

Element 14: Nonconformance & Corrective & Preventive Actions – Background

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BACKGROUND

This element ensures that the Metro District has a systematic process for identifying and responding to biosolids-related noncompliances with applicable regulatory requirements, nonconformances, and opportunities for improvement.

The procedure outlines the process for identifying, documenting, investigating, and taking corrective actions for nonconformances found through operational and maintenance activities, internal audits, or third-party verification process. It also identifies the process to document, correct, and trend (DCT) a possible nonconformance that once investigated is found to be an opportunity for improvement (OFI).

Corrective action plans will be developed to address root cause(s), and outline corrective action being taken. The plans will also identify changes to policies, programs, plans, operational controls, and monitoring/measurement procedures to prevent future nonconformances and to trend an OFI.

Department/Division Heads in the department where a nonconformance occurred will assign a specific employee(s) with the responsibility for corrective action of nonconformances in their department.

A formal work plan will be developed by the EMS Coordinator with input from the EMS Workgroup to address findings of internal and third-party EMS audits. This formal work plan will describe actions to be taken to address the audit findings, the individuals responsible, the estimated completion date, and required resources to develop and implement corrective and preventive action. Recommendation for changes to policies, programs, plans, operational controls and monitoring/measurement procedures to prevent future nonconformances will also be made. Any changes made will be documented in the corrective action plan itself, the EMS for Biosolids Manual, and other relevant EMS documentation.

The EMS Coordinator will track the progress of nonconformances and close out corrective action plans as completed.

All reports generated from nonconformances found in operational controls or during an audit will be reviewed and evaluated with respect to the EMS, biosolids activities, and goals and objectives for the coming year.

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PURPOSE

To establish and outline the process for identifying, documenting, analyzing, and implementing preventive and corrective actions resulting from a nonconformance or to document, correct, and trend (DCT) an opportunity for improvement (OFI).

SCOPE

The corrective action procedures cover nonconformances discovered through operational and maintenance activities, a regulatory noncompliance, internal EMS audits, and third-party verification process. An investigation for root causes of nonconformances will be performed with SOPs being updated and employees trained as appropriate. A possible nonconformance identified as an OFI will be documented, corrected, and tracked to identify whether a trend exists.

REFERENCES

- Element #10: Operational Controls of Critical Control Points
- Element #13: Monitoring and Measurement
- Element #16: Internal EMS Audit – Plan
- Nonconformance Investigation Report
- Incident Report (OPER 40.30)
- Metro Wastewater Reclamation District Discharge Permit Management Plan
- Record Series Index Manual
- Nonconformance (OPER 40.30)

DEFINITIONS

Corrective Action Plan - is a work plan with assigned individuals, work breakdown, schedule and completion milestones to identify the root causes of nonconformances and design and implement the necessary corrective and preventive measures.

Nonconformances - a deviation in organization's established Biosolids Management Policy and Environmental Management System from the *Code of Good Practice* principles and/or the requirements of the *EMS Elements*. Nonconformances include circumstances that have the potential to create a noncompliance situation or significant environmental impact. (**Note:** As determined by District Department/Division Head based on history of incident.)

Non-compliance - a deviation from applicable federal, state and local laws, regulations and other compliance requirements related to the organization's biosolids management activities.

Root Causes - are the underlying cause or causes responsible for loss of operational control or non-conformance with standard procedures and practices established by the EMS to assure

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that biosolids are meeting applicable legal, quality, environmental protection and public acceptance requirements.

Document, Correct, Trend (DCT) – an intermediate step taken by the EMS Coordinator to determine if an incident is a systemic issue that should be investigated and treated as a nonconformance or a non-systemic issue that should be handled as an opportunity for improvement that would then be documented, corrective action will be taken, and the incident paperwork filed and tracked to determine if there is a trend.

Opportunity for Improvement (OFI) – areas where the operational intent is met but where changes could be made to better clarify or define a process.

RESPONSIBLE PERSONS

- EMS Coordinator
- Department Heads
- Internal EMS Auditors
- Supervisors and Staff

RELATED TRAINING

For related training, please refer to Element #8 of this manual.

PROCEDURAL STEPS

NONCONFORMANCE FOUND AT OPERATIONAL CONTROL

1. The staff and supervisor responsible for discovering a possible nonconformance at an Operational Control or in the Monitoring, Measurement, and Record keeping procedures will notify the appropriate Department/Division Head who will inform the EMS Coordinator as appropriate. **(Note:** If the incident is an instance of noncompliance with permit conditions notify appropriate ES personnel as soon as becoming aware of the incident. Any noncompliance and/or incident letters that are sent to the State will be routed appropriately and the RR&R Department Head will then route a copy to the EMS Coordinator who will review to ensure that all noncompliance issues are considered to determine if they are in conformance with the EMS).
2. The EMS Coordinator and Department/Division Head will evaluate the incident to determine if there is a nonconformance or an opportunity for improvement (OFI). **(Note:** All permit noncompliance's are automatically considered EMS nonconformances and the backup documentation will be filed in the Element 14 file).
3. If the EMS Coordinator and Department/Division Head conclude that the incident is an OFI, the EMS Coordinator will:

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- summarize the incident and provide justification why the incident is categorized as an OFI (document)
 - provide what corrective action will be taken (correct)
 - notify appropriate personnel of the decision
 - file the OFI and backup documentation in the Element 14 file
 - trend the OFI (if the issue arises again, evaluate if it is a trend or has become systemic and determine if the OFI should become a nonconformance)
4. If the EMS Coordinator and Department/Division Head conclude that the incident is a nonconformance, the Department/Division Head will assign appropriate individual(s) to investigate.
5. When the investigation is complete, the investigator will submit a completed report to the Department/Division Head with suggestions of appropriate corrective actions to be taken and the personnel to perform the corrective actions. This report may vary in format but must contain the following information to prevent future nonconformances:
- date of incident or nonconformance
 - briefly describe the incident or nonconformance
 - root cause(s)
 - recommended corrective action to be taken
 - responsible individual(s)
 - estimated completion date
 - recommend changes to policies, programs, plans, operational controls, and SOPs as appropriate
 - required resources
 - date completed (may be ongoing)
- (Note: If your Department does not currently have a standard format for reporting nonconformances, a form with the minimum required criteria is attached to this element for your use. This form may be customized based on your need for specific details as long as the report contains this prescribed minimum information.)*
6. Corrective action(s) to be performed will be assigned to appropriate personnel with a suggested target date for completion.
7. The Investigator will forward a copy of a report to the EMS Coordinator.
8. The EMS Coordinator will review the nonconformance to determine completeness and if the investigation report meets all the stated criteria listed in Step #4.
- If the EMS Coordinator determines the investigation Report is not complete, it will be returned to the creator to be completed.
 - If the EMS Coordinator determined the Investigation Report is complete, it will be added into a corrective action report database for tracking.
9. The EMS Coordinator will print a monthly report from the corrective action report database and check with the appropriate personnel on the open status of the item.

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10. The EMS Coordinator will verify any changes that were identified in the nonconformance regarding a procedure or process (SOP) are incorporated appropriately.
11. If a target for completion date for any corrective action item cannot be met, the EMS Coordinator will work with the Responsible Person to determine a new target for completion date.
12. The EMS Coordinator will process any required changes as outlined in Element #12 Management for Revising EMS Documents-Procedure as it relates to operational controls in the EMS Manual.
13. The EMS Coordinator will notify the Training and Development Administrator of any additional training requirements based on corrective action report items.
14. The EMS Coordinator will close out the corrective action items that have been completed. *(Note: All hard copies of reports, memos, e-mails, etc. will be centrally filed in the RR&R Department and will be the responsibility of the EMS Coordinator to keep record series codes as outlined in the Record Series Index)*
15. The EMS Coordinator and EMS Workgroup will review all nonconformances and the tracking process for effectiveness every year in the first quarter.

NONCONFORMANCE APPEAL PROCESS

If the EMS Coordinator feels that an incident warrants a written nonconformance and there is disagreement with a Department Head or Division Head, the following steps will be taken:

1. The EMS Coordinator will communicate in writing a description of the incident and the justification for making the incident a nonconformance.
2. The EMS Coordinator will submit the documents to the Director of RR&R.
3. The Director of RR&R will request the item be discussed at the next possible Department Head meeting.
4. Department Heads will review the nonconformance justification and determine if the incident should/shouldn't be a nonconformance.
5. The Director of RR&R will notify the EMS Coordinator in writing of the Department Heads' decision.
 - If the incident is determined not to be a nonconformance, the documentation will be filed in Element #14 as backup.
 - If the incident is determined to be a nonconformance, the EMS Coordinator will notify the appropriate staff of the decision and request that a nonconformance be created.

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NONCONFORMANCE FOUND FROM AN AUDIT

1. The EMS Coordinator will forward a copy of the internal (Summary of Exceptions) or thirty-party audit findings to the EMS Workgroup for review and comment.
2. The EMS Coordinator will draft management responses with proposed corrective actions for Department Head and District Manager review and input, then final approval. The management response will include:
 - date of nonconformance
 - briefly describe the nonconformance
 - corrective action to be taken
 - responsible individual(s)
 - estimated completion date
 - required resources to develop/implement corrective and preventive actions
 - recommend changes to policies, programs, plans, operational controls, and SOPs as appropriate
 - date completed column (to use for monthly tracking)
3. The EMS Coordinator will conduct a monthly follow-up on the status of open corrective actions.
4. The EMS Coordinator will note completion of corrective action in the date completed column of the Management Response. The Department Heads and District Manager will be kept apprised of significant deviations from the established completion dates. *(Note: All hard copies of reports, memos, e-mails, etc., will be centrally filed in the RR&R Department and will be the responsibility of the EMS Coordinator to keep record series codes as outlined in the Record Series Index)*
5. The EMS Coordinator will prepare a summary at the end of each year of the audit findings with associated corrective actions for inclusion in the EMS Program Performance and Management Review report.

NON-CONFORMANCE INVESTIGATION REPORT *(document the solution)*

Title:

Incident Date: mm/dd/yy

Investigation Began: mm/dd/yy

Area:

Time:

Report Date: mm/dd/yy *(this can be used as our tracking number)*

Investigated by:

Completion Date for Investigation: mm/dd/yy _____

DESCRIPTION OF INCIDENT *(identify the problem)*

Briefly summarize the incident

RESULTS OF THE INVESTIGATION (List the sequence of events of the incident as discovered through the investigation)

- Abc
- Abc

KEY FACTORS *(identify the cause)*

- Abc
- Abc

UNDERLYING CAUSES *(identify the root cause)*

- Abc
- Abc

RECOMMENDATIONS *(solutions)*

- Abc
Responsibility:
Target for completion:
Required Resource:
Actual date of completion: *(Investigator is responsible for notifying the EMS Coordinator who will then fill in this date)*
Follow-up Comments:
- Abc
Responsibility:
Target for completion:
Required Resource:
Actual date of completion: *(Investigator is responsible for notifying the EMS Coordinator who will then fill in this date)*
Follow-up Comments:

Department Head Signature

Date signed

Copy to: Department Head responsible for area where incident occurred
ES if resulted in noncompliance
EMS Coordinator