

Guidance 091 Microbiology Laboratory Management

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.
9. Sterilization and Depyrogenation Processes used in the microbiology laboratory should be validated for each load pattern.
10. Sterilized Equipment should be labeled with the cycle number and expiration date and stored in a manner that prevents contamination (e.g., in designated storage area). Wrapped, sterilized items should be inspected prior to use for dryness and to verify the integrity of the wrapping. Wet or torn, wrapped **sterile** items should not be used and should be removed from the work area.
11. Training for Personnel Working in the Microbiology Laboratory should include, and not be limited to, the following, as applicable to the job function:
 - Departmental Standard Operating Procedures (SOP);
 - Analytical, bioanalytical, or microbiological test methods;
 - Preparation and storage of microbial cultures, reagents, buffers, reference standards, and microbiological culture media;
 - BI preparation and testing;
 - Laboratory mathematics (e.g., calculation of dilution schemes and microbial titers);
 - Aseptic techniques for applicable test procedures;
 - Gowning practices for applicable test procedures;
 - Cleaning and disinfection of work areas;
 - Environmental monitoring procedures; and
 - Use of unidirectional airflow units and biosafety cabinets.
12. Qualification of Personnel Performing Test Procedures should include demonstration of the ability to perform the test methods according to approved written procedures. Requalification in a test method should be required if the analyst has not performed the method during the past year or a significant change was made to the method since the analyst was last trained in the method.
13. Laboratory Materials, such as reagents, buffers, reference standards, microbial cultures, microbiological culture media, and BIs that are used during microbiological testing should meet the requirements specified by the applicable method and should be labelled with, at least, the following information:
 - Material name;
 - Concentration, if applicable;
 - Expiration or re-evaluation date;

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19. The Microbial Population of BIs should be verified and the *D*-value and *z*-value should be known. Testing for custom BIs should include microbial population, *D*-value, *z*-value, survival time, and Kill Time under the conditions in which they will be used.
20. Maintenance of Microbiological Control Cultures should be specified and documented and include, and not be limited to:
 - Seed lot cultures should not be more than five passages removed from the original culture strain;
 - For frozen seed lot cultures, each cycle of freezing, thawing, and revival in fresh medium is considered to be one passage; and
 - Culture strains should be obtained, when feasible, from a recognized reference source, such as ATCC and NCTC.
21. Work Performed in Bio safety Cabinets and Unidirectional Airflow Units should be conducted as follows:
 - 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.