Sections in This Document

1. Purpose

This Field Management Directive (FMD) provides criteria and instructions for releasing one copy of an Establishment Inspection Report (EIR), to the firm's top management official or designee at the inspected firm, in accordance with the agency's policy articulated at "Release of Establishment Inspection Report to the Inspected Establishment" 62 Fed. Reg. 18138, April 14, 1997.

2. Scope

To be eligible for EIR release under the process outlined by this FMD, the inspection, domestic or foreign, performed by FDA or State and local authorities under contract with FDA, must be deemed closed in accordance with 21 C.F.R. § 20.64(d)(3). Cooperative agreement inspections performed under a grant from FDA are outside the scope of this FMD.[1]

Inspections resulting in agency action (e.g., Warning Letter, Untitled Letter, Seizure) are not eligible for release until the inspection is closed in accordance with 21 C.F.R. § 20.64(d)(3). In the case of endorsed OAI inspections with Final Division Decisions, confirmation that no further agency action is planned from the appropriate Compliance Branch or Center must be obtained before release.

Inspections completed under the Mammography Quality Standards Act are released under separate procedures.

Special domestic investigation activities like those identified with the FACTS Operation Code 13 are outside the scope of the this FMD as those activities do not generate EIRs.

If a Program or Office enters a formal agreement with another Center, such as a Concept of Operations, then the agreement's release timelines will take precedence. All other requirements of this FMD will remain in effect.

[1] In general, grantees own the rights in data resulting from a grant-supported project or program. *See Rights in Data, https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf*

3. Background

In 1997, FDA announced in the *Federal Register* a policy that the narrative portion of the EIR should be routinely provided to the inspected establishment once the agency concludes that the inspection is closed.

Prior to instituting this practice, a number of industry associations expressed concerns that other requestors may receive copies of the EIR prior to the inspected establishment through the Freedom of Information Act (FOIA). These groups requested that FDA provide a copy of the EIR to the facility after the inspection**.**

The agency considered this request and determined that a copy of the narrative portion of the EIR should be routinely provided to the inspected establishment once the agency concludes that the inspection is closed. The policy stated that term “closed” will have the same meaning as it has under 21 CFR 20.64(d).

In tandem with publishing the policy, FDA instituted FMD-145. The original version of FMD-145 applied to all program areas and inspections, both international and domestic, performed by FDA or State and local authorities under contract with FDA. It required that a redacted copy of the EIR was sent via U.S. mail with a standard cover letter.

Subsequently, the agency reiterated its commitment to this policy in the notice “Expansion of Medical Device Industry Initiatives” 66 Fed. Reg. 800, Jan. 4, 2001.

In the intervening decades, ORA provided inspected establishments with a redacted hardcopy of the EIR in accordance with the policy and this FMD and its subsequent revisions.

In 2019, ORA modernized the process it uses to comply with this policy directive by establishing a system to email the EIR narrative to the inspected facility.

4. Responsibilities

Domestic EIRs will be monitored and released by the appropriate ORA Program Division or FDA Center upon final compliance classification. Foreign EIRs will be released by the appropriate Center or Program Division responsible for the final compliance classification. The releasing office will

ensure that the EIR for the closed inspection is appropriately redacted under FOIA and 21 C.F.R. Part 20 before releasing a copy to the inspected establishment.

5. Procedure

ORA will develop operating processes and procedures for Program Divisions to follow when issuing a copy of the EIR with FMD-145 Letters. These processes will ensure the following:

a. EIRs will be transmitted via electronic means when possible. The email will serve as the cover letter. When electronic means are not available, then EIRs should be transmitted in accordance with local procedures.

b. FMD-145 letters shall be transmitted within 45 calendar days of the determination that the inspection is closed per 21 C.F.R. § 20.64(d)(3). The timeline will be expedited if requested by the Division of Information Disclosure Policy in response to a FOIA request.

c. FDA should adhere to standard operating procedures in redacting EIRs and for correspondence.

d. Only the narrative portion of a redacted EIR or abbreviated report (i.e., Summary of Findings Report, State Inspection Checklist, etc.) should be released to the inspected firm. Attachments and exhibits are excluded from disclosure under this directive. If the inspection is conducted and reported on a checklist only, as is the case with some state contract inspections, and the firm has already received a copy of the checklist, it is only necessary to send the firm a FMD-145 cover letter.

6. References/Supporting Documents

a. "Release of Establishment Inspection Report to the Inspected Establishment" 62 Fed. Reg. 18138, April 14, 1997.

b. "Expansion of Medical Device Industry Initiatives" 66 Fed. Reg. 800, Jan. 4, 2001.

c. 21 CFR Part 20 – Public Information

d. Investigations Operations Manual (IOM); Chapter 5.11

e. Field Management Directive FMD# 86 – Establishment Inspection Report Conclusions and Decisions

f. Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations

7. Definitions/Glossary

N/A

8. Records

a. Completed Cover Letter – record in CMS

b. Appropriately redacted copy of the EIR – record in CMS

9. Attachments

N/A

10. Document History

Revision	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
02	R	3/1/2012	Dennis Baker, Regional Food & Drug Director	Roberta Wagner, Assistant Commissioner for Field Operations
03	R	25 JUNE 2019	**LORI HOLMQUIST** DIRECTOR OF INVESTIGATIONS, OHAFO EAST 1 **FMD 145 WORK GROUP TEAM** ORA PROGRAM REPRESENTATIVES	**VINETTA HOWARD-KING** DIRECTOR , OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS (OHAFO) EAST

* D: Draft, I: Initial, R: Revision, C: Cancel

11. Change History

Revision	Change
1.0	Original FMD on FDA.gov
2.0	Added process instructions and timelines in Section 5.0
03	Removed procedures and reflects implementation of an email-based system