Sample IQ

APPROVAL PAGE

Here you would state the name of the document, and that the document has been approved and reviewed by the signatories of this page. Signing this document signifies that it has been reviewed and that all requirements and test procedures with the document are accurate and applicable to the qualification and its intended use.

AUTHOR

DEPARTMENT	NAME	SIGNATURE	DATE

APPROVALS

DEPARTMENT	NAME	SIGNATURE	DATE

TABLE OF CONTENTS

1 INTRODUCTION

1.1 OBJECTIVE

Here you would write about the objective. In the case of IQ, the objective of this protocol is to provide documented evidence that the subject of the protocol is installed in accordance to specifications and design, and that it complies with all of the company's requirements.

1.2 SCOPE

Here you list the scope of this document. Specify the system/equipment name, the company name and location, and where the equipment is located within the building. State if this protocol and its execution follow any established protocol methods or documentation.

1.3 DESCRIPTION

Describe the equipment/system and its purpose. Figures and diagrams are added to illustrate the equipment. Detail how the equipment is used.

1.4 RATIONALE

State what this protocol is doing (defines qualifications and requirements to verify installation). Detail the classification of the system per company SOP. State the category and type of equipment. State what the document is designed to do (IQ is to fully verify the installation of the equipment) and that it follows company procedures. State what is needed for pre-approval and for review and acceptance of executed protocol. State what shall be submitted to records.

1.5 MATERIALS / EQUIPMENT

1.5.1 Materials

1.5.1.1 Materials needed for any testing done

1.5.2 Equipment

1.5.2.1 Equipment needed for any testing done

1.6 RESPONSIBILITIES

1.6.1 Validation

1.6.1.1 Here is a list of all responsibilities of the validation department
1.6.1.2 Typical: Create protocol, review, approve
1.6.1.3 Execute protocol. Coordinate with other departments
1.6.1.4 Evaluate protocol data, deviations, create report
1.6.1.5 investigations

1.6.2 System Owner

1.6.2.1 List of responsibilities for system owner
1.6.2.2 Review and approve protocol
1.6.2.3 Participate in protocol
1.6.2.4 Approve and review report

1.6.3 Quality Control

1.6.3.1 List of responsibilities for quality control
1.6.3.2 Review and approve protocol
1.6.3.3 Participate in protocol
1.6.3.4 Approve and review report

1.6.4 Quality Assurance

1.6.4.1 List of responsibilities for quality assurance
1.6.4.2 Review and approve protocol
1.6.4.3 Review against requirements
1.6.4.4 Approve and review data and report

1.7 DOCUMENTATION

1.7.1 List of company's documentation procedures. This normally includes initial and date of activities, types of ink used and correction procedures, how to label supporting documentation and how to attach them to report, if steps may be done out of sequence, use of n/a, notification of incidents, definition of deviances, additional pages requirements, data handling, and more.

1.8 CHANGE CONTROL

This section states the change control governing the qualification.

1.9 ACCEPTANCE CRITERIA

This section states the acceptance criteria for the report, or where the criteria may be found.

1.10 DEFINITIONS

1.11 REFERENCES

1.12 SIGNATURES

This section is for signatures of personnel trained on qualification. This may also be placed as a test case in the installation qualification section.

1.13 INSTALLATION QUALIFICATION - Documentation

Note - The following describes what each test case should include for reference purposes. In a normal qualification the following sections would only have brief wording similar to "This test case lists all components of the system and their details".
Note - Test cases not used are detailed "This test case is not applicable to the qualification of XX. This instrument does not utilize a computer system"

1.13.1 System Components

This test case lists all components involved in the system and their details. This includes a short description, manufacturer, model, serial number, asset number if required, location, and internal classification.

1.13.2 System Instrumentation

This test case is a list for all critical instruments including manufacturer, model, identifying codes, serial numbers, locations, and inclusion into calibration program.

1.13.3 Manual Verification

This test case lists the user manuals that are provided with the equipment and are documented and located in the correct department. The location marked in the qualification should be the permanent location of the manual when needed for reference. This may be physical, electronic, or both.

1.13.4 Technical Document Verification

This test case lists documents that may be provided with the equipment/system. This may include technical documents or certifications such as FAT, purchase orders, design documentation, factory calibration, concentration verifications for solutions, or other qualifications. The location marked in the qualification should be the permanent location of the documentation when needed for reference. This may be physical, electronic, or both.

1.13.5 Drawings Documentation

This test cast lists drawings of the system or equipment, the electrical system, or other figures are located and a location is documented with the permanent site for future reference. This may be physical, electronic, or both.

1.13.6 Computer System Documentation

1.13.6.1 Computer Systems List

This is a list of any included firmware or software associated with the system

1.13.6.2 Software Operating Parameters List

This is a list of actionable, selectable, or adjustable options provided by the system. Examples include timers, speed, temperature, or other variable adjustments in addition to reading and archiving options.

1.13.7 Component Documentation

1.13.7.1 Component List

This list identifies the separate parts of a system or equipment. For example, a manual buffing station would include a foot pedal, motor, buffing wheel. A mixing tank would include input and output locations, a mixing paddle, a motor, and a user interface. A more complicated system such as a packaging line may include a number of components: packaging material infeed, filling material infeed, thermoformer, filling station, conveyor belts, weigh station, coolant pumps, sealers, labeling, cutting station, multiple user interfaces, shrink wrapper, heat tunnel, and more.

Some of these parts may require calibration or preventative maintenance specific to the component.

1.13.7.2 Physical Operating Parameters List

A list of settings available on system, either static or adjustable. This may include speed, size, location of components, amount of air/gas provided, or other considerations.

1.13.8 Auxiliary equipment Documentation

This list identifies auxiliary equipment that may be used on or by the system, but are not controlled by the system. Such equipment may include cleaning components, coolant pumps, balances, calibration weights, among others.

1.13.9 Associated Materials and Resources

A list of all materials or resources needed associated with the system. This list includes any material that is required to be supplied to the system to ensure proper usage and that the materials are approved for use. This section may be bypassed if included in URS and URS is documented in protocol. This may also include compressed air, water, gasses, sanitizing chemicals for CIP, lubricants, standards, or other items.

1.13.10 Safety Requirements

A list of all associated safety regulations or company policies associated with system or materials. This may include such requirements as chemical storing procedures, moving parts coverage, emergency stops. This section may be bypassed if listed on URS and URS is referenced or documented in protocol.

1.14 INSTALLATION QUALIFICATION - Physical Verification

1.14.1 Nameplate verification

This test case is to verify data on nameplate matches documentation provided.

1.14.2 Physical State

This test case assesses the physical state of the system, any damage should be noted in addition to verifying all components listed in the documentation are present. This assessment may also include system level, integration into processes or auxiliary equipment, or other installation requirements.

1.14.3 Component Verification

Components on the component list are verified to be present and set up in accordance to any blueprints or drawings.

1.14.4 System Integration

The system's integration into processes or with auxiliary equipment is assessed. This includes connections to utilities, CIP, and may also include connecting areas to systems involved in product's previous or future steps.

1.14.5 Materials Verification

This test case verifies all materials documented in the associated materials list are present.

1.14.6 Safety Verification

This test case verifies all safety requirements and procedures listed in the safety requirement documentation are present.

1.14.7 Placement Verification

This test case verifies all parts and materials associated with system/equipment have a defined placement or storage area.

1.14.8 Materials of System Construction

In the event of product touching surfaces, this test case validates the construction materials for safety. This may include type of safety glass in a viewing window, type of stainless steel of pump construction. Documentation may be used for verification.

1.14.9 Utilities Verification - Water

This test verifies the correct class of water is available. Source, sterility, plumbing, and testing are validated as needed. Reference to validations and location they can be found.

1.14.9 Utilities Verification - Electrical

This test verifies the correct source of electric is available, including sockets, breakers, and wiring.

1.14.9 Utilities Verification - Gas(es)

This test verifies the correct sourc(es) of gas(es) are available. Delivery and storage systems validated as needed.

1.14.9 Utilities Verification - Pressurized Air

This test verifies the correct source of pressurized air is available. Delivery and storage systems validated as needed.

1.14.10 Environmental Requirements Verification

This test case verifies there are systems in place to ensure the correct temperature range, humidity, ventilation, and HEPA/airflow are available. The temperature and humidity are tested to be in range. Validation of ventilation and airflow may be needed depending on environmental requirements. Air changes per hour, first air validation, smoke testing, unidirectional/laminar flow, or more may be tested. Document validation of environmental systems and location validation may be found.

1.14.11 Lubricant Verification

This test case verifies lubricant used on system, equipment is correct grade for applicable use.

1.14.12 Computer System Verification - Operating System Verification

This test case verifies the operating system is installed as documented.

1.14.13 Computer System Verification - Backup Verification

This test case verifies the system backup or archive ability and location if applicable.

1.14.14 Test Instrument Calibration

This test case verifies the calibration of any test instruments used in the previous test cases.

1.15 PERSONNEL AND TRAINING VERIFICATION

1.15.1 Objective:

The objective of this test is to verify that all individuals who execute any portion of the protocol are identified and trained.

1.15.2 Procedure:

A trainer shall provide overview and assistance in understanding this protocol to each individual who will execute any part of the protocol in this document. All executors of this protocol shall provide information and signature within Table 1.15, affirming they have been provided overview of the protocol by trainers on the date indicated. Signature affirms they understand the steps required for execution.
A trainer may be author, protocol approver, validation associates, or a previously trained supervisor or lead.

1.15.3 Acceptance Criteria

All executors must be identified and trained to this protocol prior to executing any portion within.

1.15.4 Test Results

Acceptance Met Yes No
Deviation? Yes No Deviation No:_____

Performed By:_____ Date:_____

Note: Table placed on separate page to allow duplication

Table 1.15: PERSONNEL AND TRAINING VERIFICATION

(Page may be duplicated as required) Page ____ of _____

Name	Role/Department	Signature	Date

1.16 CHANGE CONTROL VERIFICATION

1.16.1 Objective:

The objective of this test is to verify that the change control has been generated and all items prior to installation qualification are completed.

1.16.2 Procedure:

1.16.2.1 Fill out Table 1.16 for change control governing protocol.

Table 1.16: CHANGE CONTROL VERIFICATION

1.15.3 Acceptance Criteria

All

1.15.4 Test Results

Acceptance Met Yes No
Deviation? Yes No Deviation No:_____

Performed By:_____ Date:_____

2.0 INSTALLATION QUALIFICATION

2.1 TEST CASE IQ-001; SYSTEM COMPONENT DOCUMENTATION

2.1.1 Objective:

The objective of this test test case is to list all components involved in the system and their details. This includes a short description, manufacturer, model, serial number, asset number if required, location, and internal classification.

2.1.2 Procedure:

2.1.2.1 Identify specifications of system components. Document the following in Table 2.1.

- 2.1.2.1.1 Name
- 2.1.2.1.2 Asset Number
- 2.1.2.1.3 Classification
- 2.1.2.1.4 Type
- 2.1.2.1.5 Manufacturer
- 2.1.2.1.6 Model
- 2.1.2.1.7 Location

2.1.3 Acceptance Criteria

All system components are documented fully in Table 2.1.

2.1.4 Test Results

Acceptance Met	Yes	No	
Deviation?	Yes	No	Deviation No:_____

Performed By:_____ Date:_____

NOTE:
TABLE PLACED ON FOLLOWING PAGE TO ALLOW DUPLICATION.
(USE TABLE 1.15 AS EXAMPLE)

ALL TEST CASES LISTED IN 1.13 AND 1.14 WILL BE DISPLAYED SIMILAR TO TEST CASE IQ-001.
TEST CASES NOT DISPLAYED FOR SAMPLE BREVITY

3.0 INSTALLATION AND OPERATIONAL QUALIFICATION CERTIFICATION

Note: This section is not always included

All tests included in prior qualification sections were properly conducted and verified.

Acceptance Met Yes No

If not completed provide justification

_____
_____
_____

APPROVAL

Name	Signature	Date

4.0 DEVIATIONS

Deviation No.	Description	Initiated by	Date

Note: following would be on separate page

5.0 ATTACHMENT LOG

This log lists the attachments included with this protocol

Attachment No.	Title	Number of Pages	Date / Initial