NONCONFORMANCE AND CORRECTIVE AND PREVENTIVE ACTION

Background and Exhibits

Things change and 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 (RCA)" 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.

There are several methodologies from which your facility can choose to conduct RCA (note that the first choice might likely be that which is used for other systems at the facility, e.g., quality, health and safety, or preventive maintenance). They can be classified generally into the following categories:

- Informal or intuitive approaches;
- Formal or structured approaches; and
- RCA software approaches.

Informal or intuitive approaches to correcting non-conformances have a definite role in an EMS context. When non-conformances pose limited risks to human health, company mission, environmental resources, or budgets, a less rigorous RCA could be resource efficient. The key to an informal or intuitive approach in an effective RCA program is ensuring that clearly defined criteria allow personnel the leeway to use the method and provide guidance that indicates when such an approach is inappropriate. That guidance may be as simple as a statement that, "If any of the following conditions exists for a deficiency, a more formal documented RCA must be conducted:

- Fines or penalties;
- A release or discharge that exceeds permit limits;
- Adverse impact;
- Repeat conformance;
- Repeat compliance issue; and/or
- Systemic management problem.

When the conditions described above do not occur, intuitive problem solving may be appropriate." In such cases, the depth of analysis, the amount of coordination among the interested parties, and the volume of documentation also will be less extensive than RCA efforts conducted for problems deemed more serious.

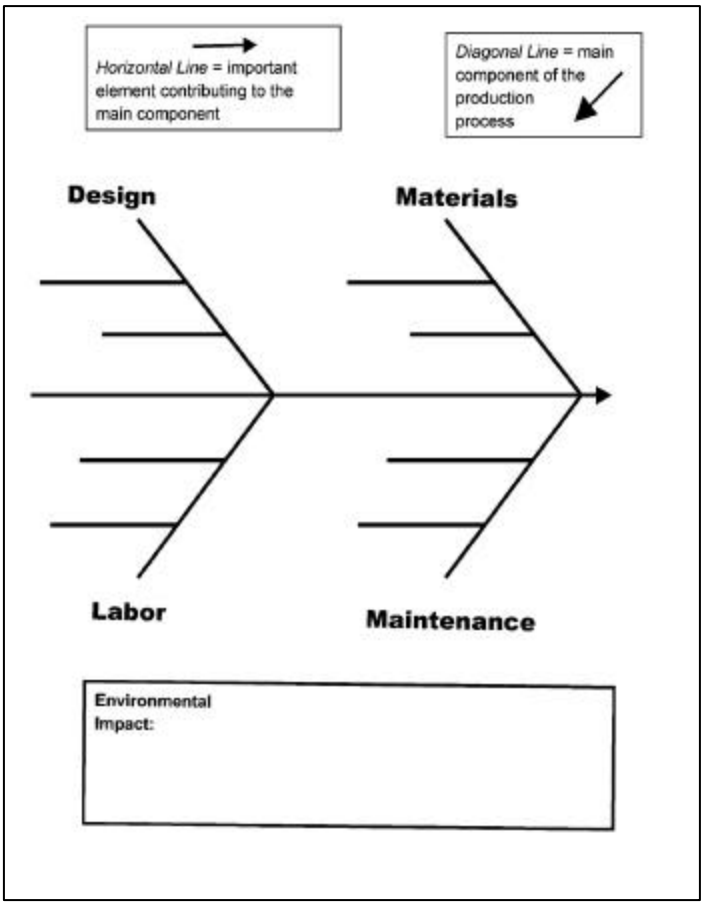
There are several types of more formal or structured approaches including cause and effect fishbone diagrams (***Exhibit 15-1: Cause and Effect Fishbone Diagram***), Pareto analysis, pick-a-cause (a variation of the cause and effect fishbone diagram is a process by which the user selects root causes from a list and places them on a cause and effect diagram), management oversight risk tree (MORT), change analysis, and barrier analysis. A number of software packages (known by a variety of names, such as fault tree and failure mode) also are available that are designed to facilitate all or part of the RCA process. Products range from those that provide a single focus (for example, factor and impact weighting in an otherwise completed root cause analysis) to those that purport to guide users through an entire RCA, from statement of the problem to the assessment of the effectiveness of the solution. To be effective RCA requires human interaction. Software programs simply follow certain pre-programmed rules to provide an answer that assists the user in better defining and prioritizing the problem. Such tools ask pre-

defined questions associated with a series of causes; doing so only limits the ultimate solution for a specific cause. Therefore, most software "answers" must be evaluated further. However, as is true of any endeavor in which sequential and iterative steps are to be followed, a standard process by which that procedure or set of procedures can be carried out generally adds value to the process, in terms of both validity and cost-effectiveness. Automation of the process offers several key advantages, such as:

- Uniformity of approach;
- Time saving in documenting issues and generating reports;
- Efficient control and tracking of documentation;
- Provision of metrics that support decisions;
- Potential to customize site-specific criteria;
- Useful when there are large volumes of data to review; and
- Real-time analyses of data and trends.

Exhibit 15-1: Cause and Effect Fishbone Diagram shows the layout of one approach that can be used to address root causes. Cause and effect analysis identifies the time sequence of a series of tasks or actions and the associated conditions that led to an occurrence. Brainstorming in groups, which is a crucial part of this methodology, facilitates consensus building and leads to the identification of root causes. With the aid of cause and effect fishbone diagrams, the group breaks problems into parts, or causes, by asking, "Why did this occur?" or "What caused the effect?" or "Why does this cause happen?" The questioning is repeated until the group finds no more answers. The answers then are presented graphically on the cause and effect fishbone diagram, which becomes a powerful communication tool that provides a "visual dialogue" of the problem and simplifies complex issues by separating them into individual parts. Effective listing of all causes leads to the selection of many solutions. The choice of solution then should be focused on prevention of the recurrence of the problem. The exercise of developing the cause and effect fishbone diagram typically is carried out by a group of three to six people who represent all the disciplines involved in the incident. Such a group will devote from one-half hour to four hours to developing the cause and effect chart (one to one and one-half hours is typical).

Exhibit 15-1: Cause and Effect Fishbone Diagram



Taking Corrective Action

Once you document a problem with respect to not doing what you said you were going to do or not meeting objectives, 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 programs). 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.

Refer to ***Exhibit 15-2: Summary Checklist*** for a step that can help you develop and maintain 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: Summary Checklist

NONCONFORMANCE AND CORRECTIVE PREVENTIVE ACTION

Step 1: Deficiencies in your EMS can be identified through audits, monitoring and measurement, and other observations. Your EMS must have a process to address system deficiencies (including legal non-compliance), ensure identification of problems and root causes, implement corrective and preventive actions (CARs and PARs), and track the effectiveness of these actions. Capture the approach used to manage PARs and CARs in a written procedure. ***Exhibit 15-3: Procedure for Corrective and Preventive Action (EP-015)*** and supporting Forms EF-015.01 and EF-015.02 serve as templates. Include this customized procedure in your EMS manual (see ***Exhibit 10-3: EMS Manual***).

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 EMS 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.

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)

<table>
<tr><td colspan="3">A. Audited Area/Department:</td></tr>
<tr><td>Audit Date:
Auditee(s):</td><td colspan="2">Auditor(s):
Date:</td></tr>
<tr><td>B. Description of Non-Conformance:

Audit Criteria:
Applicable ISO 14001 Element:</td><td colspan="2">C. Root Cause Analysis:</td></tr>
<tr><td colspan="3">D. Corrective Action:

Date of Implementation:</td></tr>
<tr><td colspan="3">E. Preventive Action:</td></tr>
<tr><td colspan="3">Date of Implementation:</td></tr>
<tr><td colspan="3">F. Verification:

Date of Verification:</td></tr>
<tr><td colspan="2">Auditor (signed):</td><td>Date:</td></tr>
</table>

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