
Manual of Standard Operating Procedures and Policies

Regulatory - Compliance

Release of Establishment Inspection Reports to the Inspected Establishments

Pursuant to Field Management Directive 145

SOPP 8504

Version #2

Date: June 19, 1998

1. Purpose

Describes the policies and procedures for releasing Establishment Inspection Reports (EIRs) to inspected establishments in accordance with Field Management Directive (FMD) 145 when a Center for Biologics Evaluation and Research (CBER) inspector was the lead inspector for the inspection, including those inspections conducted jointly with the FDA/Office of Regulatory Affairs (ORA). For inspections of facilities regulated by CBER where lead responsibility for inspections has been delegated to ORA, the lead ORA district or the Division of Emergency and Investigational Operations (DEIO) will be responsible for the release of the EIRs.

2. Background

Historically, establishments that wished to obtain copies of EIRs for inspections performed at their facilities were required to request the reports through the same Freedom of Information (FOI) procedures as the general public. Industry expressed concern to FDA that copies of EIRs were released to other requesters prior to release to the inspected facilities. The agency responded to the concerns by instituting a policy to routinely provide the EIR to the inspected establishment once the agency concludes that the inspection is closed. The policy was published as Field Management Directive (FMD) 145, effective April 1, 1997.

FMD 145 was initially intended only to apply to inspections performed by the field investigators, or inspections in which ORA was deemed to be the lead. In an effort to harmonize agency activities, CBER agreed to release EIRs in the same manner.

For the purpose of the release of EIRs, an inspection classified No Action Indicated (NAI) or Voluntary Action Indicated (VAI) will be deemed closed immediately following the final classification of the inspection. For those EIRs classified Official Action Indicated (OAI), the inspection will be deemed closed if agency action has been taken as a result of the inspection findings and is concluded or the agency has determined it will take no official action. For the purposes of this procedure, the standard to be used to determine when an inspection is closed for the purpose of releasing the EIR to the inspected firm is the same as that established by CBER, Office of Communication, Training, and Manufacturers Assistance, Access Litigation and Freedom of Information Branch for determining when an inspection is closed for the purpose of releasing inspection documents.

For inspections of establishments jointly conducted by ORA and CBER where ORA is the lead, the lead district or, in the case of foreign inspections DEIO, will be responsible for the release of the EIR. For joint inspections where CBER has the lead, or any inspections performed solely by CBER personnel, CBER will be responsible for release of the EIRs. For inspections that are performed by the field but are referred to CBER for final

classification, such as bioresearch facilities, the inspecting district will release the EIR after final classification by CBER.

These procedures apply only to the release of the EIR narratives. Endorsements and other inspection documents, including exhibits, will be released through normal FOI channels when appropriate. EIRs will only be released if doing so will not adversely affect ongoing regulatory or administrative actions, regardless of the classification of the inspection.

3. Statement of Policy

It is the policy of CBER to release EIRs to the inspected establishment after the inspection has been deemed closed, without the firm submitting an official FOI request. All EIRs released in accordance with this policy will be redacted as appropriate. Firms will not be charged fees for the EIRs released under this program

4. Procedures

1. Upon completion of an inspection of a facility in which a CBER investigator is the lead investigator, the inspection team will prepare the EIR per established procedures and time frames. When the EIR is complete, it will be forwarded to the Team Biologics Liaison Staff (TBLS), Office of Compliance and Biologics Quality, HFM-605.
2. The EIR will be assigned to a member of the TBLS for review and evaluation.
3. The TBLS team member will review and evaluate the EIR, and will classify the report as either NAI, VAI, or OAI. The original report, exhibits, and endorsement will be forwarded to DCC for filing.
4. When the inspection has been deemed closed, the TBLS Office Automation Assistant or other designated person will forward a copy of the EIR to Office of Communication, Training, and Manufacturers Assistance, Access Litigation and Freedom of Information Branch (ALFOI). The EIR will be accompanied by a cover memo, indicating that the EIR should be reviewed for appropriate redaction. The TBLS tracking system will be updated to show that the EIR was forwarded to ALFOI.
5. ALFOI will redact the EIR, as appropriate. After the EIR is redacted, the ALFOI reviewer will make a notation on the cover memo that the redaction is complete and will return the EIR to the TBLS.
6. Upon receipt of the reviewed EIR, the TBLS Office Automation Assistant or other designated person will prepare a cover letter (Attachment 1) to the firm to accompany the reviewed EIR. The cover letter should be addressed to the most responsible person at the firm. The EIR and cover letter should be reviewed by the TBLS Team Leader prior to mailing.
7. After the TBLS Team Leader reviews the EIR and cover letter, he/she will sign the letter and forward the documents to the designated person for mailing. If the EIR contains confidential or trade secret information, it should be sent via certified mail.
8. The TBLS will forward a copy of the cover letter and the initialed cover memo indicating the EIR was reviewed by ALFOI to DCC for filing in the EIR file. A copy of both documents should also be retained in the TBLS files. The TBLS tracking system should be updated to show the EIR was sent to the firm.

5. Effective Date

June 19, 1998

6. Appendix

[Letter to Accompany EIR to the Inspected Facility](#)

7. History

Comment / Revision	Approved By	Approval Date	Version Number	Comment
J. Thomas	Rebecca Devine	6/18/98	1	First Issuance

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