

Footnotes to the flowchart

(I), (E) and (I/E) mean internal-, external and internal or external cause to the deviation.

It is implied that the assigned value (AV) as a consensus value is calculated from all the results in a method group consisting of separate methods.

1. **Is there any explanation in the comment letter? Yes (E):** The comment letter may include comments regarding method means relative to the AV.
2. **Do the acceptance limits indicate a considerable deviation? NO (I):** Reconsider the acceptance limits. If the limits are expressed in %, they are probably not suitable for the lowest concentrations of the analyte (the measurement uncertainty will be larger than the acceptable limit if the concentration is low). Especially high concentrations are often less interesting and therefore also the deviation (from an analytical point of view, it might still be worth reducing the error).
3. **Is the deviation in accordance with previous EQA-results? Yes (I/E):** The deviation has probably been handled earlier. If the deviation is typical for the method (item 6), the cause is external, if not internal. If the cause is internal, make sure that IQC and patient results were correct in the period when the EQA-control was analyzed.
4. **Were the results for internal quality control (IQC) OK in the period when the analysis was performed? NO (I):** If this could explain the deviation, internal actions have to be carried out, including making sure that the patient results are correct in the period of current interest. Look for trends.
5. **Were the status of the reagents and calibration OK? NO (I):** Internal actions have to be carried out to prevent that it happen again ("status" mean that the lot number is correct, the durability of reagents and calibrator is not exceeded, that the calibration curve is OK etc).
6. **Has the manufacturer changed the recommendation regarding reagents, calibrator, or the given value of the calibrator recently? Yes (I/E):** If the laboratory should have changed the procedure, internal actions have to be carried out.
7. **Is the AV traceable to a reference method and the deviation representative for your method? Yes (E):** The error might be due either to the AV or to level of your method:
 - a. Check how large the deviations are for other methods. If they are similar to your method's, the AV might be incorrect.
 - b. Analyze a reference material or some patient samples in parallel with another reliable method.
 - c. Inform the EQA organizer and make the manufacturer of your method aware of the deviation so that they can change their level.
8. **Is AV a consensus value and the deviation representative for your method? Yes (E):**
 - a. Inform the EQA-organizer that the method group's AV is not representative for your method.
 - b. The laboratory may on a permanent basis compare their result to the method's- and not the method group consensus. The method group "Unknown" or "Other" is almost never representative for your method. If you don't know any other results for your method, contact the manufacturer or the EQA organizer and ask if they could give this information.

9. **Is AV calculated from original results (not modified locally)? NO (E):** This might (rarely) contribute to a large deviation.
10. **Is AV calculated on sufficient numbers of results? NO (E):** This might contribute to a large deviation.
11. **Was the instruction from the EQA organizer followed? NO (I):** Is the material handled (e.g. dissolved) in accordance with the instruction? Is the material stored in accordance with the instructions? Check when the control arrived at the laboratory and when it was analyzed. If the control was not analyzed immediately, how was it stored?
12. **Has the EQA-organizer registered the correct method and result? NO (E):** Ask for a new corrected report from the EQA-organizer.
13. **Has the laboratory reported the correct method and result? NO (I):** The internal routines have to be reevaluated.
14. **Have the samples been sent in a proper way? NO (E):** If the other results imply poor material, contact the actual EQA-organizer to check if there might have been any problem with the sample or with the shipment.
15. **Is the analysis performed in the way the manufacturer prescribe? NO (I):** Local modification of the method might be done in several ways:
 - a. Has there been a change in volumes and/or reagents in the method?
 - b. Is the analysis performed on another instrument than what is assumed from the manufacturer?
 - c. Is the result modified by...
 - i. ...correction with a slope (multiplication with a factor) and/or intercept (constant value is added or subtracted)?
 - ii. ...using another calibration material?
 - iii. ...using other values on the calibrator(s) than given by the manufacturer?

Yes on some of these questions, may explain the deviation. The cause is internal and should at least be documented.
16. **Is the variation in EQA results for your method large? Yes (E):** If relevant, complain to the EQA-organizer that the material is bad: some materials show especially large variation and in that case the deviation might be large compared to your limits without being large compared to the variation for your method.
17. **If several samples are analyzed (e.g. at different concentrations) – is the deviation systematic for all? NO (I/E):** A random deviation might be due to the material or a random analytical error (outlier). If the concentrations were very different in the samples, investigate thoroughly if a systematic error is present.
18. **Does repeated analysis of stored material also give a deviation? NO (I):** The method is probably OK now; the action should be to assess IQC and patient samples in the period when the EQA-sample was analyzed.
19. **Does re-analysis of new material sent from the EQA-organizer also give a deviation? NO (I/E):** It is probably a problem with the material, either the wrong material is sent or the material is changed during shipment or during storage in the laboratory.
20. **Is the instruction letter correct? NO (E):** Are the samples labeled in accordance with the instruction letter? If not, is the material correct? Is the matrix in the sample as described in the instruction letter (e.g. liquid/freeze dried)?
21. **Document that the error detection procedure is followed and that the cause for the deviation is not discovered.** The error might still remains, however, it is probably not so important when IQC does not indicate any error. The error should be followed up in later EQA surveys.