# 1. Notification of Nonconforming Event

**If the nonconforming event was a complaint, complete the complaint form first!**

## Part 1: Description of Nonconforming Event

*(to be completed by person notifying the nonconforming event)*

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| **Date:** |  |
| **Name:** |  |
| **Number of attachments:** |  |

**Description of nonconforming event:**

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**Suspected cause(s) of nonconforming event:**

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**Proposed action:**

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After completion of this page give this form to the Laboratory Manager

## Part 2: Action to be undertaken

*(to be completed by the Laboratory Manager)*

**Component where the nonconforming event took place (tick appropriate box):**

* Facilities & Safety
* Organization
* Personnel
* Equipment
* Purchasing & Inventory
* Process Control
* Information Management
* Documents & Records
* Customer Focus
* Assessment
* Nonconforming Event Management
* Continual Improvement

**Severity of nonconforming event:**

A) Severity of consequences (1= no severe consequences; 2= moderate severe consequences; 3= highly severe consequences):

 1 2 3

B) Chance for recurrence of nonconforming event (1= no change for recurrence; 2= moderate chance for recurrence; 3= high chance for recurrence):

 1 2 3

C) Score for severity (1= very low severity – no immediate action is required; 9= very high severity – immediate action is required):

Score for (A) x score for B =

**Description of SMART action point for implementation of corrective action:**

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**If applicable, description of SMART action point for implementation of preventive and/or concurrent control(s):**

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After completion of this page give this form to the Quality Officer

## Part 3: Implementation and monitoring of corrective action and preventive/concurrent controls

*(to be completed by the Quality Officer)*

**Checklist:**

* Insert this form in folder “Nonconformities”
* Discuss action nonconforming events and action points in weekly staff meeting
* Insert action points in minutes of weekly staff meetings
* Monitor timely completion of action points

Date of discussion of nonconforming event in weekly staff meeting:

**Dates of completion of action points:**

Action point for implementation of corrective action: Turnaround time: days

Action point for implementation of preventive control: Turnaround time: days

Action point for implementation of concurrent control: Turnaround time: days

After completion of all action points give this form back to the Laboratory Manager

## Part 4: Evaluation of corrective action and preventive/concurrent controls

*(to be completed by the Laboratory Manager)*

**Were the corrective action and preventive/concurrent controls effective in solving the nonconforming event and preventing it from reoccurring?**

* Yes: sign this form below for completion and give it to the Quality Officer for archiving
* No: describe the follow-up action to be taken (and make sure that the action is indeed carried out):

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***When follow-up action was effective in solving the nonconforming event and preventing it from recurring, sign the form below for completion and give it to the Quality Officer. If nonconforming event is still not solved, repeat above procedure until it is solved and the chance for reoccurrence is minimized.***

**Name, date, and signature of Laboratory Manager for completion of this form:**

Name: Date: Signature:

After completion give this form to the Quality Officer for archiving