1.0 PURPOSE:

The purpose of this document is to outline a uniform scheme for optimising the non-conformance process for instrument calibrations at the xyz site as described by xyz Calibration Policy Document.

2.0 SCOPE:

The guideline describes the scheme for reviewing and completing instrument calibration Non-Conformance Reports issued by the Calibration Group for the xyz site. The scope of this document is to provide general guidelines for use at the xyz site but not to specify detailed site policy or procedures.

3.0 DEFINITIONS:

Guideline – A document that is suggested or recommended from the Calibration Group for use by the xyz site. A guideline is not a policy or procedure. Policies or procedures are more detailed and must be adhered to.

Calibration – The set of operations which set-up the relationship, between values indicated by a measuring instrument or measuring loop or values represented by a material measure and corresponding known values of a reference standard.

CAT – Category Assessment Team, a team of people that have a vested interest in ensuring that the instrument is categorised correctly, with suitable frequency and tolerance for the duty and the instrument is fit for purpose.

Calibration Tolerance – The required accuracy limit of an instrument over the calibrated range, expressed as a deviation from a standard reading or percent of full scale, and determined by process and regulatory needs.

Non-Conformance Report – Issued by the Calibration Group on finding an instrument and/or loop that is beyond its calibration tolerance limit(s) and that may not be able to be adjusted back within its tolerance limit(s).

QR – Quality Assurance Report

4.0 RESPONSIBILITIES:

The Calibration Manager (or delegate) is responsible for issuing Non-Conformance Reports to the Plant/Equipment Owner, when an instrument and/or loop are found outside the required accuracy limit as specified by the calibration schedule. The Calibration Manager is also responsible for the closeout of any subsequent actions noted on the non-conformance form.

The Plant/Equipment owner is the accountable person responsible for reviewing the non-conformance against the defined regulatory limits for the process and/or system over the period specified, to determine whether this has caused an excursion from these defined regulatory limits. Where there is good justification for no GxP or EHS impact this should be noted on the form along with any appropriate actions i.e. where an EHS Incident report and/or QR is/are not deemed required, the findings from the review that concluded this result must be noted on the non-conformance form. Where a potential for GxP or EHS impact exists this must be noted on the non-conformance form. The QR or incident report reference number(s) must be recorded on the non-conformance form as appropriate.

QA and EHS groups are responsible for reviewing the findings of the Plant/Equipment Owner where notified, to assure that these are appropriate, that any resulting course of action is deemed suitable and corrective actions to the calibration system will minimise the possibility of any further excursions from defined limits.

5.0 GUIDELINE:

5.1 Overview

The non-conformance process should make the plant/equipment owner aware of an excursion from defined limits, allowing them to make appropriate judgments as to the effect of such excursions, informing the QA and EHS departments where this may have had a detrimental effect on personnel or plant/equipment safety, environmental emissions and/or product quality/research trial. It is also there to assist the Calibration Group in ensuring that they are calibrating the plant/equipment instrumentation to the correct frequency and tolerance, that the category is appropriate for the duty and that the instrument is fit for purpose to which it is used.

5.2 Approach

5.2.1 The Non-Conformance Report is compiled by the Calibration Manager. A PDF copy shall then be issued to the Plant/Equipment Owner via the e-mail system.

5.2.2 On receiving the Non-Conformance Report the Plant/Equipment owner must review the deviation(s) noted from acceptable limit(s) and appraise whether this has had any impact on regulatory limits.

5.2.3 The Plant/Equipment Owner should address the following when reviewing the non-conformance.

Has the system been in use during the period between calibrations?

If so, has this been for processes etc. that are under regulatory review.

Has there been any effect on GxP, whether direct or indirect.

Might this effect on GxP have been picked up by another system?

If so, has this other system reported a problem?

Has this compromised environmental, health or safety performance during this period?

Could this have been an EHS near miss reportable incident?

Is this part of a reoccurring pattern of errors for this instrument?

Has there been any change to the processes or systems that may have caused this error.

If the error had not been found at this point, what would the impact have been at some later date?

5.2.4 The Plant/Equipment Owner may request assistance from relevant personnel to aid prescribing the course of action to be taken as a result of the Non-Conformance Report. Assistance may be requested from any group on site that may have pertinent skills in helping resolve the Non-Conformance Report, e.g. EHS, QA.

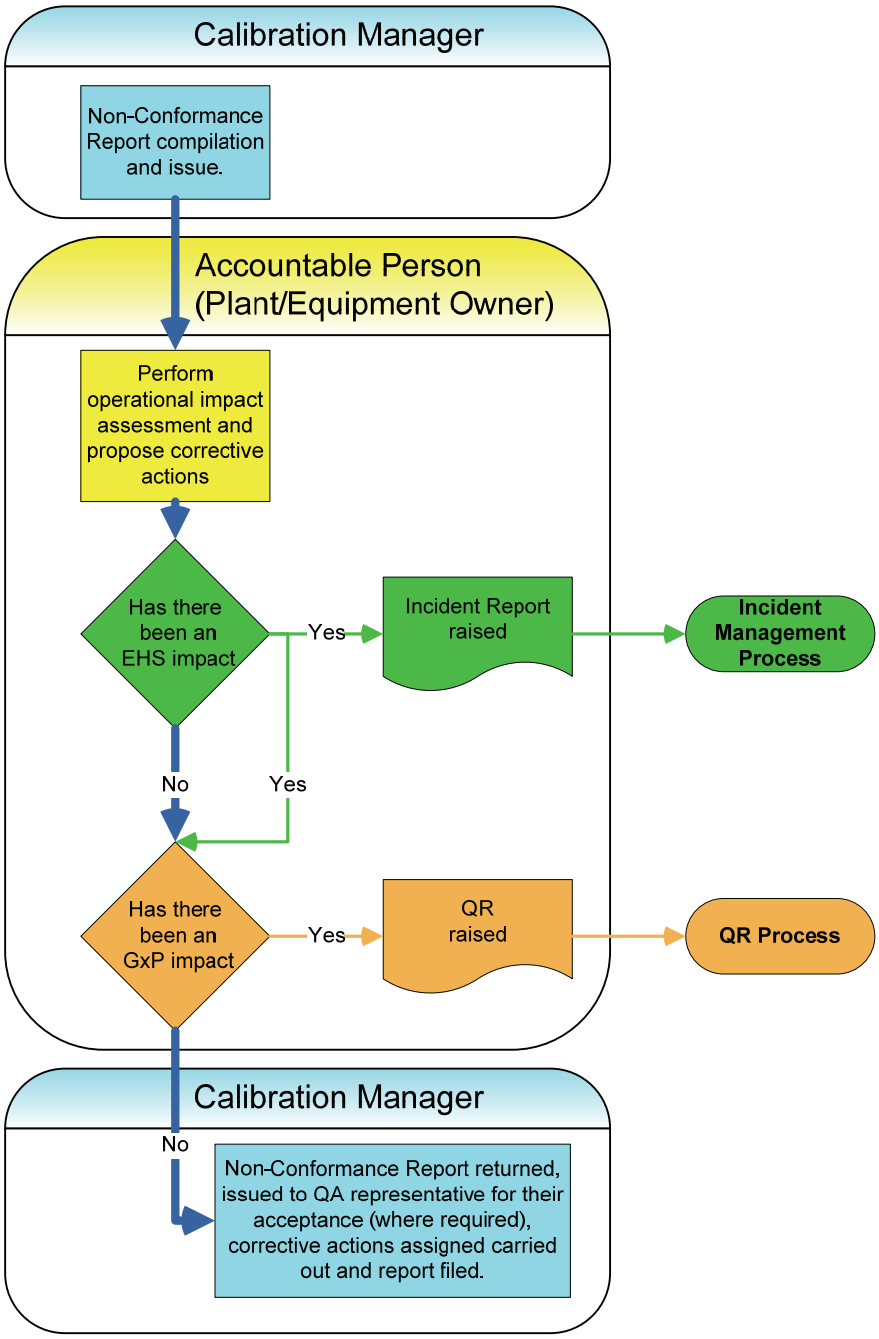
5.2.5 The Plant/Equipment Owner may request through the Non-Conformance Report that the Calibration Manager instigate the CAT process for the instrument to thoroughly review the category, frequency, tolerance and suitability of duty.

5.2.6 The Non-Conformance Report should be completed indicating the course of action to be taken; this may include noting that the non-conformance was referred to the EHS Incident System and/or QA, QR reporting system.

5.2.7 The Calibration Manager on receiving the returned Non-Conformance Report should address any corrective action stated on the report where detailed. Where a report has led to a referral through the EHS and/or QA systems, "action to result" from the investigation(s) will follow these processes and the Non-Conformance Report can be signed-off as complete.

5.2.8 Where the Non-Conformance report has resulted in an excursion from GxP limits, the Non-Conformance Report will be issued to the plant/equipment QA representative for their acceptance of the findings

from the plant/equipment owner. If the original findings of no GxP impact are not agreed, the form may be returned to the Plant/Equipment Owner to raise a QR as appropriate. Once acceptance from QA representative is completed the Non-Conformance Report should be returned to the Calibration Manager for filing.



5.3 **Benefits**

The benefits of employing these guidelines on the non-conformance process are:

Accountability in the right place - Operational impact assessment carried out by the agreed Accountable person (i.e. building/plant/equipment owner)
EHS & QA Representatives will be involved by exception based on impact assessment (but can be consulted as appropriate)
The QR and Incident Reporting systems will be used to manage Quality non-conformances and EHS 'near misses' arising from 'out of calibration events; Quality and EHS-related corrective actions will therefore be tracked within existing systems following 'handover' from calibration management process.
Corrective actions related to calibration-related issues will be retained within the calibration management system.

6.0 REFERENCES:

xyz Site Instrument Calibration Policy Document
(xyz Reference Number: ABC)

7.0 APPENDIX:

A. ABCD001 (Revision x)- Non-Conformance Report

XYZ Company – Non-Conformance and Corrective Action Report

INSTRUMENT DETAILS

The following sections to be completed by Calibration Group.

Work Order Nº:

Building Number :		Equipment Number :	
Plant/Equipment :		Loop Number :	
Service Description :		Tag Number :	

SHE ☐ **SHE/GxP** ☐ **GxP** ☐

(Tick applicable instrument category box)

CALIBRATION DETAILS

Note : Error in units used by End User.

Calibration Range :		Specified Instrument Calibration Tolerance :	+/-	Loop Tolerance :	+/-
Calibration Date :		Previous Calibration Date :		Previous Calibration Out Of Tolerance :	Yes : ☐ No : ☐
"As Found" Calibration Out Of Specification :	Yes : ☐ No : ☐	"As Left" Calibration Out Of Specification :			Yes : ☐ No : ☐
EAMS Repair Work Order Raised :	Yes : ☐ No : ☐	EAMS Repair Work Order Number :			

INSTRUMENT CALIBRATION FAILURE DETAILS

Note : Please complete engineering units in brackets.

Desired Value ( )	Actual Value ( )	Error Value ( )	Pass	Fail

Comments :

Originator :	Name :	Signature :	Date :

NON-CONFORMANCE REPORT ISSUED TO

Department :	Name :

PLANT/EQUIPMENT OWNER INVESTIGATION RESPONSE

The following sections to be completed by Plant/ Equipment Owner.

Has There Been Any EHS Impact :	Yes : ☐ No : ☐	If Yes, Please Supply Incident System Reference Number(s) :			
Has There Been Any GxP Impact :	Yes : ☐ No : ☐	If Yes, Please Supply XYZ/ XYZ Reference Number(s) :			
Specified Instrument Calibration Tolerance Acceptable :	Yes : ☐ No : ☐	If No, Please Advise New Calibration Tolerance :	+/-		
Specified Loop Tolerance Acceptable :	Yes : ☐ No : ☐	If No, Please Advise New Loop Tolerance :	+/-		
Specified Instrument Calibration Category Acceptable :	Yes : ☐ No : ☐	If No, Please Advise New Category (CAT Meeting Required To Ratify Decision) :			
Is a CAT Meeting Required To Resolve Issue(s) :	Yes : ☐ No : ☐	If Yes, Will This CAT Meeting Include All Associated Instruments With The Plant/Equipment :		Yes : ☐	No : ☐

Where no EHS and/or GxP impact noted, any details pertinent to this Non-Conformance must be documented overleaf

PLANT/EQUIPMENT OWNER SIGN-OFF

Name :	Signature :	Date :

XYZ Company – Non-Conformance and Corrective Action Report	
	Work Order N^{o}:

PLANT/EQUIPMENT OWNER INVESTIGATION RESPONSE DETAILS

QA ACCEPTANCE *The following sections to be completed by Plant/ Equipment QA Representative.*

Name :	Signature :	Date :

COMPLETION CHECKS *The following sections to be completed by the Calibration Group.*

Tick if "complete" or N if "not applicable"

CAT Meeting Arranged : ☐	Calibration Schedule Updated : ☐	Calibration Schedule Signed-Off : ☐
EAMS Work Order Complete : ☐	EAMS Updated : ☐	Corrective Actions Assigned To This Form Complete : ☐

COMPLETION CHECKS COMPLETE

Name :	Signature :	Date :