maybe be accomplished using standard clean room technologies or through the use of a barrier system/isolator.

5.1.1.2 Entry to the clean room should be via an airlock in which the operators are required to change into clean room garments.

5.1.1.3 The ability of the environmental control systems to maintain the appropriate environmental quality within the sterility test area should be validated.

5.1.1.4 An appropriate environmental monitoring program for the sterility test area should be approved and the associated methods and procedures in place.

5.1.1.5 An appropriate sanitation program for the sterility test area should be approved and the associated methods and procedures in place.

5.1.1.6 Appropriate preventative maintenance procedures for critical equipment and systems should be approved and in place.

5.1.1.7 Critical instruments and equipment should be calibrated and included in the routine calibration program.

5.1.1.8 Sterilization cycles for internally processed media, supplies, equipment and materials should be validated.

5.1.1.9 If a barrier system/isolator is used, it's associated decontamination cycles should be validated.

5.1.1.10 Sterility test analysts or technicians should have appropriate training and documentation of that training should be on file and available for review.

5.1.1.11 Sterility test methods and/or procedures should be approved, current and available for use by the analysts or technicians.

5.1.1.12 Sterility test methods should be validated and demonstrated to be appropriate for their intended use.

5.1.1.13 Samples should be taken in accordance with approved sampling procedures.

5.1.2 Methods and Procedures

The following items or issues should be addressed in approved methods and/or procedures:

- Validation and Revalidation of Sterility Test Methods.
- Sample Collection, Transport and Storage.
- Pooling of Sterility Test Samples.
- Sterility Test Methods.
- Negative Controls.
- Incubation of Sterility Test Samples.

