Nonconformance and Corrective and Preventive Action

Background and Exhibits

No EMS is perfect. You will probably identify problems with your system (especially in the early phases) through audits, measurement, or other activities. In addition, your EMS will need to change as your facility adapts and grows. To deal with system deficiencies, your facility needs a process to ensure that:

- Problems (including nonconformities) are identified and investigated;
- Root causes are identified;
- Corrective and preventive actions are identified and implemented; and
- Actions are tracked and their effectiveness is verified.

EMS nonconformities and other system deficiencies, including legal noncompliance, should be analyzed to detect patterns or trends. Identifying trends allows you to anticipate and prevent future problems.

Key steps to identifying trends include:

- Identify the problem;
- Investigate to identify the root cause;
- Come up with the solution;
- Implement the solution;
- Document the solution;
- Communicate the solution; and
- Evaluate the effectiveness of the solution.

Focus on correcting and preventing problems. Preventing problems is generally cheaper than fixing them after they occur. Start thinking about problems as opportunities to improve!

Determining Causes of Problems

You will need to establish a method to determine the causes of failing to conform. In some cases, the cause may be obvious, and in others, obscure.

EMS problems typically include:

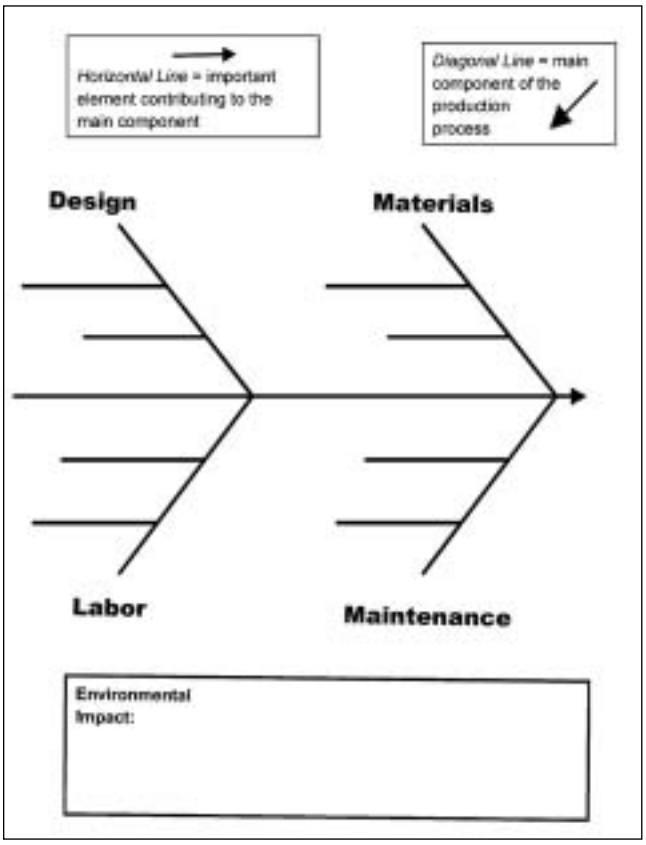
- Poor communication;
- Faulty or missing procedures;
- Equipment malfunction or lack of maintenance;
- Lack of training;
- Lack of understanding of requirements;
- Failure to enforce rules; and
- Corrective actions fail to address root causes of problems.

"Root cause analysis" is a process by which you can identify causes and preventive actions. If a spill occurs several times in your raw material transfer area, you would attempt to identify the root cause of the spill occurring so that you could address the cause and prevent the spill in the future.

Root cause analysis can be used to describe a very formal analysis process, however, it also can mean something simpler, looking past the obvious or immediate reason for a nonconformance to determine why the nonconformance occurred.

The root cause diagram, shown in ***Exhibit 15-1: Root Cause Diagram***, will help you organize your thoughts when you analyze your facility's potential for environmental impact. This analysis can be done by one person or by a group, with one person writing down the ideas produced. Each diagonal line represents a main component of the production process. Each horizontal line stemming from the diagonal represents an important element contributing to each of the main components. For example, elements of work practices might contribute to the labor component. This diagram is a device to help organize the analysis of the cause of potential environmental impacts. Use it if it helps, but don't get hung up on trying to make it work.

Exhibit 15-1: **Root Cause Diagram**



Taking **Corrective Action**

Once you document a problem with respect to meeting targets, you must resolve it. Take action as quickly as possible. Make sure assigned responsibilities for actions and schedules are clear so that correction occurs in a timely manner.

Employees in the facility may recognize the need for corrective action and provide good ideas for solving problems. Find ways to get them involved in the improvement process. It's important to determine whether a lapse is temporary or due to some flaw in the procedures or controls. For this reason, communicate any findings to employees and provide any follow-up training for changes in the procedures that may result. The following is a checklist to help complete corrective action. Have you:

- Identified the problem(s)?
- Identified the cause(s)?
- Come up with a solution for each?
- Implemented the solution(s)?
- Documented the solution(s)?
- Communicated the solution(s)?
- Documented the action(s)?

Here are some things to think about to expedite the determination of your facility's corrective and preventive action process:

- Use the corrective and prevention action process for quality that is included in your ISO 9001 management system, if you have one, as a model (or integrate with it) for EMS purposes.
- Combine some elements of your management review and corrective action processes if you can. Facilities that do use a portion of their management review meetings to review nonconformities, discuss causes and trends, identify corrective actions, and assign responsibilities.
- Don't go overboard with bureaucracy—simple methods often work quite effectively. The amount of planning and documentation needed for corrective and preventive actions will vary with the severity of the problem and its potential environmental impacts.
- Be sure that your corrective and preventive action process specifies responsibilities and schedules for completion. Once you document a problem, the facility must be committed to resolving it in a timely manner. Review your progress regularly and follow up to ensure that actions taken are effective.
- Make sure your actions are based on good information and analysis of causes. While many corrective actions may be "common sense," you need to look beneath the surface to determine why problems occur.
- Rule of thumb: Corrective actions should: (1) resolve the immediate problem; (2) consider whether the same or similar problems exist elsewhere in the organization; and (3) prevent the problem from recurring. The corrective action process also should define the responsibilities and schedules associated with these three steps.
- Find ways to get employees involved in the system improvement process (for example, via suggestion boxes, contests, or incentive pro-

grams). Initially, most EMS problems may be identified by your internal auditors. However, over the long run, many problems and good ideas may be identified by the people doing the work. This should be encouraged.

Use your answers to the questions provided in ***Exhibit 15-2: Element Review Questions*** to begin the process of determining your facility's corrective and preventive action process. ***Exhibit 15-3:*** ***Procedure for Corrective and Preventive Action (EP-015)***, and supporting forms (EF-015.01, EF-015.02), provide a sample procedure and forms for conducting corrective and preventive action. The supporting forms are guides to document the use of your procedure and to track corrective and preventive actions.

Exhibit 15-2: **Element Review Questions**

Questions	Your Answers
Do we have an **existing process** for corrective and preventive action? If yes, does that process need to be revised? In what way?	
Who needs to be involved in this process within our organization?	
How are **nonconformities** and other potential system deficiencies **identified**? (List methods such as audits, employee suggestions, ongoing monitoring, etc.)	
How do we **determine the causes** of nonconformities and other system deficiencies? How is this information used?	
How do we **track the status** of our corrective and preventive actions?	
How is/can **information** on nonconformities and corrective actions **be used within the EMS** (for example, in management review meetings, in employee training sessions, in review of procedures, etc.)	
How do we **ensure the effectiveness** of our corrective and preventive actions?	
Our next step on corrective and preventive action is to…	

Exhibit 15-3: **Procedure** for **Corrective** and **Preventive Action** (EP-015)

1.0 Purpose

The purpose of this procedure is to establish and outline the process for identifying, documenting, analyzing, and implementing preventive and corrective actions. Preventive or corrective actions may be initiated using this procedure for any environmental problem affecting the organization.

2.0 Activities Affected

All areas and departments

3.0 Forms Used

3.1 Corrective and Preventive Action Request (CAR) (EF-015.01)

3.2 Corrective and Preventive Action Tracking Log (EF-015.02)

4.0 References

4.0 Procedure for Environmental Management System and Regulatory Compliance Audits (EP-017)

4.1 Procedure for Emergency Preparedness and Response (EP-007)

4.2 Procedure for Communication with Stakeholders (EP-004)

4.3 Procedure for Document Control (EP-014)

4.4 Procedure for Monitoring and Measurement (EP-009)

4.5 ISO 14001:1996, Element 4.5.2

5.0 Definitions

None

6.0 Exclusions

None

7.0 Procedure

7.1 Where non-conformances or non-compliances are identified through the environmental audit process, the responsible and accountable area or department representative, affected area or department manager, audit team member or Environmental Management Representative (EMR), is responsible for:

7.1.1 Identifying the root cause(s) of non-conformances or non-compliances;

7.1.2 Identifying appropriate corrective and preventive actions (including modifying or creating environmental procedures and work practices);

7.1.3 Planning and implementing corrective and preventive actions; and

7.1.4 Verifying the close-out and effectiveness of corrective and preventive actions.

Exhibit 15-3: Procedure for Corrective and Preventive Action (EP-015) (continued)

7.2 Where non-conformances are identified outside the environmental audit process, the Quality Manager or designee will generate a CAR, as appropriate. The affected area or department manager, or designee, is responsible for:

a) Identifying the root cause(s) of these non-conformances;

b) Identifying appropriate corrective and preventive actions (including modifying or creating environmental procedures and work practices);

c) Planning and implementing corrective and preventive actions; and

d) Verifying the close-out and effectiveness of corrective and preventive actions.

The Quality Manager or designee will verify proper implementation of corrective and preventive actions.

7.3 Where non-compliances are identified outside the environmental audit process, the EMR or designee will generate a CAR, as appropriate.

8.0 Frequency

As needed following reviews

9.0 Records

Records shall be retained consistent with the Procedure for Environmental Records (EP-005).

Record of Revisions

Revision Date	Description	Sections Affected

Corrective and **Preventive Action Request** (EF-015.01)

A. Audited Area/Department:	
Audit Date: *Auditee(s):*	*Auditor(s):* *Date*:
B. Description of Non-Conformance: Audit Criteria: Applicable ISO 14001 Element:	**C. Root Cause Analysis:**
D. Corrective Action: Date of Implementation:	
E. Preventive Action:	
Date of Implementation:	
F. Verification: Date of Verification:	
Auditor (signed):	*Date:*

Corrective and **Preventive Action Tracking Log** (EF-015.02)

CAR #	Issue Date	Area/ Department	Problem Description	Corrective Action Completion Date	Preventive Action Completion Date	Closure Date