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# Biosolids EMS Status Review Protocol

For agencies participating in the National Biosolids Partnership Environmental  
Management System Demonstration Program

Prepared for



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Prepared by



# Introduction

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The following protocol is provided by the National Biosolids Partnership (NBP) to assist agencies participating in the Biosolids Environmental Management System (EMS) Demonstration Program. After the agency has completed the initial steps of the EMS implementation process and believes it is ready to begin the six-month operating period prior to undergoing an independent third-party certification audit, the agency can request an EMS Status Review. The review involves an evaluation of the agency's EMS with respect to the NBP EMS program requirements. Based on the results of this activity, the agency determines whether they are ready to declare that their EMS is operational<sup>1</sup> and begin the process of seeking independent third-party certification of their EMS.

The EMS Status review is based on a checklist and interview questionnaire that is used by the agency and their NBP Account Executive to evaluate whether the agency's EMS meets the requirements of the NBP EMS Elements. The EMS Status Review should be viewed as guidance to the agency and is not a guarantee of conformance with the NBP EMS Elements nor is it a guarantee that the agency is ready to undergo a third party certification audit.

The EMS Status Review checklist and questionnaire are contained in a Microsoft Excel Spreadsheet. After notifying the NBP that it is ready to conduct an EMS Status Review, the agency receives an electronic copy of the checklist and questionnaire spreadsheet and follows the protocol as detailed below.

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<sup>1</sup> In the context of an EMS, "operational" implies that documented procedures and plans are currently practiced by agency staff and contractors.

# EMS Status Review Protocol

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The 11 steps of the EMS Status Review process are outlined below.

1. Agency notifies account executive and NBP EMS Manager that it plans to begin the six month operations of its EMS. NBP EMS Manager notifies Audit Companies.
2. Account executive e-mails EMS Status Review checklist (see below) to agency.
3. Agency reviews EMS documentation and relevant activities against EMS Status Review checklist.
4. Agency sends completed self-assessment portion of checklist and electronic copy of draft EMS Manual, along with several representative standard operating procedures (SOPs) to account executive and NBP EMS Manager.
5. Account executive and NBP EMS Manager review EMS manual, SOPs, and other documentation against checklist.
6. Account executive consults with NBP EMS Manager and schedules phone interview.
7. If account executive disagrees with agency self-assessment and is concerned about potential nonconformances with the EMS Elements in EMS documentation, account executive notes these on the EMS Status Review checklist, consults with the NBP EMS Manager and returns the checklist and comments to the agency.
8. Agency reviews phone interview questions (see the attached checklist), prepares to answer them, and assembles any additional documentation (e.g., records, hard copies of documents) that may be pertinent during the phone interview. NBP EMS Manager may elect to participate in the telephone interview.
9. Account executive conducts phone interview with agency, and NBP EMS Manager, and notes any apparent nonconformances with the EMS Elements.
10. Account executive prepares final memo on their review of potential nonconformances with the EMS Elements in the agency's EMS and forwards memo to the agency and NBP EMS Manager.
11. Agency solely decides on "starting the clock." The account executive and the NBP EMS manager are giving "informal" advice to the agency. Agency starts the six-month operating clock and notifies the account executive and the NBP EMS Manager by submitting written notification to the NBP EMS Manager.<sup>2</sup>

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<sup>2</sup> Agency can, at their discretion, declare its EMS operational and address any nonconformances during the six-month operations period at the risk of not having enough data for the internal and external audits. Also, the agency could operate without addressing the nonconformances identified by the account executive-and take the risk that the external audit company would agree with the agency approach at the time of the audit.

EMS Activity	Self Assessment	Account Exec Assessment	Comment
<b>ELEMENT 1 EMS MANUAL</b>			
Document that describes the applicable policies, programs, plans, procedures, and management practices in the EMS.	<input type="checkbox"/>	<input type="checkbox"/>	
Describes those biosolids management activities assigned to and performed by contractors.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>ELEMENT 2 BIOSOLIDS MANAGEMENT POLICY</b>			
NBP Commitment Letter	<input type="checkbox"/>	<input type="checkbox"/>	
Biosolids Policy (approved by <b>sufficient level of authority</b> )	<input type="checkbox"/>	<input type="checkbox"/>	
Communicated to employees, contractors, and interested parties	<input type="checkbox"/>	<input type="checkbox"/>	
Have (or are setup to collect) Objective Evidence/Records of these communications	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Interview Questions</b>			
How have you communicated your policy to employees? Contractors? Interested parties?			
How has the policy been incorporated into the organization's biosolids programs, procedures, and practices?			
Are your biosolids contractors obligated to programs, practices and procedures set forth in the Code of Good Practice?			
<b>ELEMENT 3 CRITICAL CONTROL POINTS</b>			
Document Listing CCPs throughout biosolids value chain - cross referenced to operational controls and environmental impacts	<input type="checkbox"/>	<input type="checkbox"/>	
Have the environmental impacts/potential impacts of each critical control point been identified and documented?	<input type="checkbox"/>	<input type="checkbox"/>	
Procedure for Periodically Reviewing/Updating CCPs and associated environmental impacts analysis	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Interview Questions</b>			

Are CCPs consistent in scale and scope with the NBP National Manual of good practice? If not, why not?

Do the CCPS cover the entire biosolids value chain, including activities implemented by contractors?

Transaction test - please walk through the processes for updating your EMS to reflect an equipment or process change.

How did you consider input from interested parties when identifying environmental impacts for critical control points?

#### ELEMENT 4 LEGAL AND OTHER REQUIREMENTS

Procedure for Identifying, Tracking, and Responding to Legal and Other Requirements

Document Listing Up-to-date Legal and other requirements

#### Interview Questions

What evidence (e.g. records) can you point to that shows you are following your procedure to identify and track legal requirements?

Please go through your list of legal and other requirements and explain where applicable records are located. Does the list of applicable legal requirements appear to be complete?

Transaction test - please walk through the process (e.g. all the cascading activities and changes to your EMS) that will occur if you identify a change in a legal or other requirement that is relevant to your biosolids program.

#### ELEMENT 5 GOALS AND OBJECTIVES FOR CONTINUAL IMPROVEMENT

Procedure for Establishing and Periodically Reviewing Goals and Objectives

Document Listing Goals and Objectives for the four outcomes

Considered interested party input when establishing and updating goals and objectives

Document with Action Plan (work breakdown, schedule, milestones, resources, responsibilities)

#### Interview Questions

Describe the process you used to consider public input while initially developing biosolids EMS goals and objectives.

Action plan for meeting goals and objectives accurate and up to date?

Have individual been assigned responsibilities for implementing the action plan? Have resources been approved by management? Do the milestones sound reasonable?

How are you tracking progress towards biosolids goals and objectives?

## ELEMENT 6 PUBLIC PARTICIPATION

Proactive Plan/Procedure for Public Participation of interested parties

The Public Participation Plan/Procedure is consistent with the history of public involvement, the current situation, the method of biosolids management and other local circumstances

The plan provides mechanisms for interested party input

### Interview Questions

What public input have you received on your biosolids EMS and how did you receive it? How did you respond to it? What records of these activities do you have that demonstrate this?

Does the organization's plan identify interested parties/stakeholders? Are the method(s)/approach(es) for public participation defined?

How did you notify interested parties about your intent to receive a third party audit?

How does your audit plan reflect interested party input?

How are contractors involved in receiving and considering input from interested parties?

## ELEMENT 7 ROLES AND RESPONSIBILITIES

Assign management representative with overall responsibility for EMS

All EMS-related job roles and responsibilities defined in job descriptions or other documentation

All roles/responsibilities for biosolids management defined in job descriptions or other documentation

Document Defining Roles and Responsibilities for the EMS and for day-to-day Biosolids Management

Service Level Agreement(s) Describing Roles and Responsibilities of Contractor(s) (Note – One Service Level Agreement can address Contractor requirements for Elements 7, 8, 9, 10, 11, 12, 13)

**Interview Questions**

Transaction test - please walk through the process for changing and updating the biosolids EMS in response to a change in 1) assigned staff responsibilities and 2) a contractor.

Can an auditor use your EMS manual to identify staff responsible for specific biosolids management activities AND locate a documented job description (where are these located)?

How did you determine the level of resources required for implementing your EMS?

**ELEMENT 8 TRAINING**

Procedure describing EMS and Biosolids Management Training Activities

Records of EMS Awareness and Biosolids Skills Training

Service Level Agreement(s) that documents training activities and responsibilities of Contractor(s) (Note – One Service Level Agreement can address Contractor requirements for Elements 7, 8, 9, 10, 11, 12, 13)

**Interview Questions**

What evidence (e.g. records) do you have that demonstrate that staff and contractors have received necessary training relevant to the biosolids EMS.

Do you have contract documents that specify training requirements for contractors?

Does the training establish/document competency/mastery of required skills and knowledge? Describe ....

**ELEMENT 9 COMMUNICATIONS**

Proactive Communications Plan for Interested Parties, Employees, Contractors including mechanisms for responding to inquires and requests for information

Procedure for responding to complaints, inquiries, requests for information

Complaint and inquires procedures fully integrated across organization and with contractor(s)

Communications Materials/Documents/Brochures

Records of Inquires/Requests for Information and Responses

**Interview Questions**

What communication-related materials have you provided to interested parties?

Is there information about your biosolids EMS on your website?

Do you have records of related activities? Such as tours, interviews, articles, tours, surveys, etc.?

Do you have records of requests for information from interested parties?

Transaction test - please walk through the process that occurs after receiving a request for information from an interested party. Walk through the process that occurs after receiving a complaint.

Do you have integrated records of interested party complaints, inquires requests for information?

Describe how you communicate information on biosolids management and the EMS to staff and contractors? Do you have any records of these activities (records of meetings, bulletins, e-mails, etc).

**ELEMENT 10 OPERATIONAL CONTROLS**

SOPs/Work Instructions for all critical control points, including those managed by contractors

EMS Manual contains Document Listing SOPs and Operational Controls for all Critical Control Points

Document referencing SOPs/System for Preventive Maintenance of all Unit Processes/Equipment for Critical Control Points

Operational Controls considered National Manual of Good Practice

Operational Controls in place for relevant contractor activities

**Interview Questions**

How did you consider the National Manual of Good Practice in identifying/developing operational controls for each critical control point?

Select a few operational controls & monitoring/measurement SOPs on the list of CCPs / OCs. Are there written, documented work instructions for operational control? Records of the OC procedures?

Review operational controls for contractors - how can you verify that these are suitably established?

Are actual staff and contractor procedures/work practices consistent with documented operational controls? Will direct observation by an auditor of selected staff show any inconsistencies?

What procedures does the organization have for scheduled preventive maintenance? Do they use proprietary maintenance management software?

## ELEMENT 11 EMERGENCY PREPAREDNESS AND RESPONSE

Emergency Response Plans and Procedures at critical control points

Testing of Emergency Response Effectiveness, Including Communications (Procedures/Records)

Contractors Roles and Responsibilities and Emergency Response Plans in Place (Service Level Agreement)

### Interview Questions

Have you communicated Emergency Response plans / procedures / checklists to staff and contractors?

Do you have records of Emergency Response training activities?

Transaction test - what happens when a spill or accidental release occurs?

## ELEMENT 12 DOCUMENTATION, DOCUMENT CONTROL AND RECORDKEEPING

Document Control Procedure(s) for creating, numbering, revising, locating, and maintaining all EMS documents relevant to the biosolids EMS, including procedures, plans, SOPs, forms etc.

Management of Change Procedure Level 2 and Level 3 documents – Link with Corrective Action Plan and EMS Audits as well as other change drivers/agents such as regulatory changes and process to change

Comprehensive list of all EMS documentation (level 1, level 2 and level 3) documents, including forms and report templates

Document listing all current controlled documents (issue date, version #, revision date, document name, document number), and applicable records - should cross reference CCPs, Operational Controls

Document Describing Recordkeeping System (primary file location, retention period, archive system)

Service Level Agreement stipulating Documentation, Document Control and Records Requirements for Contractors

**Interview Questions**

Review document/records list(s) - ensure names and locations of procedures, SOPs, and records are easily located. Select a few to discuss during phone interview.

Are the various procedures and documents accessible to employees (either hardcopy or electronic) 24/7?

Have them describe their document control procedure -- methods for assuring that all EMS documents are created, implemented and maintained following the established document control procedure

Have them describe how they can identify whether the SOP/work instruction is the latest version

Have them describe how they are sure the SOPs/work instructions are being followed as written

**ELEMENT 13 MONITORING AND MEASUREMENT**

Document Listing all Monitoring and Measurement SOPs for monitoring, sampling, testing and inspection at CCPs

Monitoring and Measurement SOPs/work instructions for all sampling, testing, monitoring, inspection and measurement at all CCPs (either separate or part of OC procedures)

Procedure for Systematically Tracking Progress toward Goals and Objectives

Document Describing Recordkeeping System (can be here on in Element 12 Documents)

Contractor Monitoring and Measurement SOPs for all Critical Control Points they manage

Service Level Agreement Describing Contractor Monitoring and Recordkeeping Requirements

**Interview Questions**

How are you tracking progress towards EMS goals and objectives?

What monitoring and measurement activities are currently being performed by contractors? How is this information being used/tracked by the agency?

Are there SOPs/written work instructions for all monitoring, testing, inspection and measurement (excluding lab procedures)?

Are the standard forms and report templates for recording monitoring and measurement results? Is there a complete list of all document controlled forms and report templates?

**ELEMENT 14 NONCONFORMANCES – PREVENTIVE AND CORRECTIVE ACTION**

Procedure for Identifying Nonconformances and Taking Corrective Action

Procedure of corrective action includes root cause analysis, corrective and preventive actions for day-to-day nonconformances

Procedure for corrective action includes formal investigation, root cause analysis, preventive and corrective action plan for all nonconformances discovered through internal or third party EMS audit

Corrective Action Work Order Form

Records of all Corrective Action Items and Plans

**Interview Questions**

What records exist that indicate that this procedure has been implemented?

Transaction test - please describe the process used to identify and track a non-conformances, and associated mechanisms for formulating and tracking corrective actions.

Transaction test - please describe process used to identify and track a non-conformances identified as part of the internal audit, and mechanisms for formulating and tracking corrective actions.

**ELEMENT 15 BIOSOLIDS PROGRAM PERFORMANCE REPORT**

Procedure for Preparing and Distributing Periodic Performance Report (scope, content, schedule, responsible persons, etc.)

Records of Periodic Performance Reports

**Interview Questions**

Have you completed a biosolids program performance report? If not, when will this occur?

How is this report distributed?

**ELEMENT 16 INTERNAL EMS AUDIT**

- |   |                          |                          |
|---|--------------------------|--------------------------|
| Procedure for Internal EMS Audits   | <input type="checkbox"/> | <input type="checkbox"/> |
| Document(s) – Internal EMS Auditor Roles and Responsibilities/ Training Program | <input type="checkbox"/> | <input type="checkbox"/> |
| Internal EMS Audit Report and Records   | <input type="checkbox"/> | <input type="checkbox"/> |

**Interview Questions**

Has the first internal audit been completed? If no, has it been scheduled

Have internal auditors been selected and trained?

Have audit checklists and protocols been developed?

Transaction test -- have them describe the process they will follow, per their audit plan and procedures, to conduct internal EMS audits, report the results and take any necessary corrective action

**ELEMENT 17 MANAGEMENT REVIEW**

- |   |                          |                          |
|---|--------------------------|--------------------------|
| Procedure Describing Periodic Management Reviews of Biosolids EMS (Scope, schedule, format, content, responsible persons) | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of Periodic Management Reviews  | <input type="checkbox"/> | <input type="checkbox"/> |

**Interview Questions**

Have you conducted your first management review? Have you scheduled your first management review?