EXERCISE 3

INTERNAL AUDIT –ISO/IEC 17025 WRITING NON-CONFORMANCE

OBJECTIVE : To practice writing non-conformances based on ISO/IEC 17025
INSTRUCTIONS: Please write non-conformance statement if you feel there is non-conformance. (based on ISO/IEC 17025)

SENARIO 1

The auditor asked to see the minutes of meetings of Management Review. In the file of minutes he noted that the most recent meeting had been held 8 months ago and that only four of the nine members had been present. The Quality Manager explained that when the works were busy it was difficult to find a date for the meeting, acceptable to a quorum of members.

The auditors noted that while various quality problems had been discussed and proposals for remedial actions minuted, there was no evidence from the minutes of any follow up action to review the efficacy of the action agreed.

_____

_____

_____

SENARIO 2

The purchasing procedure SIRIM/PUR/003 requires that all purchases are to be supplied by approved vendors from the "APPROVED SUPPLIERS LIST". The auditor noted that the supplier of Purchase Order No.: 123, dated 4/5/2010, regarding supply of Certified Reference Materials was not from the list.

_____

_____

_____

SENARIO 3

When asked about how data from worksheets are transferred to the final test reports, the Laboratory Manager said that the person who did the tests shall prepare the test report and then submit the test report to the clerk for dispatch. Upon further enquiring by the auditor, the Laboratory Manager said that the data need not be checked as the laboratory personnel were well trained and qualified.

SENARIO 4

The auditor noted that test procedure BS 4456 (for customer Ditto Castings) required that a micro examination be performed. He asked to see the Test Report file for Ditto Castings. The Technician brought the file. The auditor noted that the micro examination was not reported on the report. The Technician said that the equipment was under repair and they were unable to perform the test, so it was sub-contracted to an accredited laboratory. The subcontractor issued a report directly to the customer.

SENARIO 5

The auditor noted that Report Number SIRIM 14/08 dated 1/4/2008 was signed by the Senior Laboratory Technician and not by the Technical Manager as documented in the procedure SIRIM//Test Report/Proc Q12. The auditor asked the Senior Laboratory Technician if he was the authorised person to sign test reports. The Senior Laboratory Technician said that the Technical Manager was on holiday that week and had left him in charge. He was, however, fully qualified to perform the test and asked the auditor if he would like to see his training records.

SENARIO 6

When asked about what happens to test items after testing is complete, the laboratory manager explained that it all depends on the circumstances... some customers usually wanted their test items returned, but in most cases the items were kept for a few months and then discarded as the storage areas filled up. The auditor requested to see the sample storage areas and he observed that all tested items were placed in a storage box and the boxes were kept under the staircase. The test items were mostly food samples. The space under the staircase was damp and foul smelling.

SENARIO 7

The auditor examined all requests of testing services and observed that there were no records of review of requests from March to April 2010

SENARIO 8

The lead auditor noted that there was no procedure on handling of complaints. The Laboratory Manager claimed that it was unrealistic to require a documented procedure for handling customer complaints; in his words “Every complaint is different and anyway, on rare occasions when one of our customers does query on a result, I always investigate the matter personally”.