

INDUSTRIAL EXTENSION SERVICE <b>IES</b> EP-11	<b>Non Conformity, Corrective and Preventative Action</b>	
	<b>Last Rev. Date: 10-08-2007</b>	<b>Rev. No. #2</b>
	<b>Origination Date: 01-10-2002</b>	<b>Page 1 of 3</b>

## 1.0 Purpose

This procedure defines the responsibilities and process for dealing with nonconformities with the <COMPANY A> environmental management system (EMS), for taking corrective and preventive action.

## 2.0 Scope

This procedure is applicable to <COMPANY A> Biotherapeutics operations as defined in the Scope statement in the EMS Manual Section 2.

## 3.0 Responsibilities

The EMR is responsible for investigating and managing all EMS corrective and preventative actions.

## 4.0 Forms Used

EF-11A        Corrective Action Request  
EF-11B        CAR Log

## 5.0 Procedure

5.1 Nonconformities can be identified as a result of:

- EMS audits - internal / registration / surveillance
- monitoring or measurement activities
- non-compliances with regulatory requirements
- periodic review of performance in achieving objectives and targets
- environmental incident or emergency drill results
- internal or external concerns/complaints (inspections, near hit system, etc)
- external regulatory inspections
- annual review of environmental aspects and impacts
- management review
- others

5.2 Non Conformities will be resolved using one of the following techniques:

- Correction – solutions will be implemented without having to determine root cause
- Corrective Action – Root cause will be determined and a corrective action implemented so that actual non conformities will not reoccur

- Preventive Action – Root Cause will be determined and a preventive action implemented so that potential non conformities will not occur

5.3 Where nonconformities are identified, the Lead Auditor, EMR, Audit Team, Departmental Supervisor or designee will generate CAR. A designated person will be responsible for:

- a) Identifying the severity of the incident in CAR
- b) Based in the severity, identifying the root cause and taking corrective actions and mitigating any environmental impacts
- c) Identifying and taking preventive actions to prevent their recurrence (including modifying or creating environmental procedures and work practices)
- d) Recording results of corrective and preventive actions.

5.4 Periodically monitor CAR for repeat occurrences as an indicator of effectiveness of corrective actions.

5.3 All CARs will be logged in the EF-011B

5.4 For this procedure – the following definitions will be made

- CORRECTIVE ACTION – Action taken to remedy actual EMS nonconformance.
- PREVENTIVE ACTION – Action taken to remedy potential EMS nonconformance.

5.5 **On a monthly basis**, all open CARs will be reviewed. Comments describing the progress being made may be documented in the CAR.

5.6 The CAR will be approved by area managers when completed and then closed.

5.7 The CAR will notify the user, if the nonconformity is a recurrence- which will be the indicator of corrective/preventive action effectiveness.

## 6.0 References


ISO 14001-2004, Elements 4.5.3 and 4.5.5

## 7.0 Related Procedures

EP-02 Legal and Other  
 EP-13 EMS Audits

## 8.0 Records

ER-11A Corrective Action Request

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ER-11B      CAR Log

9.0      **Revision History**

<b>Revision No.</b>	<b>Description of Change</b>	<b>Page #</b>	<b>Date</b>
1	Title Changes	1	1/10/2005
2	Minor Changes	All	10/8/2007