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From Electronic Docs To FOIA Requests, FDA Lays Bare Its Process For Remote Regulatory Assessments

by Shawn M. Schmitt

A document from the US FDA obtained by *Medtech Insight* advises medical device manufacturers on how a voluntary Remote Regulatory Assessment will unfold. RRAs are being conducted by the agency in lieu of on-site facility inspections because of the COVID-19 pandemic.

Device makers that agree to a Remote Regulatory Assessment by the US Food and Drug Administration are presented with a three-page explainer of how the agency plans to perform the RRA.

The FDA's document, sent to a Florida device firm and obtained by *Medtech Insight*, advises manufacturers on how best to transfer electronic files to the agency and who to contact if they have problems with an investigator during an assessment, among other instructions and explanations.

RRA "is a voluntary program for medical device facilities being implemented by FDA's Office of Medical Device and Radiological Health Operations (*OMDRHO*)," the FDA says in its doc. "In these assessments, an investigator from FDA will request and review electronic documents to determine your basic regulatory compliance."

The agency further says investigators won't visit manufacturing facilities for an RRA and promises that investigators will "communicate findings as applicable."

The number of in-person inspections performed by the FDA plummeted last year to an all-time low because of the COVID-19 pandemic and its related travel restrictions. While RRAs are being used in the interim to ascertain manufacturer compliance, the agency stresses that an

assessment is not an official surveillance inspection.

An RRA "is the agency's way of gaining information so they can risk-prioritize the inspections once they are able to freely move about in the field," says Ricki Chase, a former FDA investigations branch director who is now compliance practice director for Lachman Consultant Services.

"It is not an inspection, I suspect, primarily because FDA does not want to go into a legal battle with a company over the federal authority for inspection as defined by the law," she told *Medtech Insight* on 27 April. While the FDA's drug center "has unique authorities for formal record requests under a separate law unique to them, [the device center] does not."

Notably, the FDA does not say it will use video – recorded or live – during an RRA, despite the agency's earlier interest in exploring video's use during virtual assessments. (Also see "*FDA Exploring Use Of Video – 'Live Or Recorded' – To Support Virtual Inspections During Pandemic*" - Medtech Insight, 18 Nov, 2020.)

The FDA's apparent decision to not use video could be due to industry's longtime aversion to investigators taking photographs during inspections. (Also see "*Photos Snapped During FDA Device Inspections: Fair Game Or Agency Overreach?*" - Medtech Insight, 9 Feb, 2016.)

The Manufacturer's Role In An RRA

Further, the FDA's RRA document lays bare a device maker's role in the assessment.

"During the initial meeting, the investigator will request documents and records associated with your firm's operations and quality system," the agency says. "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."

When the assessment is complete, a company's top management will meet virtually with the investigator to go over any problems that were discovered. Management can respond at that time to any investigator concerns.

Manufacturers also may respond to investigator concerns in a letter to the agency.

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"RRA findings will be considered by management during future routine FDA workplans and will be a factor in deciding the need for an on-site inspection," the FDA says. And "if significant concerns are found during the RRA, an on-site inspection of your firm may be scheduled, or communication with Compliance Branch may be considered."

The agency says an assessment is voluntary and that firms "may decline to participate in the RRA at any time, and non-participation will not result in regulatory action."

But Elizabeth Miller, assistant commissioner for medical products and tobacco operations within the FDA's Office of Regulatory Affairs, said on 14 April that while an RRA is voluntary, the FDA will nevertheless "determine if a more immediate on-site inspection is needed" for companies that refuse to take part in one. (Also see "*FDA Presses Domestic Manufacturers To Engage In Remote Regulatory Assessments In Lieu Of Inspections*" - Medtech Insight, 22 Apr, 2021.)

"FDA has made it clear [that an RRA] is voluntary, although I imagine declining the request would be a red flag for when they do establish the workplan of on-site work," Lachman's Chase says. "If industry wants some feedback from FDA and wants to get off the top of the list for an on-site inspection, then this is a good opportunity – if they are compliant and feel they can demonstrate that compliance" during an assessment.

FOIA Request Necessary To Get RRA Report

Interestingly, the FDA won't provide an investigator's RRA report to the device maker unless it requests a copy through the Freedom of Information Act (FOIA).

"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," the FDA says.

FMD-145 outlines the criteria and instructions for releasing an Establishment Inspection Report to a company following an on-site inspection.

"If you wish to obtain a copy of this [RRA] report, please submit a request using the *FDA [FOIA] process*," the agency says, noting that a fee may apply.

"One thing that is interesting is that the FMD-145 belongs to the firm, so there are usually very,

very few – if any – redactions, as there are no trade secrets, *et cetera*, that FDA has to protect," Chase says. "With the FOIA request, the document has to go through the FOIA officer, and it will be curious to see what they redact from the firm's view."