

SOPP 8504: Release of Establishment Inspection Reports to the Inspected Establishments Pursuant to Field Management Directive 145

Version: 4

Effective Date: December 11, 2020

Table of Contents

| | | |
|--------------|-------------------------------|----------|
| I. | Purpose | 1 |
| II. | Scope | 1 |
| III. | Background | 2 |
| IV. | Definitions | 2 |
| V. | Policy | 3 |
| VI. | Responsibilities | 3 |
| VII. | Procedures | 4 |
| VIII. | Appendix | 4 |
| IX. | References | 4 |
| X. | History | 5 |

I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide to the Center for Biologics Evaluation and Research (CBER) staff for releasing Establishment Inspection Report (EIR) narratives to inspected establishments in accordance with Field Management Directive (FMD) 145 when CBER is the endorsing office for a “closed” inspection.

II. Scope

A. This SOPP applies only to the release of the EIR narratives generated from the following types of inspections and for which CBER is the endorsing office:

1. Office of Regulatory Affairs (ORA)-led foreign inspections, including:

- Team Biologics-led post-market surveillance inspections
- Surveillance inspections of manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated under section 361 of the Public Health Service Act
- Pre-approval and post-market surveillance inspections of manufacturers of CBER-regulated drugs and devices
- Surveillance inspections of blood establishments

- Directed inspections
2. ORA-led foreign pre-license, pre-approval and surveillance inspections conducted under CBER's Bioresearch Monitoring Program
 3. CBER-led pre-license and pre-approval inspections, regardless of location, including those led by:
 - CBER's Division of Blood Components and Devices (DBCD)
 - CBER's Division of Product Manufacturing and Quality (DMPQ)
- B.** For joint inspections that result in a single EIR and are performed either as a combination of the above types of inspections or concurrently with the inspection of products under another Center's workplan, this SOPP only applies when CBER is the endorsing office for the inspection.

III. Background

- A.** Under the Freedom of Information Act (FOIA) and FDA's regulations governing disclosures as set out in 21 CFR Part 20, any inspectional records can be requested by any member of the public and will be disclosed after review for redaction according to the statute, regulations and policies. This includes information such as an FDA Form 483, EIR, and Agency communication with a regulated establishment. Historically, inspected establishments requested their inspection information through FOIA procedures. However, industry expressed concern that other third-party requestors received a copy of the inspected firm's EIR prior to the release of the EIR to the inspected establishment.
- B.** On April 1, 1997, the Agency addressed this concern from industry and established Field Management Directive No. 145 (FMD 145), which states that, once the Agency determines an inspection is closed, the Agency will routinely provide the EIR to the inspected establishment. FMD 145 was only applicable to inspections performed by field investigators. In an effort to harmonize agency activities, CBER agreed to release EIRs in the same manner.

IV. Definitions

- A. Closed Inspection** - an inspection is considered "closed" when the closing action is completed as follows:
1. For applicable surveillance and directed inspections, the closing action occurs when a "close out" memorandum is generated by CBER and CBER determines not to take an official action, or has taken an action as a result of the inspectional findings, and the action is complete.

2. For applicable pre-approval and pre-license inspections, the closing action occurs when a “close out” memorandum is generated by CBER and the approval letter for the corresponding application or supplement is issued by CBER.

B. Endorsing Office – the Office or Center that endorses the final classification of an inspection based upon review of the EIR, exhibits, as needed, and response to Form FDA 483, if applicable.

V. Policy

Once an inspection is “closed,” a redacted copy of the signed EIR narrative, accompanied by the signed FMD 145 letter, is provided by mail to the inspected firm. Regardless of the inspection’s classification, an EIR narrative will only be released if this action will not adversely affect ongoing regulatory, compliance or administrative actions. Firms will not be charged fees for the EIR narratives released under this program.

VI. Responsibilities

A. Consumer Safety Officer (CSO), Division of Case Management (DCM):

1. Determines the final classification of the inspection and generates a “close out” memorandum for applicable manufacturing site post-market surveillance inspections, ORA-led pre-approval inspections, and DBCD-led pre-license and pre-approval inspections.

B. Consumer Safety Officer (CSO), Division of Inspections and Surveillance (DIS):

1. Determines the final classification of the inspection and generates the “close out” memorandum for applicable pre-license, pre-approval and surveillance inspections conducted under CBER’s Bioresearch Monitoring Program.
2. For all applicable inspections, once the inspection is closed, redacts, if necessary, the EIR narrative, and provides a copy of the signed EIR narrative (redacted if applicable) and the signed FMD 145 letter to the firm.

C. Inspector, Division of Manufacturing and Product Quality (DMPQ):

1. Generates a “close out” memorandum for applicable DMPQ-led pre-license and pre-approval inspections.

D. Branch Chief (BC), Division of Manufacturing and Product Quality (DMPQ):

1. Determines the final classification of the inspection for applicable DMPQ-led pre-license and pre-approval inspections.

E. Division Director (DD), Division of Inspections and Surveillance (DIS):

1. Serves as the designated signatory authority for all FMD 145 letters generated by CBER.

VII. Procedures

- A. Provide the EIR narrative and exhibits as needed for determination of the inspection's final classification. **[Inspection Lead from ORA or DBCD or DMPQ]**
- B. Review the EIR narrative, exhibits, as needed, and response(s) to the Form FDA 483, if applicable, and determine the inspection's final classification. **[DIS or DCM CSO or DMPQ BC]**
- C. Generate the "close-out" memorandum. **[DIS or DCM CSO or DMPQ Inspector]**
- D. Redact the EIR narrative. **[DIS CSO]**
- E. Prepare the FMD 145 letter. **[DIS CSO]**
- F. Verify the inspection is closed, review the FMD 145 letter and redacted EIR, and sign the FMD 145 letter. **[DIS DD]**
- G. Mail the redacted, signed EIR narrative and signed FMD 145 letter to the firm using the FDA White Oak mail service. **[DIS CSO]**
- H. Enter information regarding the letter in the appropriate regulatory system, and file the redacted, signed EIR narrative and the signed FMD 145 letter in CBER's Electronic Repository, or submit a paper copy of the redacted, signed EIR narrative and the signed FMD 145 letter to CBER's Document Control Center for filing. **[DIS CSO]**
- I. Provide a copy of the redacted, signed EIR narrative and the signed FMD 145 letter to CBER's Division of Disclosure and Oversight Management. **[DIS CSO]**

VIII. Appendix

N/A

IX. References

- A. References below may be found on the Internet:

1. [Freedom of Information Act \(5 USC 552\)](#)

2. [21 CFR 20, Policy on Disclosure of Food and Drug Administration Records](#)
3. [ORA Field Management Directive No. 145, Procedure for Release of Establishment Inspection Report to the Inspected Establishment](#)

X. History

| Written/ Revised by | Approved By | Approval Date | Version Number | Comment |
|--------------------------------|---------------------------------------------|--------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------|
| M. Monser | N/A | December 11, 2020 | 4 | Technical Update for retirement of EDR and replacement with CER and to replace "database" with "system" |
| M, Monser | N/A (Reviewed by Job Aid Coordinator) | January 13, 2020 | 3 | Technical Update: New Format/Font |
| J. Wally, PhD | Christopher Joneckis, PhD | March 17, 2019 | 2 | Updated to current procedures |
| J. Thomas | Rebecca Devine | June 18, 1998 | 1 | First Issuance |