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1. Purpose


This Field Management Directive (FMD) provides definitions, responsibilities and procedures for assigning District Office Inspection Conclusions and District Decisions to an Establishment Inspection Report (EIR) within established timeframes.

2. Scope

The classification process must be accurate, timely, and uniform since the compliance status of EIRs has broad ramifications and impacts directly on critical public health issues. The changes outlined in this FMD are modifications designed to bring greater uniformity in decisions and conclusions in conjunction with FACTS.

The procedures in this FMD apply to both domestic and foreign inspections conducted by FDA investigators. For foreign inspections, the reviewing center office serves the Compliance Branch role and responsibilities described herein. This document does not currently include classification of inspection conclusions and district decisions for Interstate Travel Program (ITP) inspections.

Violations of state law or regulations that are not actionable under current FDA policy, are not used to support NAI, VAI or OAI classifications. These violations should be pursued under the state programs and should be classified as Referred to State (RTS). Please see the procedures below related to RTS classified EIRs.

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3. Responsibility

A. Investigations Branch (IB):

1. Supervisory Investigator reviews the Establishment Inspection Reports (EIR) completed by district investigators and evidence collected to determine the Inspection Conclusion and District Decision based on relevant policy and procedure, such as the Investigations Operations Manual (IOM), Compliance Program Guidance Manual (CPGM), Compliance Policy Guides (CPG), and/or the Regulatory Procedures Manual (RPM).
2. Promptly enters the Inspection Conclusion and District Decision in FACTS for each Program Assignment Code (PAC) and product covered during the inspection following the completion of the official EIR.
3. Takes or recommends appropriate action when necessary information has not been obtained to determine the Inspection Conclusion and District Decision, including having the investigator return to the firm to collect necessary information, develop a strategy to overcome the lack of necessary information or decide the appropriate action to take in absence of this information.

B. Compliance Branch (CB):

1. Reviews the EIR, endorsement, evidence collected and other information provided when IB has determined that objectionable conditions or practices were found, that adequate evidence is present, and has recommended a District Decision of Official Action Indicated (OAI), Referred to Center (RTC) or Referred to State (RTS).
2. Evaluates the IB referral and takes appropriate action as required.
3. Develops an enforcement strategy in collaboration with IB, the reviewing Center(s), and/or ORA Headquarters as appropriate, when evidence is insufficient.
4. Enters the Final District Decision in FACTS for the District in the cases noted above, as well as when IB has recommended an Untitled Letter or Regulatory Meeting, except when the reviewing Center has the final classification


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authority, in which case the Center Compliance Office will be responsible for entering the Final Classification.

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

C. District Director Office / State Contract Inspection

1. Ensures activities are carried out in accordance with this directive for State Contract inspections by the responsible position, such as a Supervisory Investigator, State Liaison or Emergency Response Coordinator.
2. Reviews an EIR prepared by a state inspector the same as an FDA prepared EIR, except for added procedures related to tracking inspections and monitoring follow-up activities. Please see [ORA-ACRA.008, Management of ORA State Food Contract Inspection Process](#) for procedures related to reviewing state contract inspection reports. Please see specific procedures for State Contract inspection classification below.
3. Reviews the EIR and evidence collected to determine the Inspection Conclusion and District Decision based on relevant policy and procedure, such as the Investigations Operations Manual (IOM), Compliance Program Guidance Manual (CPGM), Compliance Policy Guides (CPG), and/or the Regulatory Procedures Manual (RPM).
4. Promptly enters the Inspection Conclusion and District Decision for each PAC and product covered during the inspection following the completion of the official EIR and acceptance from the Electronic State Access to FACTS system (eSAF) where applicable.
5. Take or recommend appropriate action when necessary information has not been obtained.
6. Provide copies of this FMD and any other pertinent guidelines to the State officials responsible for submitting EIRs to FDA and instruct them in the use of these criteria to assure assignment of uniform classifications to state inspections performed under FDA contracts or agreements

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4. Background


The Field has traditionally followed guidelines based on nationally established policy for the classification of EIRs published in the Regulatory Procedures Manual (RPM), the Data Codes Manual (DCM), and this FMD. Since the implementation of the Field Accomplishments and Compliance Tracking System (FACTS), the Data Codes Manual has not been maintained, however, the information in the DCM may still be used for reference. Domestic and foreign EIRs for all programs will be classified to reflect the compliance status at the time of the inspection. The classification will reflect the “Inspection Conclusion,” “District Decision,” and the recommended advisory, administrative or judicial action, if applicable.

EIRs should be completed and submitted for final classification within a timely manner 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. Please see the [Regulatory Procedures Manual](#) for timeframes associated with Administrative, Advisory and Judicial actions. In all cases, District time frames should be established and adhered to as closely as possible. Please also refer to the ACRA Timeframe Memo located on the [Office of Operations website](#). The District Decision should be determined promptly after completion of the EIR.

All endorsements with District Decisions classified as Referred to Center (RTC), 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 (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, in the EIR, and/or related documents which are cited by the District to support a specific regulatory (advisory, administrative, or judicial) recommendation or other follow-up.

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In the interest of quality and efficiency, it is imperative that IB inform CB whenever significant objectionable conditions are observed that may warrant a regulatory action or follow-up communication. IB and CB will endeavor collectively to assure that each EIR and the subsequent District Decision, Final Decision and recommendations are accurate, timely, uniform, and adequately documented.

5. References

- A. Investigations Operations Manual (IOM)
- B. Regulatory Procedures Manual (RPM)
- C. Compliance Program Guidance Manual (CPGM)
- D. Compliance Policy Guides (CPG)
- E. ACRA Timeframe Memo

6. Procedure

6.1 Investigations Branch Procedures


A. No Objectionable Conditions or Practices Found Inspections:

If the supervisory investigator concludes that no objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action, an Inspection Conclusion of No Action Indicated (NAI) should be entered. The Final Decision block should be checked in FACTS as noted below.

B. Objectionable Conditions or Practices Found Inspections:


If the supervisory investigator concludes that significant, valid and documented objectionable conditions or practices were found, the District Decision must then be one of the following:

1. If the significant, objectionable conditions or practices warrant a Warning Letter or other regulatory actions listed below in the Regulatory Actions (Advisory, Administrative, or Judicial) section, the Supervisory Investigator will enter the District Decision Official Action Indicated (OAI). This would include an establishment conducting a voluntary recall where the District has decided conditions warrant regulatory action.

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The Supervisory Investigator will include in the EIR endorsement an evaluation of inspection findings and a recommended action. Investigations Branch will inform Compliance Branch of the recommended action.

2. When an OAI classification is entered into FACTS, the supervisor will be prompted to create a compliance assignment and should either create a new compliance assignment or link the inspection to an existing assignment.
3. If significant 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 laws, regulations or administrative requirements, IB may recommend the State consider some action, assign a District Decision of Referred to State (RTS), and notify Compliance Branch of the recommendation. Compliance Branch must be informed prior to contacting the state. Please see your district's State Communications SOP and FMD 50. See also [ORA-ACRA.008, Management of ORA State Food Contract Inspection Process](#).
4. If significant objectionable conditions and practices were observed, but the District is not prepared to take or recommend any regulatory action, the supervisory investigator should then assign the District Decision of Voluntary Action Indicated (VAI) and check the Final Decision block in FACTS as noted below.
5. If the Investigations Branch determines that an Untitled Letter or a Regulatory Meeting to discuss the findings is warranted, the endorsement should reflect this decision. Typically, the Supervisory Investigator will enter the District Decision of VAI, create a FACTS Compliance Assignment and inform Compliance Branch. The Supervisory Investigator will not be able to link the "Inspection Record" to the Compliance Assignment upon creating the assignment; however, the Compliance Officer who receives the assignment can do so after changing the status of the

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assignment to “In Progress.” When an Untitled Letter or Regulatory Meeting is recommended by IB, entering the Final Decision becomes the responsibility of CB.


6. If the significant objectionable conditions or practices appear to warrant regulatory action, but the apparent violations noted constitute a compliance area for which no clear policy has been established or there are significant technical issues which require Center review and decision. The Supervisory Investigator will consult with Compliance Branch on current policy and if referral to the Center is required, the Supervisory Investigator will assign the District Decision of Referred to Center (RTC). The endorsement should reflect this decision and the EIR routed to Compliance Branch. Compliance Branch will consult with the reviewing Center prior to forwarding the EIR to the Center for evaluation. NOTE: Do not use “Referred to Center (RTC)” District Decision for Bioresearch Monitoring inspections unless there are extraordinary circumstances. The district must enter a recommended classification using NAI, VAI, or OAI, as appropriate.

6.2 Compliance Branch Procedures

A. Objectionable Conditions or Practices Found Inspections:

1. If the significant objectionable conditions or practices warrant a Warning Letter or other regulatory actions listed below in the Regulatory Actions (Advisory, Administrative, or Judicial) section, IB will enter a District Decision of OAI and create a new compliance assignment or link the inspection to an existing assignment. Compliance Branch will review the evidence collected to support the recommended OAI classification and follow-up action, entering a district consult/inspections work activity in CMS. Compliance Branch will consult with IB and Center Compliance Officers as necessary and follow procedures for case processing contained in the Regulatory Procedures Manual.


Compliance Branch is responsible for entering the Final Decision in FACTS for all OAI recommendations received

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from IB, with the exception of those program areas where the Center has final classification authority.

2. When significant objectionable conditions and practices were observed, but the District is not prepared to take or recommend any regulatory action, a Regulatory Meeting or Untitled Letter may be appropriate. In these cases, IB will initiate a Compliance Assignment in FACTS. The IB Supervisory Investigator will not be able to link the "Inspection Record" to the Compliance Assignment upon creating the assignment; however, the Compliance Officer who receives the assignment can do so after changing the status of the assignment to "In Progress." Compliance Branch will complete the FACTS Compliance Assignment and enter the Final Decision. CB will either change the District Decision to VAI or maintain the OAI District Decision pending follow-up inspection. CB will create either a CMS work activity District Consult/Inspection or a Compliance Case to track the compliance activities.
3. CB will determine the action to take and the final classification. Should the district wish to maintain the OAI classification after the issuance of the Untitled Letter or Regulatory Meeting, they may do so pending the outcome of the follow-up inspection. Compliance Branch is responsible for entering the Final Decision for these cases, which will be entered after the action has been completed (Untitled Letter issued or Regulatory Meeting held).
4. For Referred to State (RTS) recommendations, Compliance Branch will assess, concur, and prepare the memorandum for referral to the State, and monitor the State's response to the request documenting the information in CMS. In the event Compliance does not concur with IB's recommendation, they will change the District Decision and determine the appropriate Final Decision.

If the case is referred to a state, Compliance Branch or the District State Liaison (or other position assigned to review State Contract inspections) will enter the referral into the Compliance Management System (CMS) under the Work

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Activity category of “Referred to State.” This will allow the monitoring of state follow-up and the management, tracking and sorting of all associated documents under the appropriate tabs or sections. Please see the instructions for entering the Referred to State Work Activity in CMS at: <http://inside.fda.gov:9003/ORA/OfficeofRegionalOperations/OfficeofEnforcement/EducationalMaterials/default.htm>


6.3 District Director Office / State Contract Inspection Classification Procedures

A. Classification of Non-Violative State Contract Inspection Report

1. If the State Liaison (or other position reviewing report) concludes that no objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action, an Inspection Conclusion of No Action Indicated (NAI) should be entered. The Final Decision block should be checked in FACTS as noted above.
2. If significant objectionable conditions and practices were observed, but the District is not prepared to take or recommend any regulatory action, the State Liaison (or other position reviewing report) should then assign the District Decision of Voluntary Action Indicated (VAI) and check the Final Decision block in FACTS as noted below.

B. Classification of Violative State Contract Inspection Reports


FDA Districts are responsible for reviewing and assessing State Contract Inspection Reports to determine the appropriate classification and entering a final District Decision in FACTS. Classification of state conducted inspections should follow the same guidance as for FDA conducted inspections. The following guidance should be followed when the district is classifying potentially violative inspections from a state inspection. Also, consult the Regulatory Procedures Manual for guidance on using State data to support FDA action.

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1. When classifying a violative State contract inspection report, a final District Decision of OAI will be used when it is determined that further action or follow-up by FDA is necessary. When FDA takes the follow-up action on a State Contract inspection, normal procedures for tracking, monitoring and documenting outcomes are to be followed by CB and IB.
2. When the follow-up action will be taken by the state, it is imperative for the district to maintain close communication with their state partner to track and monitor the action taken and completion of follow-up inspections. In these instances, Compliance Branch, in consultation with Investigations Branch and the State Liaison, and the State Contract Agency will decide the appropriate course of action such as state regulatory action, follow-up inspection and/or collecting compliance samples. These follow-up actions should be recorded and tracked in CMS.
3. If the reviewing Supervisory Investigator or State Liaison determines that follow up by the contracting state is the appropriate action, the report shall be classified as follows:
 - i. Inspection Conclusion: Correction Indicated (CI)
 - ii. District Decision: Referred To State (RTS)
4. The District is responsible to follow up with the State Contract Agency to verify that the violations were corrected or that appropriate regulatory follow up is taken when appropriate. Upon referring an inspection to a state, Compliance Branch or the District State Liaison will enter the referral into CMS to monitor the state follow-up. Please see the Instructions for entering the work activity at: <http://inside.fda.gov:9003/ORA/OfficeofRegionalOperations/OfficeofEnforcement/EducationalMaterials/default.htm>

6.4 Final Decision Procedures – FACTS

With the exception of instances where the compliance program reserves to a Center the right of Final Classification Authority or Final Decision or the District has entered a District Decision of RTC, the appropriate District unit may check the Final Decision block in FACTS as follows:


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1. IB must enter the Final Decision for any inspections classified NAI or VAI, except when an Untitled Letter or a Regulatory Meeting has been recommended.
2. Compliance Branch must enter the Final Decision for any District Decisions of VAI for which an Untitled Letter or a Regulatory Meeting has been recommended by IB, OAI classifications, RTC for which the compliance program does not reserve the Final Decision for the Center, and any RTS classifications.
3. Final Decisions will be entered in FACTS once the final District Decision has been determined. For OAI classifications, the Final Decision shall not be entered until after the action has been taken.

6.5 Regulatory Actions (Advisory, Administrative, or Judicial):

The following are types of regulatory action that may be pursued based on an inspection. These actions will be annotated in CMS, as applicable:

- 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 Penalty
- Demand for Destruction or other Disposition
- Disqualification
- 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 initiated recalls)
- Remove from Shippers List
- Seizure/Detention
- Use Prohibited

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- Warning Letter
(See section “Compliance Branch Responsibilities” above regarding classification of Untitled Letters or Regulatory Meetings as OAI)

6.6 Referral to Office of Criminal Investigations (OCI)


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 Follow-up Inspections to Inspections Classified as OAI

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 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 within six months after an OAI classification has been finalized and any actions taken. However, there may be circumstances when a follow-up inspection may be conducted in less than six months after an OAI classification, such as when a significant hazard to health exists and/or when the Agency may be contemplating an enforcement action. There may also be instances when the follow-up inspection will be conducted greater than six months after the OAI inspection, such as when the firm is actively engaged with the District Office regarding corrective actions requiring a greater length of time to implement. If the previous inspection was OAI and the re-inspection or verified corrective action is either VAI or NAI, the new classification must be reported in FACTS promptly but not to exceed ten working days from the completion of the inspection.

6.8 Out of Business (OOB) Instructions

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

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only, or inactive, no “Inspection Conclusion,” and “District Decision” or other inspection data should be entered for this assignment. The preferred method for capturing time for work associated with the inspection assignment is to convert the assignment from an Inspection (Operation 12) to an Investigation (Operation 13). This is accomplished in FACTS by first changing the “Operational Status” of the establishment in the “Maintain Firms” module to the appropriate designation:

- Out of Business (OOB)
- Seasonal (SEA)
- Inactive (INA)

The Lead Investigator should then update the FACTS assignment by changing the assignment operation code from 12 to 13. For registered establishments, such as drug and device manufacturers, the registration must be cancelled prior to setting the firm to OOB. For further information contact the local District FACTS coordinator.

7. Definitions/ Glossary

A. Inspection Conclusions

The Inspection Conclusion indicates IB management’s evaluation of the significance of objectionable conditions and/or practices found during the inspection. The data entry block for the Inspection Conclusion is located in the “Inspected Process and Conclusions” section of the FACTS “Maintain Inspection Results” screen. This section is also used to record the Program Assignment Code (PAC) and product/process covered during the inspection. 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. Inspection Conclusion definitions are listed as follows:

Inspection Conclusion	Definition
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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, 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.
Referred to Center (RTC)	RTC is a temporary in-process conclusion showing that the EIR should be referred to the appropriate Center for the Final Decision on the Inspection Conclusion and District Decision. This conclusion should only be used when <i>there is no current policy regarding the objectionable conditions observed or significant technical issues exist which require Center review and decision</i> . A RTC classification should be made only if a FDA 483, or state equivalent, has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3.

B. District Decisions

The District Decision represents the action that the District 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

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assigning the District Decision for EIRs as outlined in the Procedure section of this FMD.

The District Decision section is located in the FACTS “Maintain Inspection Results” screen below the “Inspected Process and Conclusions” section. It includes blocks to record the “Decision Type” for each PAC and “Process (Product)” covered. If an inspection covers more than one process under a specific PAC, there must be a District Decision for each process and PAC code combination.

The following District Decisions guide will be used as applicable:

District 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 District and/or Center is not prepared to take or recommend any of the regulatory (advisory, administrative, or judicial) actions since the objectionable conditions do not meet the threshold for regulatory action. The district may use an Untitled Letter, Regulatory Meeting or other communication with responsible individuals to inform the establishment of findings that should be corrected. The district 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 a FDA 483, 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.

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Official Action Indicated (OAI)	Objectionable conditions were found and regulatory action should be recommended. Includes inspections resulting in recalls where the district has decided conditions warrant regulatory (advisory, administrative, or judicial) action. An OAI classification is most often made if an FDA 483, 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 Investigations Branch management, 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.
Referred to Center (RTC)	This District Decision Type can only be used when the objectionable conditions or apparent violations noted constitute a compliance area for which <i>no clear policy has been established or significant technical issues exist</i> which require Center review and decision. For program areas where the Center has final classification authority, such as Bioresearch, the District should enter a recommended classification, not RTC. An RTC classification should be made only if a FDA 483

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	has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3 and documented evidence is present to assist in the Center's decision. An RTC classification can be made only if the Inspection Conclusion is either CI or RTC.
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8. Records

None

9. Supporting documents

None

10. Attachments

None


Document History

Version #	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
6.0	R	1/28/2014	DAVID K. GLASGOW, ACTING DEPUTY DIRECTOR, OFFO	Ellen Morrison, Assistant Commissioner for Operations

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

Change History

Version 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.

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Version 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.

Version 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”.

Version 6.0: Complete revision. Re-ordered for QMS SOP Template. Responsibilities and Procedures separated to provide clarity.