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[Company]

[Company Address]

ISO/ IEC 17025:2017

QUALITY MANAGEMENT SYSTEM

(MANUAL)

Prepared By (Name & Sign)	Approved By (Name & Sign)	Date
	[Manager]	
Document No.: M/01	Revision No. 00	Update Date: 01/01/2020

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2. AUTHORIZATION STATEMENT

[Company] is committed to the establishment and maintenance of management system given in lab's quality manual and implemented by the team members to meet the requirements of ISO/ IEC 17025:2017.

The members of the [Company] strictly adhere to the various MS procedures and SOPs/ test methods/ calibration methods as supported by the policies outlined in this manual.

_____ has been appointed as Quality Manager of [Company]. The Quality Manager, along with the responsibilities given in JD, is responsible for ensuring compliance with the management requirements stipulated in quality manual. He is authorized and responsible to ensure that the management system as per ISO/ IEC 17025:2017 is established, implemented and maintained by the [Company] team members. The Manager, Supervisor and analysts give full support and Co-operation to Quality Manager. Manager – (Name) assumes responsibility of Quality Manager in absence of Quality Manager.

_____ has been appointed as Technical Manager of [Company]. The Technical Manager, along with the responsibilities given in JD, is responsible for ensuring compliance with the technical requirements stipulated in quality manual. He is authorized and responsible to ensure that the technical requirements of management system as per ISO/ IEC 17025:2017 are addressed, implemented and maintained by the [Company] team members. The Manager, Supervisor and analysts give full support and Co-operation to Technical Manager. Manager – (Name) assumes responsibility of Technical Manager in absence of Technical Manager.

Name

[Manager]

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EVALUATION OF MEASUREMENT UNCERTAINTY AND STATISTICAL EVALUATION

Doc.: P-03 Rev 00 Dated: 01/11/2019

Prepared By: Quality Manager

Approved By: CEO/ MD

1. PURPOSE

The purpose of this procedure is to determine the process of evaluation of measurement uncertainty and statistical evaluation.

2. SCOPE

This procedure is applicable to all tests and calibrations where [Company] perform the testing and calibration activities.

3. DEFINITIONS**3.1 Uncertain:**

Not able to be relied on; not known or definite.

3.2 Uncertainty:

The state of being uncertain.

3.3 Precision

The quality or state of being precise; exactness; accuracy; strict conformity to a rule or a standard; definiteness.

Degree of mutual agreement among data obtained in the same way.

Absolute and relative standard deviation, standard error of the mean, coefficient of variation, variance.

3.4 Accuracy

The state of being accurate; exact conformity to truth, or to a rule or model; precision.

Note: These are not synonymous when describing instrumental measurements!

Degree of mutual agreement among data obtained in the same way.

Absolute and relative standard deviation, standard error of the mean, coefficient of variation, variance.

4.0 PROCEDURE:**4.1 Performance characteristics of instruments**

The below parameters are performance characteristics of instruments

- Precision
- Accuracy
- Selectivity
- Sensitivity
- Limit of Detection
- Limit of Quantitation
- Dynamic Range

4.2 Precision

TABLE 1-5 Figures of Merit for
Precision of Analytical Methods

Terms	Definition*
Absolute standard deviation, s	$s = \sqrt{\frac{\sum_{i=1}^N (x_i - \bar{x})^2}{N - 1}}$

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4.3 Sensitivity vs Limit of Detection

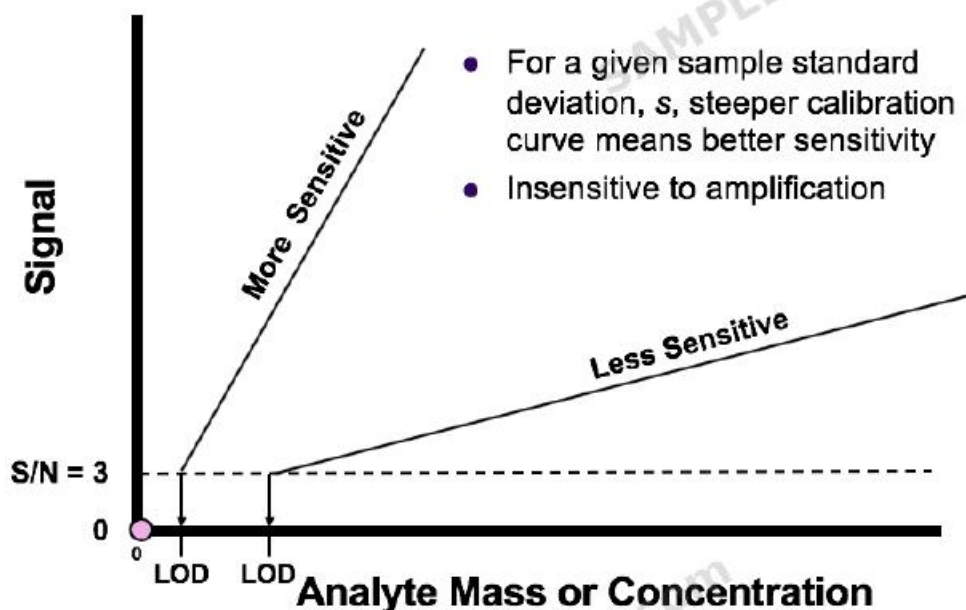
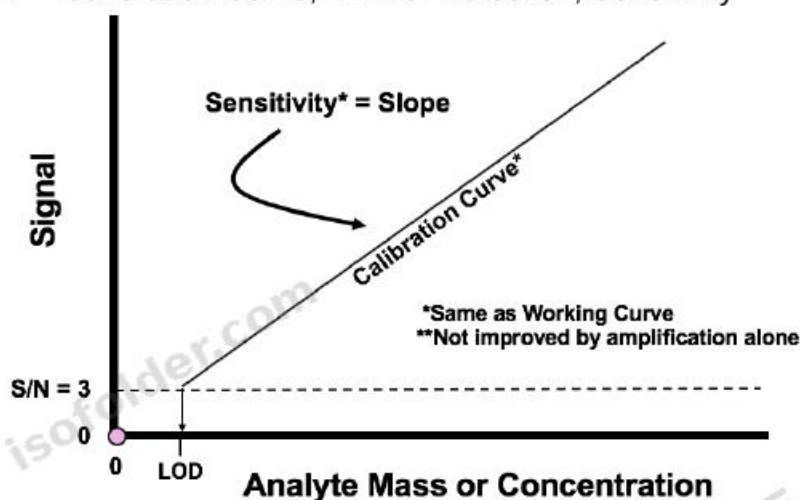
Sensitivity: Ability to discriminate between small differences in analyte concentration at a particular concentration.

- calibration sensitivity—the slope of the calibration curve at the concentration of interest

Limit of detection: Minimum concentration that can be detected at a known confidence limit

- Typically three times the standard deviation of the noise from the blank measurement (3s or 3s is equivalent to 99.7% confidence limit)
- Such a signal is very probably not merely noise

4.4 Calibration Curve, Limit of Detection, Sensitivity



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4.5 Selectivity

Degree to which a method is free from interference from other contaminating signals in matrix

$$S = m_A c_A + m_B c_B + m_C c_C$$

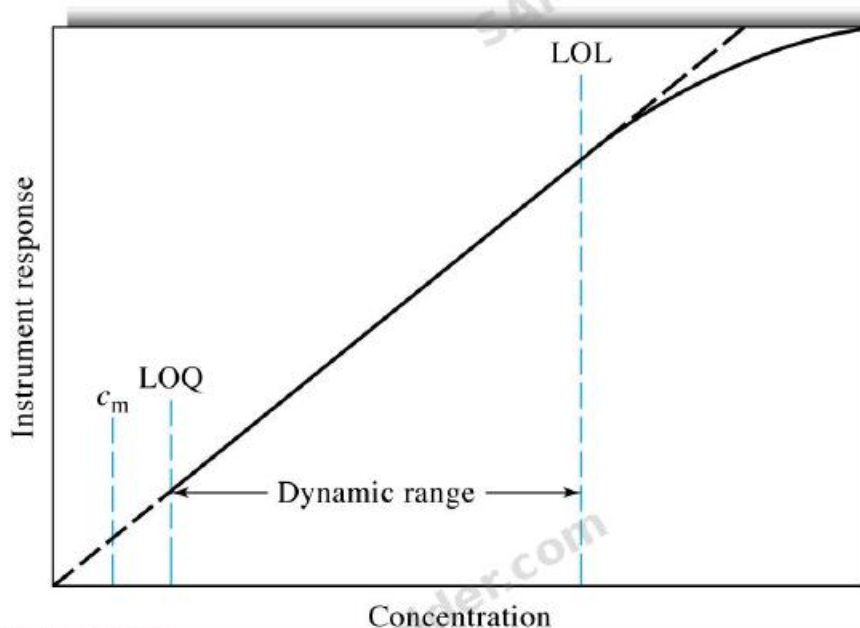
No measurement is completely free of interferences

$$k_{B,A} = \frac{m_B}{m_A}$$

Selectivity coefficient:

4.6 Dynamic range

- The maximum range over which an accurate measurement can be made
- From limit of quantitation to limit of linearity
 - LOQ: 10 s of blank
 - LOL: 5% deviation from linear
- Ideally a few logs
 - Absorbance: 1-2
 - MS, Fluorescence: 4-5
 - NMR: 6



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LAB OPERATIONS

Doc.: P-13 Rev 00 Dated: 01/11/2019

Prepared By: Quality Manager

Approved By: CEO/ MD

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Calibration Plan

Doc #: F 06

Dated: 31/12/2015

Revision: 00

Year																	
No.	Machine /Equipment	ID	Status	Month													
				Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
1			Planned														
			Actual														
2			Planned														
			Actual														
3			Planned														
			Actual														
4			Planned														
			Actual														
5			Planned														
			Actual														
6			Planned														
			Actual														
7			Planned														
			Actual														
8			Planned														
			Actual														
9			Planned														
			Actual														
10			Planned														
			Actual														

Prepared By:

Date:

Approved By: CEO

Date:

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List of Calibrated Equipment

Doc #: F 05

Dated: 31/12/2015

Revision: 00

Sr. No.	Description of Equipment	ID NO.	Serial No.	Frequency of Calibration	Calibration Status		Make	Calibration Carried out by
					Last Calibrated Date	Next due on		
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

Reviewed & Approved By: Technical Manager

Signature:

Date:

IDENTIFICATION AND ASSESSMENT OF THREATS TO IMPARTIALITY

<i>Business Aspects</i>	<i>Service Impacted</i>	<i>Potential Conflict of Interests</i>	<i>Description of potential conflict of interests</i>	<i>Company Policy to prevent conflict of interests</i>	<i>Actual Implemented measures to eliminate or control the potential / identified threats</i>

Note: A relationship that threatens the impartiality of [Company] can be based upon ownership, governance, management, personnel, finances, contracts, marketing and payment of a sales commission or other inducement for the referral new clients, etc.

Next Update will be done in

Reveiwed by and on