

Installation Qualification Operating Environment

(Reference SOP: _____)

1. OBJECTIVE

To provide documented verification that all key aspects of the selection, application, construction and installation of the facility (*description name of the process and system*) adheres to appropriate codes, cGMP's and approved design intentions and that the manufacturers recommendations are suitably considered.

2. ACCEPTANCE CRITERIA

A successful completion of the Installation Qualification process are based on the following:

- All activities listed in "Installation Qualification" have been executed.
- All entries of data have been signed and dated by the person or persons performing the activity or verification.
- All data has been adequately reviewed and reported.
- Any discrepancies that have occurred have been satisfactorily resolved and are correctly signed and dated as resolved.

3. QUALIFICATION PROCEDURES

The protocol consists of tables containing information that needs verification. The Qualification inspection and verification process are largely depended on visual inspection, comparison to "As Built" drawings and equipment specification as quoted in the protocol.

Any tables or sections not relating to process or equipment should not be deleted and the word "N/A" should be used, additional tables or sections can be included.

Other documents that support the Qualification process can be referenced or included as attachments.

All people involved in the Qualification inspection and verification process are required to fill out section 12 of this protocol.

4. FACILITY

4.1. Drawings.

The drawing ID numbers may be included as an Attachment.

Drawings for the rooms and equipment must include the location of the air supply, air returns, sensors and controls.

Drawing Identification Numbers: _____

Electronic copy supplied: Yes/No

Signed _____

4.2. Equipment / Components - Manufacturer's Specifications

Provide all specifications for the above. They may be included as an Attachment.

Manufacturer's Specifications provided? Yes/No

Signed _____

4.3. Component Materials (as detailed in design spec.)

List only those Materials detailed in the Design Specification. Include floor, wall and ceiling finishes in the facility.

4.3.1. Material of Construction - WALLS

Material Specified: _____