SOP: LFA 00062
Actions to be Taken For Unusual Observation For Instruments During Calibration

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1 Objective

Steps to take during an unusual observation of instrument during calibration

2 Scope

Applicable to all instruments being calibrated under the Quality Control Department

3 Responsibility

By: Technical Assistant
Counter Check: Executive/Manager

4 Accountability

Head of the Department

5 Procedure

5.1. Technical assistant to report to the Manager the out of calibration incident of the instrument.

5.2. Executive/Manager shall check the problem and troubleshoot the problem within the guidelines and parameters set by the manufacturer.

5.3. Executive/Manager shall inform the Maintenance Department if the problem is not rectified or solved.

5.4. If the problem is of different technical matter, the Executive/Manager should call the authorized service agent or manufacturer about the problem and request for assistance to solve the problem at the earliest time possible.

5.5. After service, re-calibrate and record the details of the service including the re-calibration of the instrument in the latter?s history card.

5.6. Analyse the batch prior to the re-calibration to confirm the results.

5.7. Variance between the old and new batch should not differ by more than one percent (1%)

5.8. If the difference in the results of the last batch is not within the +/- 1% range, choose the second to the last batch and continue the testing in reverse order until the result falls within the +/- 1% range.

5.9. List down all the batches that do not fall within the +/- 1% range. Make sure that the revised results comply with the specified limit as per the release specification.

5.10. 10 If the batch does not comply with the release specification, check to make sure that it complies with the regulatory specification.

5.11. If the batch does not comply with the regulatory specification, inform the Executive/Manager and wait for further instruction.

5.12. For raw materials, list down the RM if the revised results do not comply with the +/- 1% range.

5.13. Check that the revised result of the listed RM complies with the specifications.

5.14. If the listed RM does not comply with the specifications laid down, immediately inform the store to stop the use of the materials by following the established protocol and inform the QC personnel to wait for further action.

5.15. List down all the batches that were manufactured using the listed RM.

5.16. Repeat steps 5.9 to 5.12 for the other batches listed out.

6 Abbreviations

Q.C Quality Control

SOP Standard Operating Procedure