General Discussion

This document provides guidance for the management of microbiology laboratories including the following:

- Proper handling of samples;
- Control and maintenance of reagents, reference standards, buffers, microbial cultures, and microbiological culture media;
- Monitoring and control of the microbiology laboratory environment;
- Calibration and maintenance of laboratory equipment; and
- Documentation and control of microbiological test results.

1. An Inventory of Major Equipment in the Microbiology Laboratory should be maintained and include, at least, the following information:
   - Equipment name, manufacturer, and model number;
   - Date of installation; and
   - Equipment identification (e.g., asset or serial number).

2. A Log Book or Validated Computerized Tracking System should be maintained for the use, cleaning, and maintenance for each major piece of equipment (e.g., sterilizer, pH meter, balance, spectrophotometer) in the microbiology laboratory.

3. Laboratory Equipment Requiring Repair or Calibration should be clearly marked and, when beyond repair, the equipment should be removed from the laboratory. A description of the malfunction, repair, or calibration should be documented. If the equipment is temporarily removed from the laboratory for repair or calibration, a notation should be made of the removal in the equipment log.

4. Calibration Checks of Equipment (e.g., Balances, pH Meters, Automatic Pipettes) that are performed prior to use should be documented. If a balance or other sensitive equipment is moved, the equipment should be recalibrated prior to use.

5. Items to be Incubated should be placed in the incubator in a manner that prevents mix-ups, spills, and/or cross contamination. All items being incubated should be clearly labelled.

6. Critical Process Parameters (e.g., temperature, pressure) for incubators and sterilization/depyrogenation units should be identified during qualification and should be automatically monitored, recorded, and alarmed. Alarm conditions should be investigated and documented.

7. An Equipment Cleaning and Maintenance Log should be maintained for each incubator and should include, at least, the following:
   - Cleaning and/or disinfection of the incubator;
   - Description of maintenance/calibration;
   - Date activity performed; and
   - Name/initials of person performing the activity.

8. Incubator Records for Samples should include, at least, the following:
   - Sample identification;
   - Date and time in and out of the incubator as required by the test method;
   - Number of sample containers;
   - Incubation temperature set point; and
   - Name/initials of person performing the activity.

- Ensure that air intake on the unit is not blocked;
- Verify that pressure differential gauge readings are within specified ranges;
- Turn off any ultraviolet (UV) lamps prior to starting work;
- Disinfect the work surface before and after use;
- Gown according to the requirements for the test method;
- Allow, at least, a 15 minute air purge before use, when the unit is restarted;
- Follow the manufacturer's recommendations for placement of items on the work surface;
- Avoid mixing clean items with dirty items;
- Wipe up spills immediately using a disinfectant; and
- Seal waste materials in bags prior to disposal and eventual destruction.

22. Automated Microbial Identification Systems should be validated using a recognized reference source (e.g., ATCC, NCTC). For Microbial Identification Systems using cards or strips, the performance of each shipment of cards/strips should be evaluated using a set of known organisms. In systems requiring a complex sample preparation, a set of known standards should be included with each test performed to evaluate the system's performance.

23. Automated Quantitation Systems should be validated using preparations having known quantities of microorganisms. The results from the automated method should be compared to the results from the standard plate count or Most Probable Number (MPN) method and should be within a pre-established acceptance criteria range.

24. Environmental Monitoring of the Sterility Test Suite should include, and not be limited to, the following:
    - Surface and air monitoring of STIS units, unidirectional airflow units, and Bio safety cabinets;
    - Air monitoring of gowning and clean room facilities, including monitoring of pressure differential; and
    - Gown and glove monitoring using contact plates and touch plates of personnel performing sterility testing.

25. Sample Handling, Testing, and Preparation of Testing Materials should be documented using a controlled documentation system.

26. Approval of Contract Microbiological Testing Laboratories by the Site Quality Team should include consideration of, and not limited to, the following:
    - Historical performance of the contract laboratory;
    - Results of audit, if performed; and
    - Use of the contract laboratory for routine or special testing (e.g., one time use).

27. Contract Microbiological Testing Laboratories when used for routine testing should include provisions for, and not limited to, the following:
    - Sample controls (e.g., date shipped, date received, conditions of shipment);
    - Sample retention requirements;
    - Investigation and reporting of OOS and questionable results;
    - Documentation and reporting procedures; and
    - Periodic audits.

