Sections in This Document

Purpose

This Field Management Directive (FMD) provides definitions, responsibilities, and procedures for assigning inspection conclusions, Program Division decisions, and the final inspection classification to an Establishment Inspection Report (EIR) within established timeframes.

Scope

The classification process, which involves endorsing an inspection and entering a firm's final profile status, must be accurate, timely, and uniform since the compliance status of EIRs has broad ramifications and impacts directly on critical public health issues. The procedures outlined in this FMD are designed to bring greater uniformity in decisions and conclusions in conjunction with FDA databases (the Field Accomplishments Compliance Tracking System (FACTS), Electronic State Access to FACTS (eSAF), eNSpect, Compliance Management Services (CMS), etc.). [Note: Current business practice has mostly transitioned to using eNSpect for inspectional operations; however, FACTS may still be used on a limited basis for certain compliance operations, as well as inspection operations. Therefore, all systems are recognized and referenced in this FMD. Furthermore, FDA databases may continue to reference the former term "District Decision;" however, in this document, this will be referred to as the "Program Division Decision."]

The procedures in this FMD apply to both domestic and foreign inspections, including state contract inspections. Except for instances where Program specific procedures indicate that the relevant product center or headquarters' Division is responsible for final classification, the final classification of the inspection is made by the ORA Program Office. For foreign inspections, the reviewing center office may serve in (or as) the Compliance Branch role with the responsibilities described herein. For Produce Safety Rule inspections, the reviewing center office serves in (or as) the Compliance Branch role with the responsibilities described herein. Centers may follow their respective procedures in which they are responsible for final classification. FMDs are the primary vehicle for distributing procedural information on the management of ORA field activities and is intended as internal instructions to field managers. This document does not currently include determinations of inspection conclusions and final inspection classifications for Interstate Travel Program (ITP) inspections.

Violations of state law or regulations not actionable under current FDA policy are not used to support No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI) classifications. These violations should be pursued under the state programs and the inspection should be classified as Referred to State (RTS). Please see the procedures below related to RTS classified EIRs.

If a Program or Office enters into an agreement with a Center, such as a Concept of Operations (CONOPS), the agreement's timelines and specifics for which office will enter final classification and profiles should be followed. All other requirements of this FMD will remain in effect.

Responsibility

A. Program Division

1. Program Division Director

    a. Ensures activities are carried out in accordance with this directive by the responsible individuals under his/her authority including, but not limited to, the Investigations Branch, State Liaison, and Compliance Branch.

B. Investigations Branch (IB)

1. Director, Investigations Branch (DIB)

    a. Ensures appropriate communication with Compliance Branch, when appropriate, when IB makes inspection classification decisions.

2. Supervisory Consumer Safety Officer (SCSO):

    a. Reviews the EIR and evidence collected by FDA Consumer Safety Officers (CSO) to determine and enter the Inspection Conclusion, Program Division Decision, and where applicable, final classifications and Profiles, based on relevant policy and procedure (see Section 6 below).

    b. Recommend to Compliance Branch for appropriate action when necessary.

3. Consumer Safety Officer (CSO)

    a. Completes EIR within required timeframe for the specific classification.

C. Compliance Branch (CB)

1. Director, Compliance Branch (DCB)

    a. Ensures appropriate communication with IB, Center and State Liaisons when making final classification decisions.

    b. Reviews and assigns inspections referred to Compliance Branch.

2. Compliance Officer (CO)

a. Reviews the CMS Work Activity for inspections assigned to them by their DCB or designee. After assessing the recommended IB decision, takes appropriate action as necessary.

b. Enters the appropriate final profile status in the appropriate FDA database (e.g. eNSpect, CMS, etc.), if applicable, within required timeframe except in cases where the reviewing Center is responsible for entering the final profile.

c. Enters the final Program Division Decision in the District Decision field for each Program Assignment Code (PAC), Establishment Type, and Process Code combination in the appropriate FDA database (e.g. eNSpect, CMS, etc.) for the cases noted above within the required timeframe, except in cases where the reviewing Center is responsible for entering the final Program Division Decision.

d. Initiates further activities to evaluate the evidence, e.g. follow-up assignments, reference searches, consultations, regulatory meetings, etc., to arrive at the appropriate final decision (See RPM Chapter 10-3 for further discussion and uses of Regulatory Meetings.)

D. State Liaison

1. Reviews an EIR prepared by a state inspector and evidence collected to determine the Inspection Conclusion, Program Division Decision and where applicable Profiles, based on relevant policy and procedure, and accept the inspectional information from eSAF where applicable. Refers to ORA State Contract Inspection Process and state contract inspection's Statement of Work (SOW) for procedures related to reviewing state contract inspection reports.
2. In consultation with IB and CB, recommends compliance action when necessary.
3. Provides copies of this FMD and any other pertinent guidelines, as needed, to the State officials responsible for submitting EIRs to FDA and instructs them in the use of these criteria to assure assignment of uniform classifications to state inspections performed under FDA contracts or agreements.

Background

ORA conducts inspections of establishments that manufacture (including compounding), process, pack, or hold FDA-regulated products, before

approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA.

ORA provides initial classification of the inspection based on the observations noted during the inspection, the investigator's report, and ORA Program Office supervisory personnel review. An initial inspection classification reflects the compliance status of the establishment at the time of the inspection, based on the observations documented, and endorsed by a supervisory consumer safety officer. The compliance status of the inspection, both foreign and domestic, is reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), No Action Indicated (NAI), or Referred to State (RTS) (e.g., inspection classification). The initial classification will reflect the "Inspection Conclusion," "Program Division Decision," and the recommended advisory, administrative or judicial action, if applicable.

Final classifications (submission, supervisory endorsement, and Program Division Decision) of EIRs should be completed in accordance with the current regulatory action time frames for the anticipated regulatory action, commensurate with the classification. Refer to the Statement of Work (SOW) for timeframe requirements associated with inspections conducted pursuant to a state contract. Please see the Regulatory Procedures Manual for timeframes associated with administrative, advisory and judicial actions.

All endorsements with Program Division Decisions classified as Referred to State (RTS), VAI or OAI must (1) cite or be associated with a violation(s) of a specific law, regulation, or administrative requirement, (2) identify the specific action being recommended, and (3) be supported by documented evidence as follows:

- FDA's jurisdiction and interstate commerce (unless the classification is RTS and FDA cannot or will not take action), and/or
- A summary of objectionable conditions listed on the Inspectional Observations Form FDA 483, and Produce Farm Inspection Observations Form FDA 4056 in the EIR, and/or related documents which are cited by the Program Office to support a specific regulatory (advisory, administrative, or judicial) recommendation or other follow-up.

Investigations Branch and State Liaisons inform CB whenever objectionable conditions are observed that may warrant a regulatory action or follow-up communication. IB, State Liaisons and CB will collaborate to ensure that each

EIR and the subsequent Program Division Decision, Final Decision, recommendations, and final profile status are accurate, timely, uniform, and adequately documented.

References

A. Investigations Operations Manual (IOM) (Chapter 5)
B. Regulatory Procedures Manual (RPM)
C. Compliance Program Guidance Manual (CPGM)
D. Compliance Policy Guide (CPG)
E. Guidance for Industry (GFI)
F. Management of ORA State Contract Inspection Process (SOP-000115)
G. FMD-50 State Communication
H. State Contract inspection's Statement of Work (SOW)

Procedure

6.1. ORA Conducted Surveillance Inspections

A. The EIR should be written and endorsed within a timeframe commensurate with the current regulatory action time frames for the anticipated regulatory action, but generally not to exceed 30 working days when no further action is expected from the "Close Date" of the inspection if the inspection will be classified NAI or VAI, unless specific program policy and/or CONOPS dictates otherwise. For OAI classification, For-Cause Assignments and/or ORA Compliance Follow-up Assignments, see the Regulatory Procedures Manual and/or program specific CONOPS for timeframes associated with administrative, advisory and judicial actions.

B. SCSO reviews the EIR and supporting evidence and determines if any objectionable conditions exist.

C. If objectionable conditions exist and IB is recommending regulatory action see section F. (NOTE: IB should consult with CB as soon as possible if an advisory, administrative, or judicial action is being considered. IB should also consult with CB if a recall activity is in progress or being considered.)

D. NAI Classification

1. If no objectionable conditions or practices were found during the surveillance inspection, the SCSO enters an Inspection Conclusion and final Program Division Decision of No Action Indicated (NAI), checks the Final Decision block for each PAC, Establishment Type, and Process Code combination, and finalizes profiles, if applicable, in eNSpect, unless the Program requires the Center or Compliance (for example: a for-cause, compliance follow-up) to review and finalize.

E. VAI Classification with no recommended action or CB referral

1. If objectionable conditions or practices were found during surveillance inspections, and the Division is not prepared to recommend an advisory, administrative or judicial action, the SCSO enters the Inspection Conclusion of Correction Indicated (CI), a final Program Division Decision of Voluntary Action Indicated (VAI), checks the Final Decision block for each PAC, Establishment Type, and Process code combination, and finalizes profiles, if applicable, in eNSpect unless the Program requires the Center or Compliance (for example: a for-cause, or compliance follow-up) to review and finalize.

F. Inspections referred to CB

1. After communication with CB, if IB concludes that valid and documented objectionable conditions or practices warrant consideration for advisory, administrative, or judicial action, the SCSO enters in eNSpect the Inspection Conclusion of Correction Indicated (CI) for a Program Division Decision that is recommended as VAI or Official Action Indicated (OAI).
    a. If applicable, the CSO or SCSO enters the initial profile status for the firm.
    b. The SCSO does not enter a final decision in eNSpect for any PAC associated with the inspection.
    c. The SCSO includes in the EIR endorsement a summary of inspection findings and a recommended action.
    d. IB refers the case to CB. Refer to IOM Chapter 5.11 Reporting, Exhibit 5-14.1 and 5-14.3.10 for violative inspections.
2. CB reviews the evidence collected to support the recommended classification and action. CB consults with IB and Center Compliance Officers as necessary and follows procedures for case processing contained in the Regulatory Procedures Manual, Program procedures and, if applicable CONOPS.

a. For OAI compliance cases that require Center review, the CO should enter an OAI classification decision to reflect the ORA Compliance Branch Review. For this circumstance, the OAI classification entered by the CO should NOT be marked as the final Program Division decision.

b. Unless roles and responsibilities are specified in a written agreement between ORA and the Center (Example: CONOPS), the ORA Compliance Officer enters the final Program Division Decision and checks the Final Decision block for each PAC, Establishment Type, and Process code combination, and if applicable, finalizes profiles in the appropriate FDA database (e.g. eNSpect, CMS,etc.) within 5 working days of an action being taken, or a decision has been made not to pursue an action. The ORA CO enters the following:

   i. If the final action taken is a Warning Letter, the Final Decision must be OAI.

   ii. If the final action taken is an Untitled Letter, the Final Decision must be VAI.

   iii. If the action taken is a Regulatory Meeting, where the previous inspection was classified OAI and a Warning Letter, administrative, or judicial action was taken, the Final Decision may be OAI.

   iv. If the action taken is a Regulatory Meeting, where the previous inspection was not classified OAI, the Final Decision should be VAI unless the Center or the Program determines the inspection is OAI as documented in the CMS case (e.g. in a decision memo or a CMS “Activity Note”). (See RPM Chapter 10-3 for appropriate uses of Regulatory Meetings.)

c. Within 5 working days of an action being taken or a decision has been made not to pursue an action (NOTE: This decision should be documented) the division compliance officer enters the final Program Division decision, checks the Final Decision block for each PAC, Establishment Type, and product code, and if applicable, finalizes profiles in the appropriate FDA database (e.g. eNSpect, CMS, etc.)

G. Referred To State (RTS) Classification

1. If objectionable conditions or practices are present, but the Agency either does not have jurisdiction over the apparent violation or it is determined that state action is the most efficient method of obtaining the establishment’s compliance with applicable federal or state laws, regulations or administrative requirements, IB may endorse in

eNSpect a Program Division Decision of Referred to State (RTS) for all applicable PAC, Establishment Type, and Process code combinations, and notify Compliance Branch of the recommendation. Compliance Branch must be informed prior to contacting the State.

2. The Program Division Decision of RTS should not be used for inspections where valid and documented objectionable conditions or practices warrant consideration for regulatory actions under the Agency's jurisdiction. In these cases, an inspection is viewed as OAI, and the IB must enter an Inspection Conclusion of Correction Indicated (CI) and a recommendation of OAI as the Program Division Decision and follow the steps for OAI inspection classifications per section 6.1.F.
3. The Division maintains close communication with their state partner to monitor the action and follow-up inspections, to verify the violations were corrected, and/or to ensure appropriate regulatory follow up action is taken when appropriate. These follow-up actions must be recorded and tracked in CMS under the appropriate Referred to State work activity.
4. If CB concurs with the IB Referred to State recommendation, CB or State Liaison prepares the memorandum to the State and creates and enters the referral action in CMS under the Work Activity category of "District - Referred to State." CB or State Liaison monitors the State's response and uploads corresponding documentation in CMS under the appropriate tabs or sections.
5. If the final Program Division Decision is different from what was recommended, CB or State Liaison changes the Division Decision to reflect the appropriate Final Decision in eNSpect.

6.2. ORA Conducted Compliance Follow-Up

A. Background:

An OAI classification indicates that an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health. It also may delay an establishment seeking government contracts or approvals. Therefore, an appropriate and timely follow-up inspection is encouraged and usually the standard to ensure compliance and corrections to violations at an establishment where the most recent inspection was classified as OAI. ORA's goal is for these follow-up inspections to be conducted at domestic

establishments within six months after an OAI classification has been finalized and any actions taken.

B. Assignment Creation Timeframes:

1. CB will issue to IB a Compliance Follow-up Assignment. Further CB will work with IB and/or the Center (if applicable) to schedule a follow-up inspection to normally be conducted within six months after an OAI classification has been finalized and any actions taken for domestic inspections. Exceptions include:
2. A domestic follow-up inspection may be conducted in less than six months after an action is taken as the result of an OAI classification, such as when a significant hazard to health exists and/or when the Agency may be contemplating an enforcement action.
3. A domestic follow-up inspection may be conducted greater than six months after an action is taken as the result of an OAI classification, such as when the firm is actively engaged with the Division regarding corrective actions requiring a greater length of time to implement or when there are limited resources or there are higher priority assignments. If this occurs, the Compliance Officer documents the reason in CMS. For foreign establishments with an OAI classification, the reviewing Center will determine if a re-inspection is needed and work with ORA to schedule the re-inspection.

C. Completion of Follow Up Inspection:

1. The EIR should be written and endorsed within 10 working days from the “Close Date” of the inspection if IB is recommending the inspection be classified NAI or VAI unless program specific policy and/or CONOPS dictate otherwise. For OAI classification, see the Regulatory Procedures Manual for timeframes associated with administrative, advisory and judicial actions. NOTE: If shorter timeframes are identified in the assignment, follow these timeframes.
2. SCSO reviews the EIR and determines if any objectionable conditions exist. Further IB review may occur. IB may also consult with CB (See 6.1.C).
3. The SCSO endorses the EIR and enters in eNSpect the initial Inspection Conclusion and recommended Program Division Decision for all PACs for each Establishment Type, and Process Code combination, and if applicable, enters the initial profile, in eNSpect. For OAI classification, follow procedure in 6.1.F. For RTS classification, follow procedure in 6.1.G.

4. For Compliance Follow-up, the Compliance Officer enters the final Program Division Decision and checks the Final Decision block for all PACs for each Establishment Type and Process Code combination, and if applicable finalizes the profiles, in the appropriate FDA database, such as (e.g. eNSpect, CMS, etc.) within 10 working days of concurring with the IB endorsement for NAI or VAI inspections. For OAI inspections, CB follows procedure in 6.1.F.

6.3. ORA Conducted for Cause Inspections (ORA or Center Initiated)

A. If the inspection is classified NAI or VAI follow procedures under 6.1.D or 6.1.E, unless program specific policy and/or CONOPS dictate otherwise. If the inspection is classified as OAI, follow procedures under section 6.1.F. If the inspection is classified RTS, follow procedure in 6.1.G.

6.4. ORA Conducted Pre-Approval Inspections

A. The timeframes above should be adhered to for NAI, VAI and OAI classifications unless program specific policy and/or CONOPS dictates otherwise. Follow program specific requirements for determining if the Program or the Center finalizes the Program Division Decision in the appropriate FDA database (e.g. eNSpect, CMS, etc.).

6.5. Inspections Conducted Under State Contract

A. Upon completion of a state inspection conducted under contract, states classify inspections in eSAF. Classifications provided for states in eSAF vary from those available for FDA within FACTS. The following chart compares how the available state eSAF codes transfer over once the inspection appears in FACTS. There are two codes in eSAF which appear in FACTS as NAI, two eSAF codes which translate to VAI in FACTS, one eSAF code that transfers over as OAI in FACTS and one other code in eSAF which transfers over into FACTS as RTS.

eSAF Classification	eSAF Code	Transfer Code	FACTS Code	FACTS Classification
No action indicated	NAI	N	NAI	No Action Indicated (NAI)
No action/follow-up inspection	NFI	N	NAI	No Action Indicated (NAI)
Voluntary action indicated	VAI	E	VAI	Voluntary Action Indicated (VAI)
Violation/follow-up inspection	VFI	E	VAI	Voluntary Action Indicated (VAI)
Action referred to FDA	RAI	A	OAI	Official Action Indicated (OAI)
State/Title action indicated	SAI	I	RTS	Referred to State (RTS)

6.5.1. Classification of non-violative state contract inspection report

A. After review of a state contract inspection report, if the State Liaison concludes that no objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action, then the State Liaison must accept or endorse the state designated NAI or NFI (No action/follow-up action) inspection classification in the eSAF system. Note that the inspection classification codes in eSAF of NAI or NFI are equivalent to the NAI inspection classification in FACTS.

B. For medical device state contract inspections, the Office of Medical Device and Radiological Health Operations (OMDRHO) Supervisor reviews the contract inspection report to verify if the classification is correct. This information is shared with the State Liaison who will accept the code in eSAF**.**

C. If objectionable conditions and practices were observed, but the Division is not prepared to take or recommend any regulatory action, or the objectionable conditions found do not justify further action, then the State Liaison should accept or endorse the state designated VAI or VFI (Violation/follow-up inspection) inspection classification in eSAF. Note that the inspection classification codes in eSAF of VAI or VFI are equivalent to the VAI inspection classification in FACTS.

   1. Medical device state contract inspections that find significant actions are followed-up by the state, not OMDRHO.

D. The State Liaison is responsible for approving or endorsing the NAI, NFI, VAI or VFI inspection classification or inspection package in eSAF as soon as possible, but no later than 15 working days after completing the review of the inspection report and/or package.

6.5.2. Classification of violative state contract inspection reports

A. Classification of state conducted inspections should follow the same procedures as for FDA conducted inspections. The following procedures should be followed when the division is classifying potentially violative inspections from a state inspection. Also, consult the Regulatory Procedures Manual for procedures on using state data to support FDA action.

B. If the State Liaison concludes that valid and documented objectionable conditions or practices warrant consideration for advisory, administrative, or judicial action, and it is determined that further action or follow-up by FDA is necessary, then the State Liaison must accept or endorse the state-designated RAI inspection classification in eSAF. The

RAI code in eSAF is equivalent to the OAI inspection classification in FACTS. In these instances, the division should not use the RTS designation.

C. The State Liaison includes in the EIR endorsement an evaluation of inspection findings and a recommended action and informs CB of the recommended action. The State Liaison creates a Division – Inspections/Consults work activity in CMS which sends a notification to CB in CMS. When FDA takes the action on a state contract inspection, IB or State Liaison and CB must follow normal procedures for tracking, monitoring and documenting actions and outcomes per procedure 6.1.F above.

D. Compliance Branch reviews the evidence collected to support the recommended OAI classification. If appropriate, CB converts the Work Activity in CMS to a compliance case. Compliance Branch consults with the State Liaison and Center Compliance Officers as necessary and follows procedures for case processing contained in the Regulatory Procedures Manual.

E. The Compliance Officer enters the final Program Division Decision and checks the Final Decision block for all PACs for each Establishment Type and Process Code combination, and if applicable, finalizes profiles in FACTS within 5 working days of an action being taken or a decision has been made not to pursue an action is made.

F. For OAI inspection classifications resulting in cases where Center concurrence is required, and the Center Compliance Officer changes the action and/or classification to VAI, CB enters the final Program Division Decision, documents the reason for the change in the Remarks section, checks the Final Decision block for all PACs for each process code, and if applicable, finalizes profiles in FACTS within 5 working days of an action being taken or a decision has been made not to pursue an action.

6.5.3. Classification of state contract inspection report where state action is indicated

A. After review of the state contract inspection report, if objectionable conditions or practices are present, but the Agency either does not have jurisdiction over the apparent violation in question or it is determined that state action is the most efficient method of obtaining the establishment's compliance with applicable federal or state laws, regulations or administrative requirements, the State Liaison may recommend the State consider some action and notify Compliance Branch of the recommendation. The State Liaison must accept or

endorse the state-designated state contract inspection in eSAF as SAI. Note that the inspection classification code of SAI in eSAF is equivalent to the RTS inspection classification in FACTS. The State Liaison notifies Compliance Branch of the State's action and activities. Compliance Branch must be informed prior to contacting the State.

1. The division must maintain close communication with their state partner to track and monitor the action taken and completion of follow-up inspections and to verify that the violations were corrected or that appropriate regulatory follow up is taken. These follow-up actions must be recorded and tracked in CMS under the Program Division – Referred to State work activity. The State Liaison is responsible for creating the work activity in CMS and monitoring the State's follow-up actions or activities. All associated documents must be uploaded to the record under the appropriate tabs or sections.

6.6. Referral to Office of Criminal Investigations (OCI)

A. Whenever an EIR is referred to OCI for further investigative follow-up or as part of an OCI case, the report should be classified as OAI. Please see IOM 5.2.2.5 for information related to when evidence related to potential criminal activity is found during a regulatory inspection.

6.7. Monitoring Inspection Report Conclusions and Decisions

A. The Program Division Director, or designee, evaluates the data on the ORA Program Accomplishment Dashboard to monitor the number of inspections without a final decision on a periodic basis.

B. The Program Division Director, or designee, reconciles any inspections without a final decision that are outside the timeframes in this FMD and ensures corrective actions are taken to prevent recurrence.

6.8. Instructions for Washouts

A. Whenever an establishment assigned to be inspected is determined to be Out of Business (OOB), or no inspection was made since the firm is not FDA regulated, seasonal operations only, or inactive, no "Inspection Conclusion" and "Program Division Decision" or other inspection data should be entered for this assignment.

1. In this case, an inspection operation should be converted to an investigation operation (OP13 if domestic and OP15 if foreign) and reported as a "washout". eNSpect User Guide contains instructions to convert the inspection operations to an investigation operation and "set to washout" for one of seven different reasons, including:

inactive, not official establishment inventory, out of business, firms don't meet assignment criteria, not FDA obligation, pre-production, and seasonal.

7. Glossary/Definitions

A. The Inspection Conclusion:

1. Indicates IB management's (or State Liaison's) evaluation of the significance of objectionable conditions and/or practices found during the inspection. NOTE: If an inspection covers more than one PAC and product/process, there must be an Inspection Conclusion recorded for each PAC and product code combination.
2. Inspection Conclusion definitions are listed as follows:

Inspection Conclusion	Definition
No Action Indicated (NAI)	No objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further FDA action).
Correction Indicated (CI)	Objectionable conditions and practices were found during the inspection, for which the establishment failed to meet either regulatory or administrative requirements. A CI conclusion should be made only if an FDA 483, FDA 4056, or state equivalent, has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3. Correction may be achieved through the firm's voluntary action or FDA action.

B. Program Division Decisions

1. The Program Division Decision represents the action that the Division will take or recommend after considering the findings of the inspection, any events that occurred following the findings, and Agency policy. Investigation and Compliance personnel are responsible for entering the Program Division Decision for EIRs as outlined in the Procedure section of this FMD. The Final Program Division Decision represents the final classification of the inspection and is completed after an action being taken or a decision has been made not to pursue an action. Each PAC will require a Final Division Decision and the worse-case PAC is the overall final

classification for the inspection. For example, an inspection may have several PACs, some of which have a Final Division Decision of NAI, VAI, and OAI (see definitions below). In this case, the final classification for the inspection would be OAI. In FDA databases, this may be referred to by the former term, "District Decision."

The following Division Decisions will be used as applicable:

Division Decision	Definition
No Action Indicated (NAI)	No objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).
Voluntary Action Indicated (VAI)	Objectionable conditions were found and documented but the Division and/or Center is not prepared to take or recommend any of the following regulatory actions (warning letter, administrative, or judicial) since the objectionable conditions do not meet the threshold for these actions. The division may use an Untitled Letter, Response Letter, or Regulatory Meeting or other communication with responsible individuals to inform the establishment of findings that should be corrected. The division may request a written response from the establishment, but this is not necessary. Any corrective action is left to the establishment to take voluntarily. A VAI classification should be made only if an FDA 483, FDA 4056. or state equivalent, has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3. A VAI classification can be made only if the Inspection Conclusion is CI.
Official Action Indicated (OAI)	Objectionable conditions were found and regulatory (advisory, administrative, or judicial) action should be recommended. NOTE: There are specific criteria described in the above procedure that must be met for a regulatory meeting to be classified OAI. An OAI classification is most often made if an FDA 483, FDA 4056, or state equivalent, has been issued and the documented evidence supports the action recommended unless the only significant observations are non-reportable, as specified by IOM 5.2.3.3, or in matters referred to OCI, as noted in "Referral to Office of Criminal Investigations (OCI)" above. An OAI classification may also be made when a state contract inspection is

	determined to be violative and the State Liaison, in consultation with Compliance Branch and/or the State Contract Agency determine FDA follow-up or action is required. An OAI classification can be made only if the Inspection Conclusion is CI.
Referred to State (RTS)	Referred to state, local, or other federal office. This classification may be used when either there is no federal jurisdiction over the apparent violation in question or it is determined state action is the most efficient method of obtaining the establishment's compliance with applicable federal laws, regulations, or administrative requirements. An RTS classification can be made only if the Inspection Conclusion is CI.

C. Field Management Directive: The Field Management Directives (FMD) Manual is the primary vehicle for distributing procedural information on the management of Office of Regulatory Affairs (ORA) field activities. The manual is issued on the authority of the Associate Commissioner for Regulatory Affairs (ACRA) and is intended as INTERNAL instructions to field managers. Introduction to the Field Management Directives Manual | FDA

Records

The following systems contain the electronic records created during the inspection's conclusion and decision process.

A. FACTS
B. CMS
C. eSAF
D. eNSpect

Supporting Documents

N/A

Document History

Revision	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
6.0	R	01/28/2014	David K. Glasgow, Acting Deputy Director, OFFO	Ellen Morrison, Assistant Commissioner for Operations
07	R	12/14/2022	DCB Advisory Committee	Judy McMeekin, ACRA

* - D: Draft, I: Initial, R: Revision

Change History

Revision #	Change
3.0	Provided the determination of appropriate classification, the follow-up with State Contract Agency to verify violations or appropriate regulatory follow-up is taken, and the authorization to insert "Final Decision" in FACTS to the District's IB or Compliance staff for State Contract Inspections; Added OAI follow-up inspection recommended timeframes.
4.0	Revision to Referred to State District Decision, clarifying language to assist in the classification of state contract inspection reports and providing guidance on using Case Management System (CMS) to track inspections referred to the state for action.
5.0	The following clarifications/changes have been added: **Section 5.1**.,item (2) a) added "which will be entered after the action has been completed (Untitled Letter issued or Regulatory Meeting held)" **Section 5.2**, item 1) clarified "the compliance officer will enter the final decision in FACTS after the appropriate action has been taken or the decision to reclassify has been made." 2) Added "and enter the Final Decision in FACTS upon completion of the action or reclassification." 3) Added clarification "final classification will be entered by the compliance officer after any appropriate actions have been taken or the inspection re-classified." 4) Clarified sentence "and take or recommend any appropriate action. The compliance office will enter the "Final Decision" in FACTS after any actions have been completed or the inspection re-classified." **Section 5.3**, item 3) added "Final decisions will be entered in FACTS once the final District Decision has been determined. For OAI classification, the Final Decision shall not be entered until after the action has been taken."
6.0	Complete revision. Re-ordered for QMS SOP Template. Responsibilities and Procedures separated to provide clarity.
07	Complete revision. Reformatted to follow the inspectional flow and current naming/numbering scheme. Clarified timeframes for NAI/VAI endorsement to include both EIR writing and SCSO endorsement and added timeframes for Compliance Officers to complete final Division Decision. Included reference to CONOPS. Revised classification requirement for Untitled Letters and clarified classifications for regulatory meetings. Removed Refer to Center (RTC) classification option. Clarified ORA's 6-month goal for OAI follow-up inspections apply to domestic inspections only and added exemptions for limited resources or high priority assignments. Added clarifications for state contract inspection classifications. Added requirement to monitor inspection status (6.7). Updated Definitions section. Removed reference to District and changed reference to Division or Program Divisions.

Attachments

List of Advisory, Administrative, and Judicial Actions that could be recommended by the SCSO to the Compliance Branch.

List of Attachments

Attachment A - Advisory Actions

See Regulatory Procedures Manual Chapters 4

Untitled Letter

Warning Letter

Attachment B - Administrative and Judicial Actions

See Regulatory Procedures Manual Chapters 5, 6, 7

Application Action: e.g. {Recommendation for Denial of Pending Application (NDA, NADA, ANDA, PMA, etc.); Recommendation for Revocation of Approved Application (NDA, NADA, ANDA, PMA, etc.)}

Banning

Certification Withholding or Revocation Citation

Civil Money Penalty

Demand for Destruction or other Disposition

Disqualification

Administrative Detention

Suspension of Registration

Emergency Permit Disapproved

Injunction

License Action: e.g. {Denial, Suspension, or Revocation; Notice of Intent to Revoke License (for Biologics)}

Prosecution

Provisional Listing

Recall (FDA mandatory)

Remove from Shippers List

Seizure/Detention

Attachment C - Other Procedures

See Regulatory Procedures Manual Chapter 10

Regulatory Meetings