Faculty of Science
Sample Part 2 Oral Examination Question and Model Answer

Common Question

A scientist in your laboratory brings to your attention the results of an External Quality Assurance program. The EQA program shows the sample result from the EQA is discordant with the original result reported by your laboratory:

a) Describe how you would investigate this assay. What subsequent actions would you take given the following two situations:
   I. The quality controls on the same run as the sample were within expected limits
   II. The quality controls on the same run as the sample had failed
b) What alternatives to a formal EQA program can be used if there is no EQA program available?

Answer

a)
   i. The possible problems with EQA programs should be described including: non-patient material, clerical error, EQA sample preparation, EQA sample deterioration, method misclassification. They should also be aware of the limitations of internal QC and to review other EQA and QC data.
   ii. This is a more serious situation and suggests that the assay was out of control. A coincidental QC mix-up should be considered etc, but this is most likely a true error. The emphasis should now be on determining the extent of the problem. Is the assay in control now? A review of all QC and EQA is necessary, followed by an investigation of the method to see what is likely to have changed to have led to failure – eg. reagent, calibration, column, operator, new instrument. The likely impact on patients analysed during the out of control period needs to be discussed. There should be a policy of repeat of all patient samples, or of some defined sampling procedure – eg every 5th sample. Results need to be re-reported and where there has been a critical change, these need to be notified.

b) ISO 15189 states that:

   "Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results."

   In such a situation, appropriate materials should be used, examples of which include:
   - certified reference materials;
   - samples previously examined;
   - material from cell or tissue repositories;
   - exchange of samples with other laboratories;
   - control materials that are tested daily in interlaboratory comparison programmes.