

**Westmoreland Sanitary Landfill, LLC**

**Environmental Management System Manual**

**Version 1.0**

**Date: December 29, 2023**

<b>TOPIC</b>		
<b>Environmental Management System Manual</b>		
<b>LOCATION</b>	<b>OWNER</b>	
	<b>Environmental Personnel</b>	
<b>Version:</b> <b>1.0</b>	<b>Approved By:</b>	<b>Issue Date:</b>

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<b>Revision Number</b>	<b>Date of Issue</b>	<b>Author(s)</b>	<b>Brief Description of Change</b>
1.0			Initial Issue

## **1. INTRODUCTION**

Westmoreland Sanitary Landfill, LLC (WSL) owns and operates the Westmoreland Sanitary Landfill (Landfill) in Belle Vernon, Westmoreland County, Pennsylvania. WSL is committed to improving their environmental performance by conforming to applicable environmental operating permits and other related compliance obligations. WSL recognizes that compliance with operating permits and environmental regulations plays a major role in preserving natural resources for future generations.

### **1.1 Purpose**

This manual describes the Environment Management System (EMS) developed and implemented to continually improve the environmental performance of WSL, including the processes needed and their interactions to ensure compliance with applicable regulatory permit conditions and environmental laws and regulations. The main purpose of the EMS is to establish a long term plan for achieving and maintaining environmental compliance. In designing the EMS, WSL has defined the scope, considering the structure of the organization, responsible parties, interested parties and stakeholders, environmental operating permits, and applicable regulatory obligations. This manual delineates authorities and responsibilities and interrelationships of the processes described herein. Further, WSL has established an Environmental Policy that is included as Appendix A.

### **1.2 EMS Manual Scope**

This EMS Manual is applicable to the Landfill located in Belle Vernon, Pennsylvania.

## 2. DEFINITIONS

**Audit** – systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

**Competence** – ability to apply knowledge and skills to achieve intended results.

**Compliance Obligations** – Legal requirements that an organization has to comply with and other requirements that an organization has to or chooses to comply with.

**Continual improvement** – recurring activity to enhance performance.

**Effect** – A deviation from the expected, whether positive or negative.

**EMS Audit** – A systematic and documented verification process of objectively obtaining and evaluating evidence to determine whether an organization's EMS conforms to the environmental management system audit criteria set by the organization, and for communication of the results of this process to management.

**Environment** – Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships.

**Environmental Aspect** – Element of an organization's activities, products and/or services that interacts or can interact with the environment.

**Environmental Impact** – Change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's environmental aspects.

**Environmental Management System** – Part of the management system used to manage environmental aspects, fulfil compliance obligations, and address risks and opportunities.

**Environmental policy** – intentions and direction of an organization related to environmental performance, as formally expressed by its top management.

**Interested Party** – A person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

**Nonconformity** – non-fulfillment of a requirement.

**Objective** – A result to be achieved.

**Organization** – A person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives.

**Qualification** – The characteristics or attributes gained through training and/or experience that enable an individual to perform a required function.

**Risk** – Effect of uncertainty, expressed as a combination of consequences of an event and associated likelihood of occurrence.

**Uncertainty** – The state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequences, or likelihood.

### **3. ACRONYMS**

**EMS** – Environmental Management System

**EPA** – United States Environmental Protection Agency

**PPC** – Preparedness, Prevention, and Contingency

**SMART** – Specific, Measurable, Achievable, Relevant, and Time-bound

**WSL** – Westmoreland Sanitary Landfill, LLC

#### **4. ENVIRONMENTAL MANAGEMENT SYSTEM REFERENCES**

The EMS requirements imposed by government regulatory authorities were considered during the development of this EMS and shall be used for continuous updating of applicable procedures and elements of the EMS. A list of these authorities can be found in the Working EMS Planning Tool under Interested Parties. All permit requirements can be found in the Permit Requirements Summary that will be maintained by WSL Environmental personnel.



## **5. NONCONFORMITIES OR NONCOMPLIANCES**

### **5.1 Definition**

5.1.1 Nonconformities or noncompliances are deviations from applicable environmental compliance obligations or regulatory and/or permit requirements that are identified in the WSL Permit Requirements Summary. Examples of such nonconformities or noncompliances include but are not limited to the following: failure to follow procedural steps in the prescribed order and within specified tasks; failure to document or maintain documents prescribed by a regulator; and failure to appropriately report environmental incidents.

### **5.2 Training/Awareness**

5.2.1 Employees are made aware of potential nonconformities or noncompliances through several means including:

- 5.2.1.1 Environmental training and awareness.
- 5.2.1.2 On-the-job training.
- 5.2.1.3 Routine internal environmental inspections and audits.

## **6. ENVIRONMENTAL ORGANIZATIONAL CONTEXT**

### **6.1 Defining the EMS**

#### **6.1.1 Context of the Organization**

6.1.1.1 To fully understand the context of the WSL EMS, the organization documents relevant to external and internal issues, interested parties and their requirements – including those that may become compliance obligations, and environmental conditions affecting or capable of affecting the purpose and intended outcomes of the EMS. Such information will be documented in the Working EMS Planning Tool EMS Overview Table.

#### **6.1.2 Internal and External Issues**

6.1.2.1 Internal and External Issues that may be relevant to the context of the WSL EMS must be considered and may include:

- Environmental conditions related to air quality, water quality, and land use, relevant to compliance obligations and environmental operating permits;
- Legal, regulatory, financial, technological, and economic whether, national, regional, or local;
- Internal characteristics or conditions of the organization, such as its activities, services, strategic direction, culture, and capabilities (i.e., people, knowledge, processes, systems); and
- External cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive circumstances, whether international, national, regional or local.

#### **6.1.3 Interested Parties**

6.1.3.1 Interested Parties relevant to the EMS have been identified by WSL. Such parties and their expectations and requirements will be documented on the Working EMS Planning Tool EMS Overview Table. The table identifies any such requirements that will be addressed as compliance obligations within the EMS. Relevant interested parties and their requirements will be monitored and updated as necessary.

#### **6.1.4 Scope of the Environmental Management System**

6.1.4.1 The Scope of the WSL EMS is limited to the following:

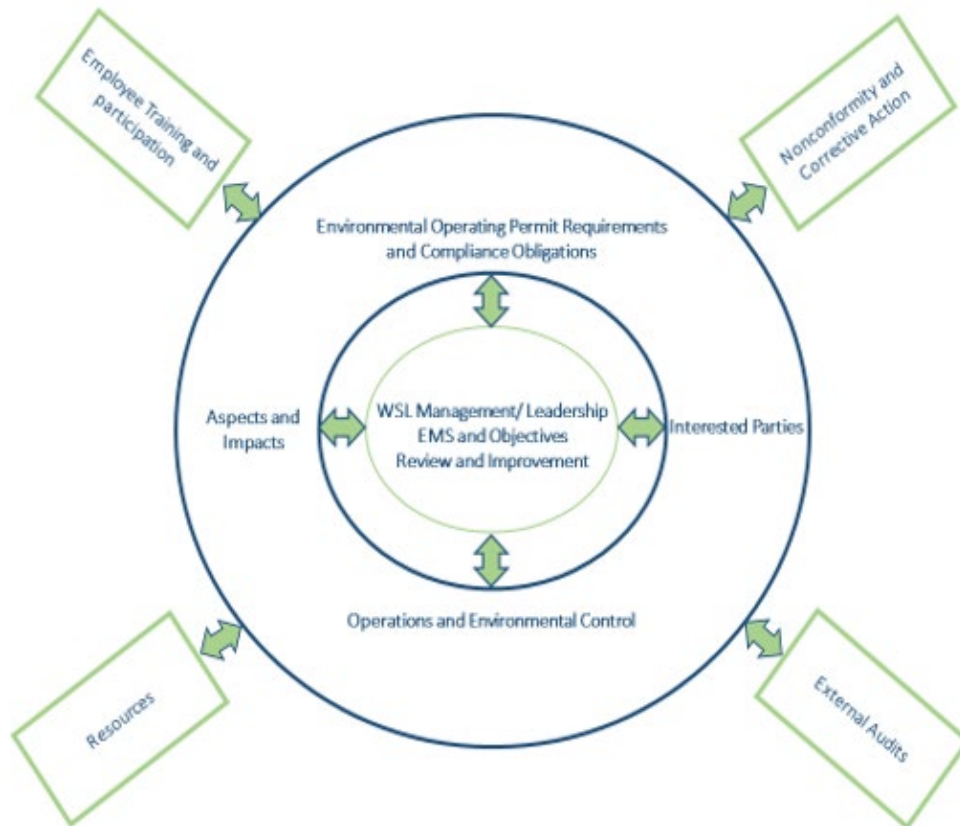
- The external and internal issues referenced above;
- Environmental Operating Permits and environmental compliance obligations as they apply;

- The site functions and physical boundaries; and
- WSL’s ability and authority to exercise control and influence.

### 6.1.5 Environmental Management System

6.1.5.1 To achieve intended outcomes and to enhance environmental performance, WSL has established, maintains, and continually improves its EMS. The EMS has been developed, considering the information gained by the determination of external and internal issues and requirements of interested parties as they are relevant to the purpose of the EMS. See the EMS Process Interaction Diagram below.

#### **EMS PROCESS INTERACTION DIAGRAM**



## **7. LEADERSHIP**

### **7.1 Leadership and Commitment**

7.1.1 The leadership of WSL is committed to the development and improvement of an effective EMS. This is demonstrated by:

- Taking accountability for the effectiveness of the EMS;
- Establishing WSL commitment to carry out the aspects of the EMS;
- Ensuring the integration of the EMS requirements into the company's business processes as necessary;
- Ensuring the resources are available for the EMS to meet its intended results;
- Communicating to the organization the importance of effective environmental management and of conforming to the EMS requirements;
- Ensuring the EMS achieves its intended outcomes; and
- Engaging, directing, and supporting employees to contribute to the effectiveness of the EMS.

#### **7.1.2 Environmental Management System Policy**

The Environmental Policy paves the pathway to carry out the goals to assist WSL with meeting their environmental commitments. The Environmental Policy was created at the direction of WSL management and is intended to ensure the EMS is carried out within the defined scope by:

- Development to include the appropriate organizational context and impacts to the environment by site activities.
- Providing a framework for setting environmental objectives and meeting operating permit conditions and compliance obligations;
- Including a commitment to the protection of the environment, lessening environmental impacts, and devotion to meeting operating permit conditions and compliance obligations.

The Environmental Policy is included in this manual as Appendix A.

#### **7.1.3 Roles, Responsibilities, and Authorities of the EMS Team**

7.1.3.1 The authority of control over the SWL EMS has been defined and is listed in the Working EMS Planning tool EMS Overview Table. WSL has identified authorities and responsibilities for relevant jobs and tasks to carry out the goals of the EMS. These authorities and responsibilities are identified for each process within the associated procedures.

7.1.3.2 The roles and responsibilities include ensuring that the EMS is carried out within the defined scope and ensuring environmental personnel are reporting EMS performance to site leadership.

## **8. IDENTIFY ENVIRONMENTAL ASPECTS AND IMPACTS**

### **8.1 Environmental Aspects and Impacts**

- 8.1.1 WSL evaluates their site activities to determine impacts to air, water, and land.
- 8.1.2 Environmental Aspects and Impacts are identified by site activities, considering normal operating conditions and reasonably foreseeable emergency conditions.
- 8.1.3 Environmental Aspects and Impacts are evaluated for significance based on frequency or likelihood of a situation occurring and severity of the environmental impacts if the situation were to occur.
- 8.1.4 WSL documents Environmental Aspects and Impacts, and they are maintained within the Working EMS Planning Tool.

### **8.2 Compliance Obligations**

- 8.2.1 WSL recognizes the environmental laws, regulations, and operating permit conditions relevant to its environmental aspects of its activities. WSL has created and maintains a list of environmental regulations and operating permit conditions that are applicable to site activities relevant to the boundary of the EMS.

### **8.3 Planning Action to Address**

- 8.3.1 WSL has plans to address its:
  - Identified significant environmental aspects, and
  - Environmental compliance obligations through ongoing evaluation of environmental compliance. Any identified and required actions are tracked using the Working EMS Planning Tool.
- 8.3.2 Based on the identification of planning actions as stated above, WSL determines how to develop, initiate, and implement solutions into its EMS processes and evaluates the effectiveness of these actions. This is done by internal compliance reviews and direction provided by site leadership.
- 8.3.3 When determining solutions, WSL evaluates the solutions based on:
  - Effectiveness of the solution;
  - Conflicts with operating permits or environmental regulations;
  - Additional environmental impacts;
  - Technological options;
  - Impacts to site operations; and
  - Financial feasibility.

## **8.4 Environmental Objectives and Planning to Achieve Them**

- 8.4.1 WSL directs the EMS scope by documenting measurable environmental objectives and goals. The environmental objectives and goals are made in line with the environmental policy and are relevant to the interests of WSL. WSL selects objectives that are Specific, Measurable, Achievable, Relevant, and Time-bound (SMART).
- 8.4.2 WSL establishes environmental objectives and goals by considering the following:
- Operating permit conditions and compliance obligations;
  - Significant environmental aspects; and
  - Supports and is consistent with the Environmental Policy.
- 8.4.3 Planning and development of the EMS site objectives includes the determination of the following:
- What will be done;
  - Who will be responsible;
  - When it will be completed; and
  - How the results will be evaluated, including indicators for monitoring progress toward the achievement of its measurable environmental objectives.

## **9. SUPPORT**

### **9.1 Resources**

WSL determines and provides the resources needed to implement, maintain, and continually improve the EMS. Resource requirements and resource allocation are assessed and discussed as a part of Management Review.

### **9.2 Competence and Training**

9.2.1 WSL will provide training to all employees on awareness of the EMS.

9.2.2 Personnel performing work affecting environmental performance and the fulfilment of compliance obligations shall be deemed competent on the basis of qualifications such as appropriate education, training, skills, and experience.

9.2.3 Training needs are developed based on job tasks.

9.2.4 Training events are developed and presented as required based on job tasks. Comprehension and competency of trained materials will be determined by tests or quizzes.

9.2.5 WSL training records will be retained in accordance with relevant environmental regulations.

### **9.3 Awareness**

9.3.1 WSL will provide awareness presentations, trainings and communications as necessary ensure that personnel are aware of:

- The WSL Environmental Policy;
- The significant environmental aspects and related actual or potential environmental impacts associated with WSL operations;
- Their responsibility in contribution to the effectiveness of the EMS; and
- The implications of not conforming with the EMS requirements, including not fulfilling the WSL site environmental permit conditions and environmental compliance obligations.

### **9.4 Communication Plan**

9.4.1 WSL will determine the communication requirements needed for internal and external communication relevant to the EMS. The Working EMS Planning Tool contains a written Communication Plan. At a minimum, the communication plan will contain:

- What will be communicated;
- The method of communication or delivery;
- When communications will occur - triggering event; and
- Who will be communicating the information.

9.4.2 Information regarding the EMS will be communicated externally as required by compliance obligations and relevant communication requests received from interested parties.

## **9.5 Document and Record Control**

### 9.5.1 Document Control

9.5.1.1 WSL EMS documentation includes both documents and records. Documents required for defining processes to carry out the EMS are developed in a planned manner and will be controlled.

9.5.1.2 All controlled documents will contain: a document title, issue date, and revision number.

9.5.1.3 For external documents that exist outside of WSL's control, users are responsible for ensuring that the most current versions of the documents are obtained.

### 9.5.2 Record Control

9.5.2.1 Environmental records will be controlled and maintained as specified by the WSL environmental operating permits and compliance obligations.



## **10. OPERATIONAL CONTROLS**

### **10.1 Implement Operation Controls**

10.1.1 WSL has identified site operations and activities that are associated with environmental aspects and impacts and are considered when creating environmental objectives. Controls for environmental aspects and impacts for operations and activities have been identified in the Working EMS Planning Tool.

10.1.2 Operational controls are utilized to ensure WSL complies with environmental operating permit conditions and other environmental regulatory obligations. WSL considers the environmental aspects as part of the overall operations and operational controls. Operational controls identified at the Landfill may be in the form of, but not limited to:

- Electronic or Mechanical technology to reduce environmental impacts;
- Routine preventive maintenance programs to reduce wear and substandard function of equipment which may prevent a problem that could impact the environment;
- Monitoring and documenting equipment performance;
- Emergency Response Plans; and
- Operating procedures – documented or verbal.

10.1.3 Using the environmental policy and objectives as a guide, WSL continually evaluates, determines, and reviews its operations and activities associated with its environmental aspects through internal audits, management review, and maintenance of the EMS. WSL plans the functions of operations including maintenance, ensuring that they are carried out under conditions specified by environmental operating permits and compliance obligations. This is done through:

- Establishing and maintaining documented procedures to prevent deviation from environmental operating permit parameters; and
- Permitted operating criteria such as preventative maintenance schedules, calibration of equipment, and routine inspections.

#### **10.1.4 Emergency Preparedness and Response**

10.1.4.1 Proper preparations for and responses to emergency situations minimize adverse environmental impacts in the event of an actual emergency. WSL maintains a Preparedness, Prevention, and Contingency (PPC) plan. The plan is intended to prepared WSL employees on how to:

- Respond in emergency situations; and
- Take action as appropriate in response to an emergency situation and potential environmental impact.

10.1.4.2 Emergency drills are conducted to:

- Assess and document the effectiveness of the plan; and
- Ensure that employees receive appropriate training and understand their responsibilities related to the PPC Plan.

## **11. CHECK – EMS PERFORMANCE EVALUATION**

### **11.1 Monitoring, Measurement, Analysis, and Evaluation**

11.1.1 WSL recognizes that periodic monitoring and evaluating is necessary to verify its environmental performance in achieving its EMS objectives and to determine effectiveness of controlling environmental impacts. Monitoring and measurement will be performed in conjunction with activities to improve performance and achievement of environmental objectives. Using the site environmental objects, list of environmental regulations, and operating permit conditions applicable to the site, WSL will identify:

- What will be monitored and measured;
- The methods for monitoring, measurement, analysis, and evaluation to ensure valid results, including indicators associated with environmental performance criteria;
- When the monitoring and measuring will be performed; and
- The required records to be retained as evidence of the monitoring and measurement.

11.1.2 WSL will communicate relevant environmental performance information both internally and externally, as identified in the Communication Plan and as required by its compliance obligations.

### **11.2 Self-Evaluation of Compliance**

11.2.1 WSL will develop processes and procedures needed to evaluate compliance with environmental operating permits and regulatory compliance obligations. The evaluation procedures are intended to determine if established environmental operating permit requirements and regulatory compliance obligations are being satisfied.

11.2.2 Compliance obligations are reviewed at least annually or as needed if changes occur. Records of compliance obligations are retained in the list of environmental regulations and operating permit conditions applicable to the site.

### **11.3 Internal Audits**

11.3.1 WSL will establish and implement, an Internal Audit program to evaluate their site for compliance with environmental operating permits and applicable environmental regulatory compliance obligations.

11.3.2 The Internal Audit procedure will define the following:

- The audit criteria and scope for each audit; and
- Requirements to ensure that results of audits are reported to management and external interested parties as appropriate.

11.3.3 Final Audit Reports are retained as evidence of the implementation of the audit program and results.

11.3.4 Audit findings and corrective actions are documented in in the Working EMS Planning Tool.

#### **11.4 Management Review**

11.4.1 WSL evaluates and reviews the performance and effectiveness of the EMS on at least an annual basis to ensure the effectiveness of the EMS.

11.4.2 The Management Review will be conducted as a meeting with senior management to at a minimum review the following:

- The results of the EMS determined by monitoring and measurement and internal auditing;
- Changes in:
  - External and internal issues relevant to the EMS;
  - The needs and expectations of interested parties, including compliance obligations;
  - Significant environmental aspects;
  - EMS risks and opportunities; and
  - The EMS.
- The extent to which environmental objectives have been achieved; and
- Information on WSL's environmental performance, including trends in:
  - Nonconformities and Corrective Actions
  - Monitoring and measuring results;
  - Fulfilment of compliance obligations,
  - Audit results;
  - Adequacy of resources;
  - Relevant communications from interested parties, including complaints; and
  - Opportunities for continual improvement.

11.4.3 Records of Management Review Meeting Minutes and Presentations will be retained with the EMS for a minimum of 3 years.

## **12. IMPROVEMENT**

### **12.1 Noncompliance and Corrective Action**

- 12.1.1 WSL will implement corrective actions to eliminate causes of noncompliance and prevent recurrence. The process for addressing Environmental and EMS nonconformities, including: cause analysis, corrective and preventive actions, evaluation of the effectiveness of such actions and necessary changes to the EMS is defined below.
- 12.1.2 Noncompliances identified during monitoring and measurement, routine EMS evaluations, internal audits, and other mechanisms shall be documented in the Working EMS Planning Tool.
- 12.1.2.1 The noncompliance documentation shall include a description of the noncompliance, corrective action to mitigate the noncompliance, personnel responsible for implementing the corrective action plan, the date corrective actions are to be in place, and a mechanism to prevent future occurrences.
- 12.1.3 Noncompliance shall be reported to management as soon as practicable and reported to interested parties as appropriate, in accordance with WSL's environmental operating permits and applicable environmental regulatory obligations.
- 12.1.4 Noncompliances shall be investigated, and root cause determined by use of the Corrective and Preventive Action (CAPA) Form included in Appendix B.
- 12.1.5 EMS corrective actions plans shall be appropriate to the significance of the effects of the nonconformities, including the environmental impacts.

### **12.2 Continual Improvement**

- 12.2.1 WSL site management identifies opportunities for improvement of the EMS and its processes to achieve the intended outcomes of the EMS, and enhance environmental performance. The individuals listed as having authority of control over the SWL EMS in the Working EMS Planning tool EMS Overview Table may direct the amendment or update of the EMS at any time.
- 12.2.2 Opportunities for improvement may be documented and tracked as Opportunities, Environmental Objectives, or as actions in the Working EMS Planning Tool. Other methods may also be used as deemed appropriate by Management.

## **Appendix A – Environmental Policy**



# Environmental Policy

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We are an industry leading environmental services company that offers innovative technologies and practices for solid waste management. To achieve our environmental goals and objectives we act on economically viable, ecologically responsible, and socially responsible solutions through our environmental management system in order to:

- Achieve compliance with applicable federal, state, and local environmental statutes, regulations, enforceable agreements, and permits;
- Minimize risks to the environment from unplanned or unauthorized releases of hazardous or harmful contaminants;
- Continue to improve environmental performance;
- Provide adequate personnel and other resources for the environmental management system;
- Demonstrate our commitment to continual improvement of the environmental management system;
- Care for, conserve, and protect the environment and prevent pollution;
- Consider the environmental impacts of activities, products and services;
- Demonstrate our commitment to fulfill compliance obligations;
- Promote awareness of this policy, our environmental management system, and our significant environmental aspects; and
- Facilitate open communication with employees, suppliers, contractors, customers, community members and stakeholders.

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President

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Date

**Appendix B – Corrective and Preventive Action (CAPA) Form**



# CORRECTIVE and PREVENTIVE ACTION

## - CAPA FORM -

<b>(1) REQUESTOR:</b> Name: _____ _____	<b>(2) WSL TRACKING/ STATUS:</b> Tracking Number: _____ Date Assigned: _____ Date Closed: _____		
<b>(3) TEAM INFORMATION:</b> Assigned To: _____			
<b>(4) PROBLEM DESCRIPTION &amp; SCOPE:</b> <i>Problem Statement (and location):</i> _____ _____ _____ <i>Observation(s):</i> _____ _____			
<b>(5) CONTAINMENT ACTIONS:</b> <i>Effective Date:</i> _____	<b>(6) INTERIM ACTIONS (SHORT TERM):</b> <i>Effective Date:</i> _____		
<b>(7) PROBLEM SOLVING TOOLS:</b> <input type="checkbox"/> 5-Whys <input type="checkbox"/> Brainstorming <input type="checkbox"/> Other: _____	<b>(8) ROOT CAUSE OF NONCONFORMANCE:</b>		
<b>(11) CORRECTIVE ACTIONS (LONG TERM):</b>		<b>(12) PREVENTIVE ACTION(S):</b>	
<b>Actions Implemented/ Target Completion Date:</b>	<b>Documents Affected:</b> <small>Control # / Rev/ Title</small>	<b>Date Closed:</b>	<b>Impact to Similar Processes:</b>
<b>(13) REVIEW AND APPROVAL by WSL:</b>			
<b><u>Verification of Effectiveness:</u></b>		<b><u>Yes/ No/ NA:</u></b>	<b><u>Comment(s):</u></b>
New and/or modified documents, processes, and/or inspections are in place and functional:		_____	_____
Actions above should prevent or eliminate further noncompliances:		_____	_____
Verification Audit to be added to Audit Schedule		_____	_____
<b>Approved By:</b> _____		<i>Name:</i>	<i>Title:</i>

## GUIDANCE FOR COMPLETING A CAPA FORM

The following guidelines are for completing corrective action responses to environmental or EMS audit reports that identify nonconformities. However, these guidelines can also be applied to

### **STEP 1: Curative / Containment Action:**

- The first step is to address the symptom. These are the actions necessary to cure or contain
- What immediate actions were taken to ensure that the process is now being executed in
- What immediate actions were taken to contain and verify any products that may have been
- Examples of supporting evidence might include: updated procedures, work instructions, control plans, etc. to show any changes were defined. Additionally, evidence of effective implementation of the changes is also required such as completed work order documentation, inspection records,

### **STEP 2: Determining the Root Cause:**

- Finding the actual root cause is critical to ensure that the nonconformance is prevented from
- All defects are created by errors. The key is to identify the ERRORS that caused or allowed
- What controls of the management system were ineffective in preventing the ERRORS that
  
- **Evidence of the use of disciplined problem solving tools is expected to show how the root cause was determined and can be relied upon. Examples might include:**
  - ✓ 5-Why root cause analysis
  - ✓ Process Analysis (value stream mapping, internal audits, use of process definitions,
  - ✓ Cause and Effect Diagrams
  - ✓ Fault Tree Analysis
  - ✓ Statistical studies identifying the causes of variation
  - ✓ Brainstorming process results
- Examples of unacceptable root cause statements:
  - ✓ Restating / rewording the nonconformance
  - ✓ Failure to follow procedures (Why did the management system allow this?)
  - ✓ Operator error (Why did the process allow the operator to make an error?)
  - ✓ Management oversight (Why did the management system allow this?)
- If there is more than one finding listed in the nonconformance statement then there must be a root cause analysis performed and described for each finding where applicable.

### **STEP 3 - Determining the Corrective Action plan necessary to address the root cause:**

- A corrective action plan must be developed for each non-conformance.
- Corrective action requires CHANGE. If we continue to do the same things we will continue to
- These actions must describe the formal CHANGES that were implemented to address each
- A statement in a corrective action response is not evidence of formally changing the management system. Changes resulting from corrective actions must be defined in formal
- Examples of supporting evidence might include: updated procedures, work instructions, control
- Additionally, evidence of effective implementation of the changes is also required such as completed work order documentation, inspection records, training records, audit records, etc.
- For each statement of change in the corrective action please also state the specific document names, document numbers, revision levels, pages, etc. that show where the change was defined
- **Wherever possible the expectation is that formal management system controls were added or improved to prevent or detect the ERRORS that caused the nonconformance. This is called fail-safing, fool-proofing, or error-proofing. The preferred approach is to**
  - ✓ Automated controls added to processes to prevent errors

## GUIDANCE FOR COMPLETING A CAPA FORM

- ✓ Additional manual verification points added to processes to detect the errors
- ✓ Additional internal audit requirements to verify conformance to process requirements
- Examples of unacceptable corrective action statements:
  - ✓ Reinforced the importance of following procedures (What improved controls were)
  - ✓ Retrained operators (Why did the training not work the first time? Maybe even the best training will never be enough because the process needs to be error-proofed?)
  - ✓ Records were found after the audit (Why were they not available during the audit?)
- If there is more than one finding listed in the nonconformance statement then there must be a corrective action described for each finding where applicable.

### **STEP 4 - Global Application of Corrective Actions**

- Auditing is a sampling process. In many cases the nonconformance was only found in one process or product but could also occur in similar processes or products that were not sampled.
- Therefore, the corrective action must also describe an assessment of similar processes, and where applicable, the actions taken to apply the curative and corrective actions elsewhere.

### **STEP 5 - Verifying the Effectiveness of Corrective Actions:**

- In some cases the root cause analysis does not lead to the actual root cause and/or the corrective actions taken do not effectively prevent the nonconformance from recurring.
- Therefore, the corrective actions taken must be verified to ensure that they were effective in eliminating the root cause and preventing the nonconformance from recurring.
- There are many methods that may be used. The method(s) to be used must be described and
- Examples of verification methods include:
  - ✓ Additional process monitoring until it is demonstrated that the process is stable and capable of consistently meeting requirements (recording and analysis of process)
  - ✓ Additional internal audits to specifically verify the effectiveness of the corrective actions
  - ✓ Associated metrics showing significant improvement resulting from the corrective

### **STEP 6 – Identifying and Documenting the Objective Evidence**

- You must provide full supporting evidence to demonstrate how root causes were determined and that all described containment and corrective actions have been fully and effectively
- A statement in a corrective action response is not evidence of formally changing the management system. Changes resulting from corrective actions must be defined in formal
- Examples of supporting evidence might include: updated procedures, work instructions, control plans, forms, schedules, etc. to show any changes were defined.
- Additionally, evidence of effective implementation of all corrective actions is also required. For every statement of “we did”, “was done”, “was performed”, “was implemented”, etc. evidence is
- Examples of supporting evidence might include: completed work order documentation, inspection records, training records, audit records, analysis reports, etc. NOTE: for any changes to procedures, work instructions or other process documentation, evidence that the affected employees were trained on these changes is also required to demonstrate implementation. For