

SEAICRN Laboratory Quality Assessment Policy

Purpose:

To ensure that the SEA ICRN laboratories:

1. Evaluate the effectiveness of the laboratory processes and facilitate continuing improvement of laboratory quality system.
2. Use appropriate specimen, instruments, reagents, controls and calibrator for testing patient specimens.
3. Appropriately train personnel on the test procedures and have the required competency for handling the instruments, analysis of the specimens and interpretation of results.
4. Interpret test results appropriately and correctly report them to the recipients in timely manner.
5. Have safe working environments for laboratory personnel and for the environment.

Responsibility:

1. The Laboratory management and quality officer of the respective laboratory will be responsible for implementation of quality assessment policy.
2. The Network Coordinating Center (NCC) laboratory monitor or NCC appointed contractor will oversee the quality implementation policy.

Key components:

1. All laboratory personnel receive essential trainings and competency testing before starting testing in the laboratory. This includes but is not limited to:
 - a. Specific training on tests (to be performed), instrument calibration, analysis and interpretation of the results and reporting,
 - b. Universal precaution training,
 - c. Dangerous goods transport,
 - d. Safe waste disposal and bio-safety training,
 - e. Fire drill and emergency evacuation plan.
2. All instruments used for pre-analytic and analytic process are properly maintained and used by trained person including:
 - a. Routine maintenance of the instrument and documentation of such maintenance,
 - b. Preventive maintenance of the instruments by authorized person,
 - c. Periodic calibrating of instruments as recommended by the manufacturer and documentation of the calibration,
 - d. Using appropriate controls before testing patients sample and using appropriate kits as recommended by the manufacturer,
 - e. All records related to the instruments are kept in such a way that they are available when needed.

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3. High quality kits, controls, reagents, chemicals and supplies are used for testing patient specimens to ensure high quality and accurate results. This includes:
 - a. All tests are done with kits before expiry,
 - b. Kits, controls, reagents, chemicals and supplies and kept in recommended temperature and condition,
 - c. Recommended controls are used in each test, or test batch,
 - d. The laboratory establishes internal quality control system and participates in EQAS program, and periodically evaluates the results of EQAS and take necessary action for corrective measure and improvements.

4. All laboratory documents, records and forms and electronic record backups are stored for recommended period and are available whenever necessary. This includes:
 - a. Proper storage of source documents, tests reports, calibration records and other documents related to procurement, tests and instruments,
 - b. Timely backup and storage of all LIMS data.

5. The laboratory is safe for personnel working in the laboratory and all waste disposal facilities as per national and international recommendations are in place. This includes:
 - a. The laboratory has appropriate waste disposal policy, process and procedures and is followed by staffs,
 - b. Infectious, noninfectious, sharp and liquid waste are collected separately and disposed as recommended,
 - c. Infectious specimens are handled in recommended environment (e.g. class II Bio-safety cabinet) and appropriate disinfection/decontamination of outgoing air from the laboratory,
 - d. Laboratory transports specimen as per national and international guideline for dangerous good transport guideline