number of emails (e.g. “1 of 3”).

b. *Recalls of Medical Devices*

If your firm plans to, or has initiated a recall, you should contact the email address below and a recall coordinator will contact you.

oradevices2recalls@fda.hhs.gov

Meredith Address, (407) 475-4722

Marie Fink, (504) 846-6109

Lisa Warner, (407) 475-4735

c. *General Regulatory Information*

If you have general medical device or radiological health regulatory questions, you may contact the Center for Devices and Radiological Health’s (CDRH) Division of Industry and Consumer Education (DICE) at the following.

DICE@fda.hhs.gov

1(800) 638-2041 or (301) 796-7100

www.fda.gov/DICE

9. How can I get a copy of the report for my RRA?

Since an RRA is not an inspection, FMD-145 does not apply and a copy of the report will not automatically be provided to you. If you wish to obtain a copy of this report, please submit a request using the FDA Freedom of Information Act (FOIA) process, outlined here:

<https://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm>. Please note you may be charged a fee for processing your request.

To view the Office of Medical Device and Radiological Health Operations web page use the QR code below.

