

# **Non Conformity, Corrective and Preventative Action**

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# 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
		rtequest

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



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- 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 <u>mitigating</u> any environmental impacts
  - c) <u>Identifying</u> 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.

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### 6.0 References

ISO 14001-2004, Elements 4.5.3 and 4.5.5

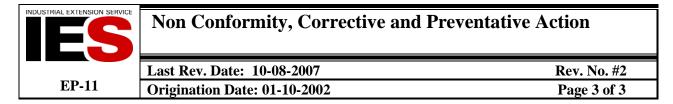
### 7.0 Related Procedures

EP-02 Legal and Other

EP-13 EMS Audits

### 8.0 Records

ER-11A Corrective Action Request



ER-11B CAR Log

# 9.0 **Revision History**

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

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