**1. PURPOSE**

To establish acceptable limits for each test for each control used and to verify that the performance of each test is within allowable limits of error.

**2. SETTING INITIAL MEANS AND ASSIGNED STANDARD DEVIATIONS**

2.1 For low volume tests, analyze each new lot of control material 10 times over a period of several days, in parallel with the controls in use.

2.2 For high volume tests, analyze the new control material 30 times over a period of not more than 30 days, in parallel with the controls in use.

2.3 If it is not possible to analyze controls in parallel, set up tentative means and standard deviations based on the manufacturers recommended values usually found in the control or method inserts. Analyze the new controls 10 times over a period of several days and check to ensure that the values remain within the manufacturers recommended limits.

* 1. Compare the means and standard deviations obtained for the new controls with expected values from the manufacturer and with IQMH recommendations.

2.5 Set provisional means and assigned standard deviations and incorporate these into the analytical protocol for the test.

**3. ADJUSTING MEANS FOLLOWING A SHIFT, OR A DRIFT IN QC VALUES**

3.1 Investigate the cause of the shift. It could be due to a change in control, reagent, or

calibrator, to changing environmental conditions, instrument malfunction, or to no identifiable cause. See the Investigation and Corrective Action Procedure section.

3.2 These biochemical tests have inherent variability and can be expected to change from time to time. Check the insert ranges, the allowable limits of error and the any recent changes. If the shift is large and control values are close to the limits of acceptability, then take the appropriate corrective action.

3.3 If the shift is small, can be explained on the basis of a change in assay parameters, and the controls are still within acceptable limits, then adjust the mean to a value calculated from at least the last 10 data points. The more data points used, the more accurate the new mean will be.

3.4 Monitor the test until 30 data points have been accumulated and adjust the mean again if necessary.

3.5 Recalculating means only has to be done if there is a significant shift, or drift in values.

3.6 Monitor monthly means using the Unity QC program to ensure that there the shifts or drifts do not become excessive over time.

**4. VALIDATION OF A NEW LOT OF REAGENT**

1. New reagent lots must be validated before patient results are reported.
2. Analyze each level of control in duplicate using the new reagent lot for each analyzer.
3. Compare the control values with those obtained with the current lot of reagent in use. The new control values should be within acceptable limits (+ 2 sds of the fixed means).
4. Analyze 5 patient samples with the current and new lot of reagent. Test results for the new lot of reagent should be within +/- 10% of the values obtained with the old lot of reagent.
5. If control and patient values are within acceptable limits, the new reagent lot is validated and patient testing may start.
6. If the shift in control mean is more than + 2 sds and the patient values obtained with the current and new lot of reagents compare within +/- 10%, then the new lot of reagent can be used, and the control means adjusted to the new values.
7. If the patient values do **not** compare within 10%, then the new lot of reagent must **not** be used and the investigation and corrective action process should be started.
8. Document all results obtained and actions taken in Bio-Rad Unity and/or on the pertinent action logs and forms.
9. Whether the new reagent lot has been accepted, or rejected, label it appropriately and keep it segregated from the old reagent lot while the latter is still in use.

**5. VALIDATION OF CALIBRATION**

1. Calibrate for each assay pertaining to the new, or the same lot of calibrator to be tested and then analyze controls. This should be done for each analyzer involved.
2. If control values should be within + 2 sds of the fixed means.
3. Analyze 5 patient samples with the old and new calibration. Test values for the new calibration should be within +/- 10% of the values obtained with the old calibration.
4. If any control exceeds + 2 sds of the mean, perform a calibration verification (tests all calibrator levels by running them as patients for each assay). The results of each level of calibrator should be comparable with the predetermined set values.
5. If all results are acceptable, the calibration is validated and patient testing can commence.
6. If the calibration passes, patient samples are all within acceptable limits and one or more control value is outside 2sd limits the calibration may be accepted and patient testing can start. This should happen infrequently.
7. If the calibration fails, the controls and patient samples are out of range, or analyzed calibrator values are not comparable with set values, the new calibration and calibrators must **not** be used and the investigation and corrective action process should be started.
8. Document all results obtained and actions taken in Bio-Rad Unity and/or on the pertinent action logs and forms.
9. Whether the new calibrator lot has been accepted, or rejected, label it appropriately and keep it segregated from the old calibrator lot while the latter is still in use.

**6. AUTHORIZATION**

A medical laboratory technologist or other responsible person shall authorize changes made and commencement of patient sample testing.

**7. REFERENCE**

IQMH - Broadsheet - Internal Quality Control Practice Update