Validation of Measurement Methods in the UAL and WBC

Validation Statement

The measurement methods used in the UAL and WBC will be validated by a combination of the following processes:

1. Calibration using standard reference material and/or phantoms
2. Systematic investigations by using controls running with the samples whenever applicable. The controls are self made by using a certified standard solution
3. Laboratory intercomparison
4. Performance Testing

For processes 2, 3 and 4 the performance criteria explained below will be applied. The method will be considered validated if all performance criteria are met.

Performance Criteria.

Relative Bias

A relative bias is defined for the purpose of performance testing of a finite number of measurements,

$$\mathbf{Bri=(Ai-Aai)/Aai}$$

Where

Ai is the value of the ith measurement

Aai is the actual quantity in the test sample

In order to avoid the expense of a large number of samples at eact activity level , the relative bias , which may be obtained at different activity level is calculated form the relative biasBri as:

$$\mathbf{Br=Bri=\ Bri\ /\ N}$$

Where

N is the number of test samples measured by the lab. N should be at leats 5.

For testing purposes B shall be within **–0.25 to +0.50** when Aai, the actual quantity in the test sample is greater than or equal the minimum testing level (MTL) for any specified radionuclide.

$$\mathbf{-0.25 < Br < 0.50}$$

The MTL should be at least 5 to 10 times the Minimum Detectable Amount (MDA) as defined by

$$MDA = \frac{4.65\, sb + 3}{K\, T\, e}$$

Where

sb is the standard deviation of the total blank count

K is the calibration constant

λ is the radiological decay constant

Δt is the elapsed time between an establish reference date and the analysis date.

Therefore a MTL should be determining for each radionuclide based on the MDA for each specific measurement method. .

Relative precision.

The relative precision of the measurement process is selected to be the relative dispersion of the values of Bri from its mean Br and it is defined to be:

$$SB = \frac{(Bri - Br)}{(N-1)}$$

For testing purposes the relative precision Sb, should be in absolute values less that or equal to 0.4 when Aai is at the MTL .

$$/ SB / < 0.4$$

The statistics **Br** and **SB** were selected to be unbiased estimators of the underlying expected bias and precision.

Validation of Plan at UAL

The following plan is similar for each measurement method used at the UAL. The tasks comprise:

1. Calibrate the detector system using standard reference material and record the calibration results.
2. Determine the MDA for each radionuclide of concern.
3. Set the limits values for the MTL base on the criteria 5 times MDA to 10 times MDA.
4. Prepare a testing sample with activity value above the MTL for each radionuclide of concern.
5. Carry out repetitive measurement (minimum 5) and record the results.
6. Calculate Br and SB as indicated above.
7. Compare Br and SB with the acceptance values.
8. If the calculated values meet the performance criteria the method is accepted as validated. If the calculated values do not meet the performance criteria the method is not accepted as validated and corrective actions should be implemented. The validation process should be repeated after the completion of the corrective action.

If the lab already has sufficient data collected characterizing the background and control measurements it is not necessary to prepare new samples for the calculation of these values and the recording information could be used

To the extend possible and based in the specificity of the measurement method this process should be repeated by each technician certified to carry out the measurement.

Validation of Plan at WBC.

The following plan is similar for each measurement method used at the UAL. The tasks comprise:

1. Calibrate the detector system using appropriate phantoms and record the calibration results.
2. Determine the MDA for each radionuclide of concern in relation to each phantom
3. Set the limits values for the MTL base on the criteria 5 times MDA to 10 times MDA.
4. Prepare a testing phantom with activity value above the MTL for each radionuclide of concern.
5. Carry out repetitive measurement (minimum 5) and record the results.
6. Calculate Br and SB as indicated above.
7. Compare Br and SB with the acceptance values.
8. If the calculated values meet the performance criteria the method is accepted as validated. If the calculated values do not meet the performance criteria the method is not accepted as validated and corrective actions should be implemented. The validation process should be repeated after the completion of the corrective action.

If the lab already has sufficient data collected characterizing the background and phantom measurements it is not necessary to prepare new samples for the calculation of these values and the recording information could be used.

To the extend possible and based in the specificity of the measurement method this process should be repeated by each technician certified to carry out the measurement.