

Key comparison results and the determination of the KCRV

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The most recent key comparison result is the value that is always used in the KCDB to demonstrate degrees of equivalence. However, while writing the activity comparison reports for the KCDB, a number of issues have been raised and the following policies have been applied.

1. Re-analysis of early activity key comparison results

- The earlier CCRI(II) and SIR comparisons were running long before the MRA so participants were not constrained by the current procedures as to what method they should use for their measurements nor the status of the results they submitted. Some of these early results may have been submitted in the frame of what would now be called a pilot study. Consequently, some NMIs may wish even now to withdraw their earlier results from the KCDB.
- When a laboratory has used several methods in the earlier CCRI(II) comparisons, a weighted mean often produces the best estimate of the laboratory's result. However, it may not represent the laboratory's standard as currently disseminated. This is particularly true when these several methods give significantly different results. In such cases, some selection of the method is necessary, in consultation with the NMI concerned.

2. Determination of the KCRV

The KCWG policy already in use, as approved by the CCRI(II), is as follows:

The key comparison reference value

The key comparison reference value is derived from the unweighted mean of all the results submitted to the SIR with the following provisions:

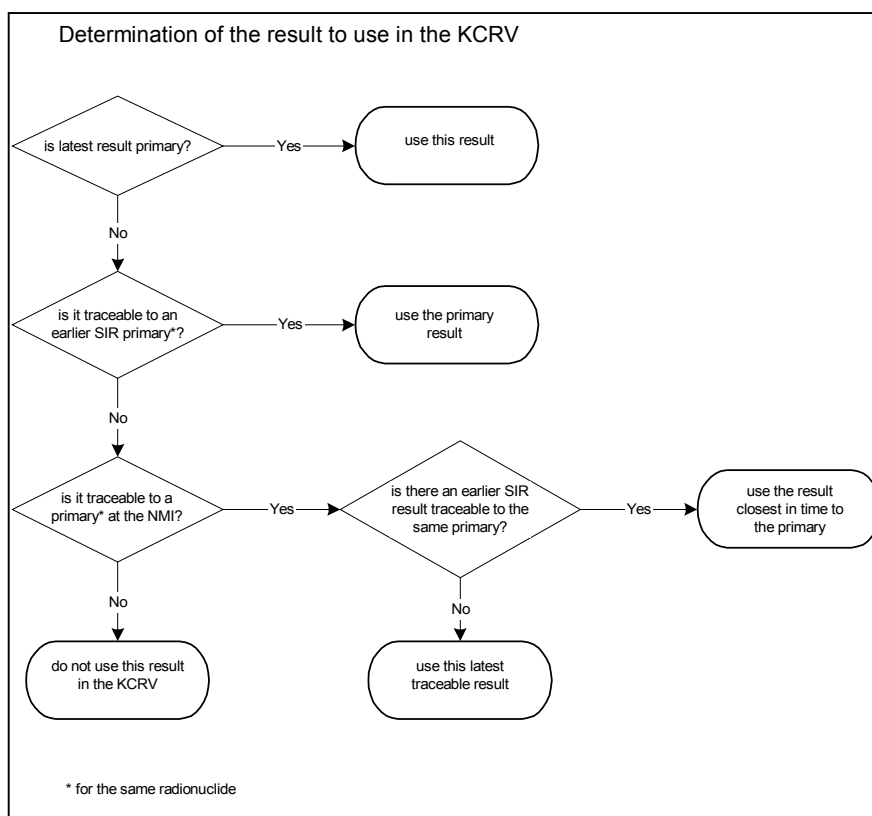
- a) only primary standardized solutions are accepted, or ionization chamber measurements that are directly traceable to a primary measurement in the laboratory;*
- b) each NMI or other laboratory has only one result (normally the most recent result or the mean if more than one ampoule is submitted);*
- c) any outliers are identified using a reduced chi-squared test and, if necessary, excluded from the KCRV using the normalized error test with a test value of four;*
- d) exclusions must be approved by the CCRI(II).*

The reduced data set used for the evaluation of the KCRVs is known as the KCRV file and is the reduced data set from the SIR mother-file. Although the KCRV may be modified when other NMIs participate, on the advice of the Key Comparison Working Group of the CCRI(II), such modifications are only made by the CCRI(II), normally during one of its biennial meetings.

More detail on points a) and b) is needed when an NMI has submitted primary standardized solutions originally and solutions measured in an IC subsequently:

1. when the IC measurement is traceable to a primary measurement previously submitted to the SIR, then the primary measurement is the candidate for the KCRV;
2. when the IC measurement is traceable to a primary measurement but not that previously submitted to the SIR, then the IC measurement is candidate for the KCRV;
3. when several IC measurements are submitted to the SIR consecutively and these are all traceable to the same primary standardization that has not itself been submitted, then the earliest IC measurement submitted is normally candidate for the KCRV.

The following flow chart applies:



Only SIR results have been used for the KCRVs. The CCRI(II) comparison results are linked to the SIR but do not enter into the KCRV. Indeed, this could bias the KCRV as all the participants in a CCRI(II) comparison measure the same solution with a given chemistry and activity concentration.

Finally, note that RMO key comparisons are linked to the SIR, usually through the pilot laboratory. However, an RMO key comparison does not contribute to the KCRV except through the pilot laboratory, nor does it have a separate KCRV.