

Attachment 8

Example Calibration Report Standard Operating Procedure

STANDARD OPERATING PROCEDURE

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Title	Method for Preparing a Calibration Report				
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## 1.0 OBJECTIVE

This procedure defines the method for preparing a Calibration Report following a calibration activity on a single piece of equipment or a list of equipment requested by the plant to be calibrated, in accordance with DOCUMENT..and DOCUMENT...and as required by this procedure also covers the generation and circulation of an Exception Report.

A Calibration Report is:

Prepared by the Authorized Technician responsible for carrying out the calibration request to highlight any concerns that have arisen following the completion of the calibration activity.

To inform the production department of any instrument that might have failed, and the degree of its failure. To allow production to discuss, possible product implications with QA.

To inform the production department of the instruments that have failed, which were replaced and which were adjusted

To assist the engineering teams to trend any instrument drift in order to justify its replacement on the grounds of reliability.

This report must represent all the issues that arise from the calibration activity, even if action has already taken place to correct any concerns.

## 2.0 SCOPE

This Report structure applies to all Calibration Reports produced within the company. If a Calibration Report does not conform to this structure then a reason for this must be stated in the introduction.

The Calibration Report should cover all the following issues:

List all the instruments that have passed as defined by the production department but have required recalibration to return to the defined instrument accuracy.

List all the instruments that have failed the production defined limits but were successfully recalibrated following an adjustment, also providing the Exception Report number and the reason.

List all the instruments that failed the production defined limits and were replaced, also providing the Exception Report number and the reason.

## 3.0 RESPONSIBILITIES

**Report Author** Authorized Technician, as defined in XYZ

**Process Owner** Head of Production Department or nominated deputy

## 4.0 PROCEDURE

### 4.1 Introduction

This section must contain the following information:

- (a) Who produced the report, under what authority, and for what purpose?

- (b) The area and the equipment covered by the report.
- (c) Relationship of the report to the type of request.
- (d) Summary of the type of recommendations listed within the report.

4.2 Test Results Summary

This section must contain the following information in the form of a table of results in the order of the instrument calibrated during the calibrating activity:

Type of instrument being calibrated

Instrument Tag Number

Duty

Pass / Fail

Date

Exception Report Number, if required

Example shown below:

Type of Instrument being calibrated

Type of Instrument	Tag Number	Pass / Fail	Date

This section must also contain the following information:

A list of all the instruments that failed and required adjustment, and then passed the calibration activity.

Example shown below:

Type of Instrument being re-calibrated

Type of Instrument	Tag Number	Exception Report Number	Date

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This section must also contain the following information:

A list of all instruments that, having failed the calibration activity, also failed the adjustment and required replacement.

Example shown below:

**Type of instrument and serial number, being calibrated following replacement**

<b>Type of Instrument</b>	<b>Tag Number</b>	<b>Exception Report Number</b>	<b>Date</b>

#### **4.3 Engineering Observations**

This section should contain the following information:

Any inaccuracies noted in loop drawings, user manual, P&ID drawings and the calibration procedures.

Any issues relating to access to plant and equipment requiring calibration.

Any recommendations to assist the future calibration activities.

#### **4.4 Instrument Calibration Exception Report**

The Exception Report is shown in example Appendix B and must be completed for each “Fail”. This report should be filled in after each day’s testing and must not be left until the end of the calibration campaign. This report must be sent to the Process Owner and the QA Regulatory Compliance Manager.

#### **5.0 Conclusion**

This section should contain the following information:

The final result as to whether the calibration activity has been successfully completed.

All calibration activities detailed within the product critical instrument list have been completed and, with the stated exceptions, all instruments were found to be within the defined process accuracy over the process operating range.

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## 6.0 APPENDIX

### Appendix A – Definitions

#### **CALIBRATION**

The set of operations, which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

#### **PRODUCT CRITICAL INSTRUMENTS**

A product critical instrument is an instrument whose failure may have a direct effect on product quality.

#### **PROCESS / SYSTEM CRITICAL INSTRUMENT**

A process / system critical instrument is an instrument whose failure may have a direct effect on process or system performance without affecting final product quality, or safety.

#### **SAFETY / ENVIRONMENTAL CRITICAL INSTRUMENT**

A safety/environmental critical instrument is an instrument whose failure may have a direct effect on safety/environment

#### **NON-CRITICAL INSTRUMENT**

An instrument whose failure is deemed to have no effect on product quality, process / system performance, safety or environment.

#### **INSTRUMENT PRE-CALIBRATION CHECK**

An instrument pre-calibration check is where the applied signal to the temperature transmitter is compared and corresponds to the displayed reading. The test equipment used is traceable to national standards.

#### **INSTRUMENT CALIBRATION**

An instrument, which fails the pre-calibration check, is adjusted following the Site Engineering procedures and the manufacturer's guidelines to within the manufacturers specified range.

#### **INSTRUMENT POST CALIBRATION CHECK**

Exactly the same as a pre-calibration check, and is only required whenever an instrument has been calibrated. The same criteria for pre-calibration checks apply.

#### **VALIDATION**

The action of proving, in accordance with the principles of GxP, that any procedure, process, equipment material, activity or system actually leads to the expected results.