SAFETY, HEALTH AND ENVIRONMENTAL MANAGEMENT SYSTEM OPERATING PROCEDURE

Corrective / Preventive Action Process

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APPROVED:

//SIGNED//	02/03/10
Peer Reviewer	Date
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Recertified:

Name	Christopher Taylor				
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ATTACHMENTS: None

A. PURPOSE AND APPLICABILITY

The purpose of this Operating Procedure (OP) is to define authorities, procedures, and responsibilities for investigating and eliminating actual and potential regulatory noncompliances and management system nonconformances. The desired outcome of this OP is the elimination of noncompliances and nonconformances, along with any adverse impacts that may be caused by them, and to prevent their recurrence. This OP applies to all facets of the Region's Safety and Health Management System (SHMS) and Environmental Management System (EMS).

B. DEFINITIONS

All definitions may be found in the document titled *US Environmental Protection Agency Region 7 Safety, Health, and Environmental Management System Terms and Definitions* (SHEMS 007.9000.02) contained in the EMS Manual or in the SHMS Manual. For the purposes of this OP, the following terms apply:

- Corrective Action
- Document
- Record
- Internal Audit
- Noncompliance
- Nonconformance
- Preventive Action
- Responsible Manager
- Senior Management

C. PROCEDURAL STEPS

Actual and potential regulatory noncompliances and management system nonconformances are typically discovered during program management reviews, compliance assessments, or conformance audits. However,

1. If possible, actions to address regulatory compliance deficiencies should be taken by employees at the time a noncompliance is identified in order to bring the process back into a state of compliance.

2. If the actual or potential regulatory noncompliance or management system nonconformance deficiency is discovered and the EMS Coordinator or SHMS Coordinator (*i.e.*, Coordinator) is not part of the discovery process the person(s) making the discovery shall notify the appropriate Coordinator as soon as possible whether or not the deficiency was corrected.

3. The Coordinator shall initiate the Corrective/Preventive Action Process. This process may proceed formally, as described in the remaining steps of this OP, or the Coordinator may opt to document the deficiency and the decision not to proceed formally in the Nonconformity – Corrective Action – Preventive Action folder in the

EMS or SHMS Manual. If the Coordinator determines that the formal process should go forward, they will begin this process by gathering information to complete Sections 1 – 3 of the Corrective/Preventive Action Form (CPAF – SHEMS 082.5250.00). The Corrective/Preventive Action Control Code number will be the same as the document control number and will be assigned by the Coordinator in accordance with SHEMS 006.7210.02, *Document Control*.

4. The Coordinator, Responsible Manager in the area where the noncompliance or nonconformity was observed, and/or members of the Responsible Manager's staff will conduct a root cause analysis using the "Five Whys" technique[1] to determine the most likely factor(s) that contributed to the deficiency and annotate the results of the analysis in Section 4 of the CPAF.

5. Following root cause analysis, the Responsible Manager and the Coordinator will determine the appropriate action(s) needed to correct and/or prevent the recurrence of the deficiency. The Coordinator will then determine if the potential exists for similar deficiencies to occur in other parts of the Region. If a potential deficiency exists, organizational elements with a stake or interest in the proposed action(s) must be consulted with and concur with the proposed preventive action. If the action requires a significant change in organizational structure or the commitment of resources, the Responsible Manager will raise the issue to Senior Management for their concurrence and action. Actions to be taken, performance indicators related to the actions, due dates and actual completion dates for the actions, and persons responsible for the actions will be annotated in Section 5 of the CPAF by the Responsible Manager. The Responsible Manager will document progress toward completion of the actions in Section 6 of the CPAF.

6. The Responsible Manager shall ensure that all actions are completed, working, and documented on the CPAF. When satisfied that this is done, the Responsible Manager will sign and date Section 7 of the CPAF and return it to the Coordinator. If the Coordinator agrees that all necessary corrective and/or preventive actions are complete, they will countersign and date in Section 7 and fill in the "Date Actions Completed" portion of Section 1.

7. Following a reasonable period of time (typically 2 – 6 months), the Coordinator will assess the corrective/preventive actions taken to determine if they are effective in achieving the desired result(s) and document their findings in Section 8 of the CPAF.

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1 The "Five Why's" is a method for rapidly determining the root cause of a problem popularized by Taichi Ohno, the father of the Toyota Production System. His technique was to approach any problem and keep asking "Why" until he was satisfied that the answer showed him what was really the source of the problem. He found over time that by asking "why" five times he usually ended up with the right information to go and fix the problem, hence the name "Five Whys."

If it is determined that the actions are not effective, the Coordinator will meet with the Responsible Manager to establish a new plan of action to achieve desired results.

D. RECORDS MANAGEMENT

This OP may result in the generation of EMS or SHMS records. Any records created will be managed in accordance with the most current version of SHEMS 006.7210.02, *Document Control*, and SHEMS 006.7210.17, *Records Management*.

E. QUALITY ASSURANCE AND QUALITY CONTROL

The quality assurance and quality control (QA/QC) success of the corrective and preventive action process, as detailed in this OP, will be determined through the completion of Step 7 above and through the internal and external conformance audit processes. Deficiencies noted during these audits will be managed through the Region's Corrective/Preventive Action Process as defined in this OP.

F. REFERENCES

Current versions of the following references are assumed if no date is provided.

1. ISO 14004:2004(E); *Environmental Management Systems – General Guidelines on Principles, Systems, and Support Techniques*; November 15, 2004

2. OHSAS 18001:2007; *Occupational Health and Safety Management Systems – Requirements*; July 2007

3. US EPA R7, *US Environmental Protection Agency Region 7 Safety, Health, and Environmental Management System Terms and Definitions*, SHEMS 007.9000.02

4. US EPA R7, *Document Control,* SHEMS 006.7210.02

5. US EPA R7, *Records Management,* SHEMS 006.7210.17

6. US EPA R7, SHEMS *Corrective/Preventive Action Form Template*, SHEMS 082.5250.00