Installation Qualification: Installation Qualification Template

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1. Introduction

This Installation Qualification (IQ) protocol describes in detail the activities required to execute the IQ phase of qualification of the Installation Qualification Template at Company Name's [Company Address] manufacturing facility. It defines testing and documentation required to ensure that the equipment is installed as intended and compliant with all relevant regulations.

2. Scope

This protocol applies to the Installation Qualification Template. It considers finishes, materials of construction, suitability for purpose, as-built status, availability of services, supply of documentation and integration into quality systems.

2.1. Exclusions

List only items specific to the scope which could reasonably expect to part of the testing. Refer to the alternative testing documentation or state justification if not tested.

3. Responsibilities

The responsibilities defined below refer to the signatories on the front page. The text within should be consistent with the responsibilities defined within the VMP and any relevant VPP and VP. Edit as necessary to maintain consistency.

Personnel executing and/or assisting with the execution of the Installation Qualification are recorded in the Signature Register in Test Section 1. Persons signing the front page of this protocol are confirming compliance with the information below:

3.1. Preparer

The preparer shall be the primary author of the document, or a delegate with an appropriate level of understanding of the technical content of the document. The preparer signs to confirm that, to their knowledge, the document is complete, complies with the validation plan and is free from errors.

3.2. Verifier

The verifier shall be the system owner or a delegate with an appropriate level of understanding of the functionality of the equipment/system. The verifier signs to confirm that, to their knowledge, the document fulfils all relevant testing requirements, is logical and executable and is free from errors.

3.3. Quality Approval

The quality approver shall be the Quality Manager or a delegate with an appropriate level of understanding of the quality systems relevant to this protocol. The quality approver signs to confirm that the document complies with relevant quality systems (including the VMP), can be adequately resourced in the time frame anticipated for execution and is free from errors.

4. Equipment/System Description

4.1. Details

Provide a brief overview of the equipment/system

4.2. Qualification Requirements

Provide a summary of the 'how' of the execution:

- room conditions, commissioned, cleaned, in routine operation, etc.
- the type of testing – simulated, 'live' testing, placebo, etc.
- Number of people involved and whether they active or passive
- Estimated duration of testing if known
- Information on multiple or single trials
- Any other general information that may be useful to the reader to understand what will occur during the testing phase

4.3. Justifications

Acceptance criteria for most qualification tests have been established in accordance with regulatory requirements, internal policy standards and established industry standards.

In some cases, it is necessary to define criteria without these established references. Any instances of these criteria in this protocol are explained below:

Test Reference	Criteria	Explanation

5. Test Section Details

The testable sections of this protocol are listed below. All sections marked as mandatory or applicable must be completed prior to final approval of the qualification.

Some sections will not be applicable for some qualifications. Wherever a section is not required, a brief statement as to why must be included. The test section itself should be left in, but the relevant table should be deleted and a statement of justification inserted in its place.

Test Section	Applicable?	Reason if Omitted
1. Signature Register	Mandatory	
2. Drawings	Yes	N/A
3. Documentation	Yes	N/A
4. Architectural and Functional Components	Yes	N/A

Test Section	Applicable?	Reason if Omitted
5. Mechanical Components	Yes	N/A
6. Electrical & Instrumentation Components	Yes	N/A
7. Computer Hardware Components	Yes	N/A
8. Computer Software Components	Yes	N/A
9. Plant Services	Yes	N/A
10. Product Contact Chemicals	Yes	N/A
11. Instrument Calibration	Yes	N/A
12. Preventative Maintenance	Yes	N/A
13. Exception Reports	Mandatory	
14. Handover/Progression Certificate	Mandatory	
15. Attachments	Mandatory	

6. Qualification Instructions

6.1. Data Collection

The Installation Qualification will comprise:

1. The approved copy of this protocol completed as indicated in clear handwriting and of attached documents, annotated where indicated in this protocol and listed in Test Section 15.
2. The completed Progression Approval (Test Section 14), as described in Section 6.2.

Additionally, the following specific data collection instructions must be followed:

- All persons entering data in this protocol must be identified in Test Section 1.
- All handwritten entries must be made in blue or black ink.
- Corrections to handwritten data must be made with a single strikeout, initial and date.
- Data entry spaces must be populated or marked not applicable (N/A).
- Corrections and ‘N/A’ markings must be accompanied by a brief reason where the reason is not self-evident. The entry must be initialed and dated.
- "Ticks" or "crosses" are not permissible. Appropriately descriptive words and figures must be used to complete data entry spaces.
- The executor should make any comments arising from the checks in the comment section shown. Comments should be continued in an attachment if necessary.
- Individual comments must be initialed and dated.
- All sections should be completed by the executor as soon as possible after completion of the test.

6.2. Interim Progression

Qualification may move to the next stage, or the equipment/system handed over to the owner for routine use on completion of the requirements listed in Test Section 14. These requirements are the pre-requisites for the next phase, and may not include all testing. The Interim Progression Approval must be completed and approved by the equivalent level of authorisation to the protocol.

At the completion of all testing requirements, the Progression Approval shall be updated to reflect the final status of the qualification.

7. Deviations & Deficiencies

Deviations and deficiencies observed during the execution of the protocol must be addressed in an exception report. The exception reports shall include the following information:

- Details of the protocol
- The relevant phase of testing, and the date which the exception was observed
- A description of the exception
- A root cause analysis
- Corrective action(s) if any
- Final outcome of the exception

Exception reports shall be approved by the Quality Manager or appropriate delegate. Exception reports shall be numbered [Subject]-ERXX, where XX represents a sequential number starting at 01. All exception reports shall be listed in Test Section 13.

8. Protocol Approval Requirements

8.1. Acceptance Criteria

The executed protocol must meet all requirements defined in this protocol. Any deviations from the requirements and instructions defined within must be addressed through exception reports.

The specific acceptance criteria for testing are defined within each test section. Deviations from the instructions in the appendices must also be addressed through exception reports.

When all criteria, requirements and instructions have been met, or any exceptions have been adequately justified through exception reports, the final qualification report may be approved and issued.

8.2. Reporting

When the qualification protocol is complete, including the completion and approval of all exception reports, the results shall be summarised in a Validation Summary Report (VSR). It shall summarise the results of the executed protocol relative to acceptance criteria, detail exceptions; discuss relevant issues arising from the execution and make a concluding statement regarding the success of the qualification exercise. The report shall have an equivalent level of approval to the protocol.

The report may combine the results of multiple qualifications from the same project.

9. Referenced Documents

Ensure the following documents are read and understood before executing this protocol

Document Number	Document Title

10. Definitions

Term/abbreviation	Definition

11. Test Section 1 – Signature Register

Instructions & Criteria
Complete table for each person involved in performing or documenting the qualification, including reviewers. Acceptance Criterion: All personnel involved have been identified and acknowledged their role.

Name	Title	Department/Company	Role in Qualification	Signature	Initials

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

12. Test Section 2 – Drawings

Instructions & Criteria

Inspect the drawings listed below against the completed installation. Note the number and version of the originally inspected drawing. Confirm that the drawings represent the 'as-built' state.

If the drawing is not 'as-built', then amend drawings by hand, stamp as superseded and generate a corrected version. Attach corrected version to this protocol

Acceptance Criteria: The table is completed for all identified drawings and an 'as-built' copy is attached to the executed protocol.

Test No.	Spec Ref.	Drawing No.	Title	Version No.	Drawing As Built Yes/No	Updated Version No.	Initial and Date
2.1	U7						
2.2	N/A						
2.3							
2.4							
2.5							

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

13. Test Section 3 – Documentation

Instructions & Criteria
Ensure that the documents below are available, complete and appropriately located. Acceptance Criteria: At least one copy of each document is available, appropriately located for reference and complete.

Test No.	Spec No.	Documentation Description	Document ID	Actual Results	Initial & Date
3.1	U12			Copies available: _____ Primary copy location: _____	
3.2	N/A				
3.3					
3.4					
3.5					

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

14. Test Section 4 – Architectural & Functional Components

Instructions & Criteria
Visually inspect the installation to confirm that the key architectural and functional components of the system have been provided. Acceptance Criteria: Refer to individual tests.

Test No.	Spec Ref.	Test Description / Procedure	Acceptance Criteria	Actual Result	Pass / Fail	Initial & Date
4.1	U13					
4.2	N/A					
4.3						
4.4						
4.5						
4.6						

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y / N					

15. Test Section 5 – Mechanical Components

Instructions & Criteria
Complete table for each individual critical mechanical component. Attach material and weld certification where relevant. Note that material and weld certificates are only required as applicable for product contact equipment. Acceptance Criterion: Table is complete for each identified mechanical component.

Specification								Quality Compliance Certification		
Test No.	**Spec Ref.**	**Item Description**	**Supplier/ Manufacturer**	**Model**	**Serial No.**	**Equipment ID**	**Location**	**Product Contact (Y/N)**	**Materials Certified (Y/N/NA)**	**Welds Certified (Y/N/NA)**
5.1	D201									
5.2	N/A									
5.3										
5.4										
5.5										

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

16. Test Section 6 – Electrical & Instrumentation Components

Instructions & Criteria
Complete table for each different critical electrical or instrument component. Acceptance Criterion: Table is complete for each identified electrical or instrument component.

Test No.	Spec Ref.	Item Description	Supplier / Manufacturer	Model	Serial No.	Equipment ID	Location
6.1	D134						
6.2	N/A						
6.3							
6.4							
6.5							
6.6							

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y / N					

17. Test Section 7 – Computer Hardware Components

Instructions & Criteria
Complete table for each different critical computer hardware component. Acceptance Criterion: Table is complete for each identified computer hardware component.

Test No.	Spec Ref	Item Description	Supplier/ Manufacturer	Model	Serial No.	Location
7.1	U55					
7.2	N/A					
7.3						
7.4						
7.5						
7.6						

Comments:	

Acceptance Criteria Met		**Related Exception Reports**	**Initial and Date**	**Checked by**	**Initial and**
Y/N					

18. Test Section 8 – Computer Software Components

Instructions & Criteria
Complete table for each different critical computer software component. Provide reference any related software testing (eg OQ or specific software qualification testing). Acceptance Criterion: Table is complete for each identified computer software component.

Test No.	Spec Ref.	Item Description	Manufacturer	Version No.	Serial No.	Location	Software Test Reference
8.1	U58						
8.2	N/A						
8.3							
8.4							
8.5							
8.6							

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

19. Test Section 9 – Plant Services

Instructions & Criteria
List all critical services required by this equipment/system and confirm the suitability and availability of each service. Acceptance Criteria: Refer to individual tests.

Test No.	Spec Ref.	Service	Service Available (Yes/No)	Acceptance Criteria	Actual Result	Pass/ Fail	Initial & Date
9.1	U77						
9.2	N/A						
9.3							
9.4							
9.5							
9.6							

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

20. Test Section 10 – Product Contact Chemicals

Instruction & Criteria

List all cleaning agents and/or lubricants which are used on product contact surfaces.

Acceptance Criteria: All identified product contact chemicals have been detailed in the table and accepted for use.

Test No.	Spec Ref	Description	Grade/type	Supplier	Manufacturer	Location of Use	Change Out Frequency	Grading Certificate Attached (Yes/No)	Initial & Date
10.1	U91								
10.2	N/A								
10.3									
10.4									
10.5									

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

21. Test Section 11 – Instrument Calibration

Instructions & Criteria
Confirm that all critical instruments have been calibrated and are entered on the Calibration Register as per Company Name procedures. Add to the register any instruments discovered to be absent, or provide justification if not required. Acceptance Criteria: All identified critical instruments have current calibration and are included in the calibration register or justified where absent.

Test No.	Spec Ref.	Instrument description	Instrument ID	Calibration Expiry	Certification Location	In Calibration Register (Y/N)	Justification if No	Initial & Date
11.1	U66							
11.2	N/A							
11.3								
11.4								
11.5								
11.6								

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

22. Test Section 12 – Preventative Maintenance

Instructions & Criteria

Confirm that all components requiring preventative maintenance have been entered on the Preventative Maintenance Register as per Company Name procedures.

Add the register any equipment or tasks discovered to be absent, or provide justification if not required.

Acceptance Criteria: All identified equipment items are included in the PM register or justified where absent.

Test No.	Spec Ref.	Equipment ID	Description	In Maintenance Register (Y/N)	Justification if No	Initial & Date
12.1	U80					
12.2	N/A					
12.3						
12.4						
12.5						
12.6						
12.7						

Comments:	

Acceptance Criteria Met		Related Exception Reports	Initial and Date	Checked by	Initial and
Y/N					

Comments:					
Acceptance Criteria Met		**Related Exception Reports**	**Initial and Date**	**Checked by**	**Initial and**
Y / N					

23. Test Section 13 – Exception Reports

Instructions					
List all exception reports generated during this qualification. Provide a brief summary of the information in the full reports.					
Exception Report No.	**Brief Description of Exception**	**Brief Description of Cause**	**Brief Description of Resolution**	**Closed (Yes/No)**	**Initial & Date**

24. Test Section 14 – Progression Approval

Instructions					
This progression approval lists the minimum requirements for progression to the next phase of use for the equipment/system. Confirm that the progression requirement has been met, or non-compliance has been adequately justified within an approved exception report. Provide justification for why progression is acceptable prior to completion of all sections. On completion of all tests and exceptions, completion the Final Disposition section of the certificate. If all tests and exceptions are completed prior to progression, strike out the progression justification and approvals section.					
Progressing To		OQ / PQ / CV / PV / Routine Use (Circle One) or Other: _____			
Protocol Test Section	**Test number(s)**	**Progression Requirement**	**Result**	**Approved Exception Report No.(s)**	**Initial and Date**

Instructions
This progression approval lists the minimum requirements for progression to the next phase of use for the equipment/system. Confirm that the progression requirement has been met, or non-compliance has been adequately justified within an approved exception report. Provide justification for why progression is acceptable prior to completion of all sections. On completion of all tests and exceptions, completion the Final Disposition section of the certificate. If all tests and exceptions are completed prior to progression, strike out the progression justification and approvals section.

Progression Justification	

Operations Approval for Progression				**Quality Approval for Progression**			
Name		Sign & Date		Name		Sign & Date	

Final Disposition of Qualification (complete after qualification finalised)	

Operations Approval of Completed Qualification				**Quality Approval of Completed Qualification**			
Name		Sign & Date		Name		Sign & Date	

25. Test Section 15 – Attachments

Instructions	
List and describe all attachments to the qualification report here.	
Attachment No.	**Attachment Description**

Document Information

Revision History

Revision	Modified by	Change Control No.	Description of Change
01			

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company's systems if required (eg. change control).

Associated forms and procedures

Doc. No.	Document Title

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

Associated records

Doc. No.	Document Title

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.