Quality System Procedure			
Document Number: D00197452	***Revision:*** 016	***QMS Owner:*** Cook Incorporated	***Page:*** 1 of 20
Title: Equipment Qualification			

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1.0 PURPOSE

A comprehensive approach to Equipment Life Cycle Management ensures that Cook Inc. process systems and applications are properly planned and managed, controllable, suitable, and support the mission and business goals of Cook Inc. while maintaining process state of control compliant to all applicable regulations.

Equipment qualification is performed to ensure all equipment used in manufacturing and inspection processes meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

This procedure establishes Cook Incorporated's (Cook Inc.) practices in the equipment life cycle phases:

- Initiation/Development
- Acquisition
- Implementation
- Maintaining a Validated/Qualified State
- Retirement

2.0 SCOPE

This procedure applies to equipment utilized in production, including inspection, of commercialized product, Engineering Verification or Engineering Validation activities, at Cook Inc.

Equipment classification and qualification information must be documented in the Equipment Validation Plan (EVP). Refer to **D00521044** for instructions regarding the EVP. Refer elsewhere in this document for details regarding equipment classification and qualification.

This procedure does not apply to business operations or office equipment, facility utilities equipment, or buildings.

3.0 ROLES AND RESPONSIBILITIES

ROLE	RESPONSIBILITY
Validation Coordinator	• Write qualification protocols and reports in accordance with this instruction. • Coordinate with Environmental Health & Safety (EHS) Engineer to obtain safety requirements for the system being qualified. • Confirm approvers are properly assigned.
System Owner (Generally Manufacturing Engineering)	• Provide input to the qualification requirements for the system(s) within the scope. • May write qualification documents for the system(s). • Evaluate the impact of changes to the equipment/system and the need for revalidation/requalification. • Review and approve qualification documents to confirm requirements are met for the system(s). • May act as the Validation Coordinator.
Development Engineering	• May review qualification documents to confirm product requirements are met. • May write qualification documents for the system(s).
Environmental Health & Safety (EHS) Engineering	• Provide safety requirements for the equipment/system being qualified. • Review and approve safety portion of the qualification protocols to confirm safety requirements are defined.
Manufacturing Engineering	• Provide guidance during validation activities, including assisting the author with creation of qualification protocols.
Quality Assurance	• Assist with resolving deviations that occur during execution of the protocol and confirming the objectives of the qualification are achieved. • Review and approve the qualification protocols, deviations, and reports to confirm quality system compliance and help resolve any issues. • Review supplier documentation when required for acceptance of equipment qualification documentation.
Executors	• Execute qualifications in accordance with the protocols. • Any of the above Department/Titles may be also be an executor, excluding the post-execution approving QE.

4.0 REFERENCES

4.1 D00178655, Tooling Qualification - Template

4.2 D00178663, Equipment Software Qualification

4.3 D00178875 (QSP14), Calibration

4.4 D00181007, Process Monitoring And Maintenance

4.5 D00181021 (QSP22-A), Asset Management

4.6 D00182901 (QSI28-B-05), Work Instructions For Requesting Raw Material Computer Part Numbers (CPN)

4.7 D00184940, Process Development, Verification, And Validation

4.8 D00184946, Process Development, Verification, And Validation Terms And Definitions

4.9 D00184956 (QSP22), Equipment And Facilities Maintenance Program

4.10 D00186664 (QSI01-E-02), First Article Inspections

4.11 D00186716, Production Specification Development

4.12 D00186722, Installation Qualification -Template

4.13 D00186961 (QSP28), Supplier Controls

4.14 D00188594 (QPM-Attachment_07), Record Retention Schedule

4.15 D00195491 (QSI22-C-02), Equipment Component Change Management

4.16 D00195765 (QSP14-A), IM&TE Implementation

4.17 D00197459, Equipment User Requirement Specification or Traceability Matrix – Template

4.18 D00506213 (QSI22-A-02-F01), EAM Load File

4.19 D00521044, Instructions for the Equipment Validation Plan (EVP)

4.20 Refer to D00309161 for listing of applicable documents/standards/regulations external to Cook.

5.0 TERMS

Refer to D00184946 for a list of terms and definitions.

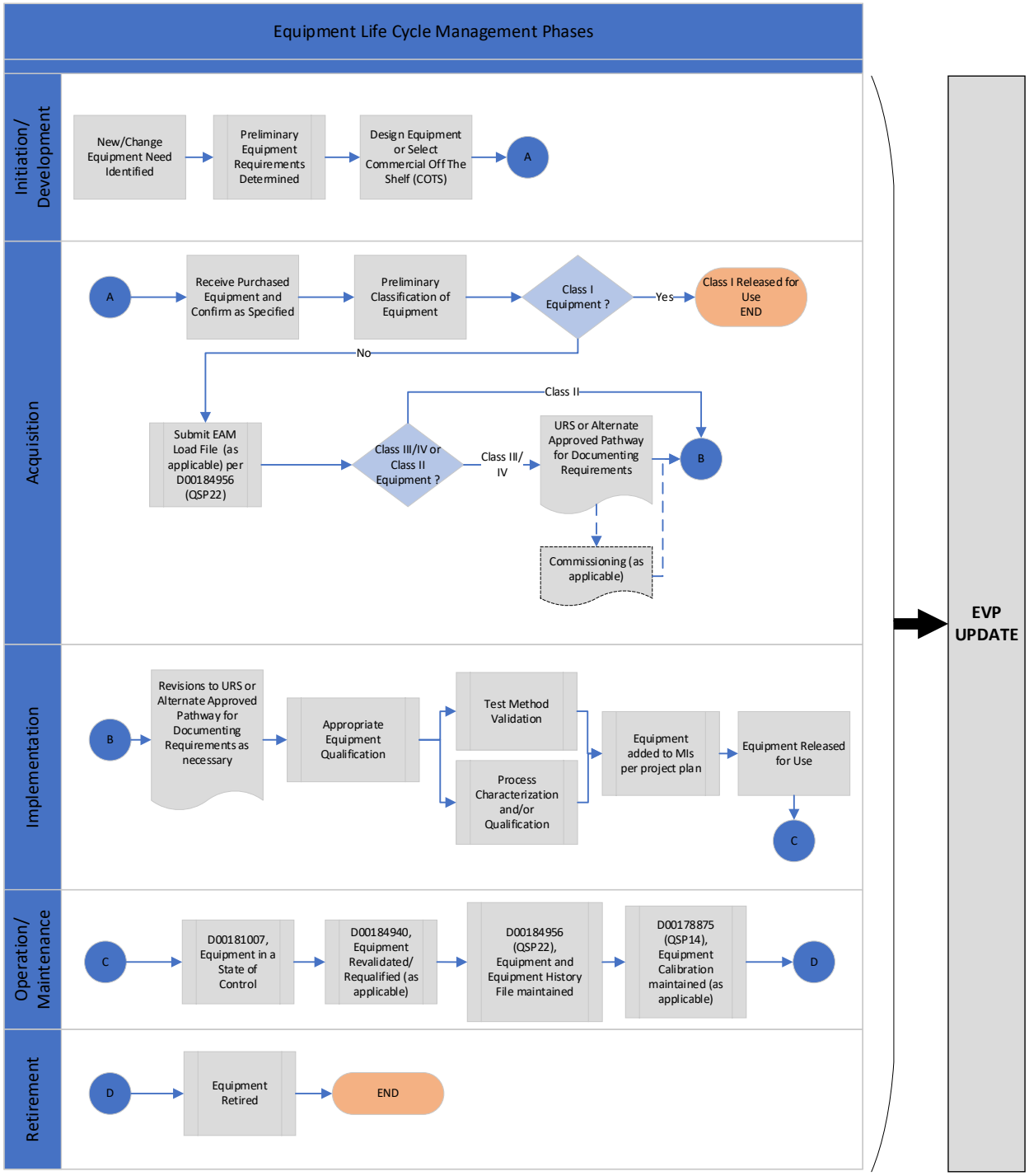
6.0 PROCEDURAL DESCRIPTION

6.1 General Description

6.1.1 This procedure ensures equipment is properly selected, developed, and maintained to yield safe and effective product. All equipment within scope of this procedure shall be controlled to ensure the following conditions are met:

- Equipment used in the manufacturing processes shall meet specified requirements and be appropriately designed and constructed to be suitable for its intended use.
- Maintenance activities shall be established per **D00184956** (QSP22) to ensure manufacturing equipment is properly maintained.
- Calibration activities shall be established **D00178875** (QSP14) to ensure all applicable IM&TE are properly maintained.

6.2 Process Flow



Update to the Equipment Validation Plan (EVP) may be necessary at various points throughout the flow indicated above. Refer to **D00521044** for instances requiring update to the EVP.

6.3 Initiation/Development/Planning

6.3.1 When new equipment needs are addressed, the validation coordinator establishes an agreed upon plan for how to document requirements and execute equipment qualification deliverables. The intended use and requirements are generally documented in the high-level description of the project plan to help guide the agreed upon pathway.

6.3.2 The validation coordinator is responsible for assessing and documenting the detailed system intended use and user requirements. **D00197459** is used for instruction and documentation of the User Requirements Specification (URS) for Class III or Class IV equipment unless an alternate path of documentation is approved.

6.3.2.1 A URS is not required to be created in the following cases (VRB approval not required):

- Equipment is used in an existing process or test method
- No change to process or test method
- No change to intended use of the equipment
- No change to make and model of the equipment
- Simplicity of the change to the equipment and no potential impact to product quality due to the change

6.3.2.2 In cases that do not require a project plan, such as updating a protocol (for example IQ or SQ) to the newest template or updating formatting in an existing protocol, the existing qualification can serve as the legacy URS as long as no changes to requirements or intended use are made. A URS per **D00197459** is not required in these cases.

6.3.3 When equipment is developed in-house, it shall be developed to meet the approved requirements.

6.3.4 Custom designed equipment requires approved and revision-controlled drawings with critical dimensions noted. Critical dimensions are dimensions or specifications which are deemed, through engineering experience and evaluation such as a Failure Modes and Effects Analysis (FMEA), to be critical to the form (mating/contacting relationship) or process (function, safety, reliability, or compliance) of the equipment.

6.3.5 Additional outputs of equipment may include mechanical or electrical drawings necessary for the intended use and maintenance of the equipment, operating guides, manuals or work instructions defining the proper installation, use, safety protocols and maintenance of the equipment.

6.3.6 For modified equipment, addendums shall be made to the existing user manual to explain any necessary changes. These addendums will be placed with the original manuals in the Equipment History File per **D00184956** (QSP22).

6.3.7 Custom software shall be developed and qualified according to **D00178663**.

6.4 Acquisition

6.4.1 New equipment may be acquired per **D00186961** (QSP28) whenever the need for new equipment or change to existing equipment is identified.

6.4.2 User Requirements Specification (URS) and Traceability Matrix (TM)

6.4.2.1 The user requirements and traceability matrix shall be documented according to the instructions in URS and TM Template **D00197459**.

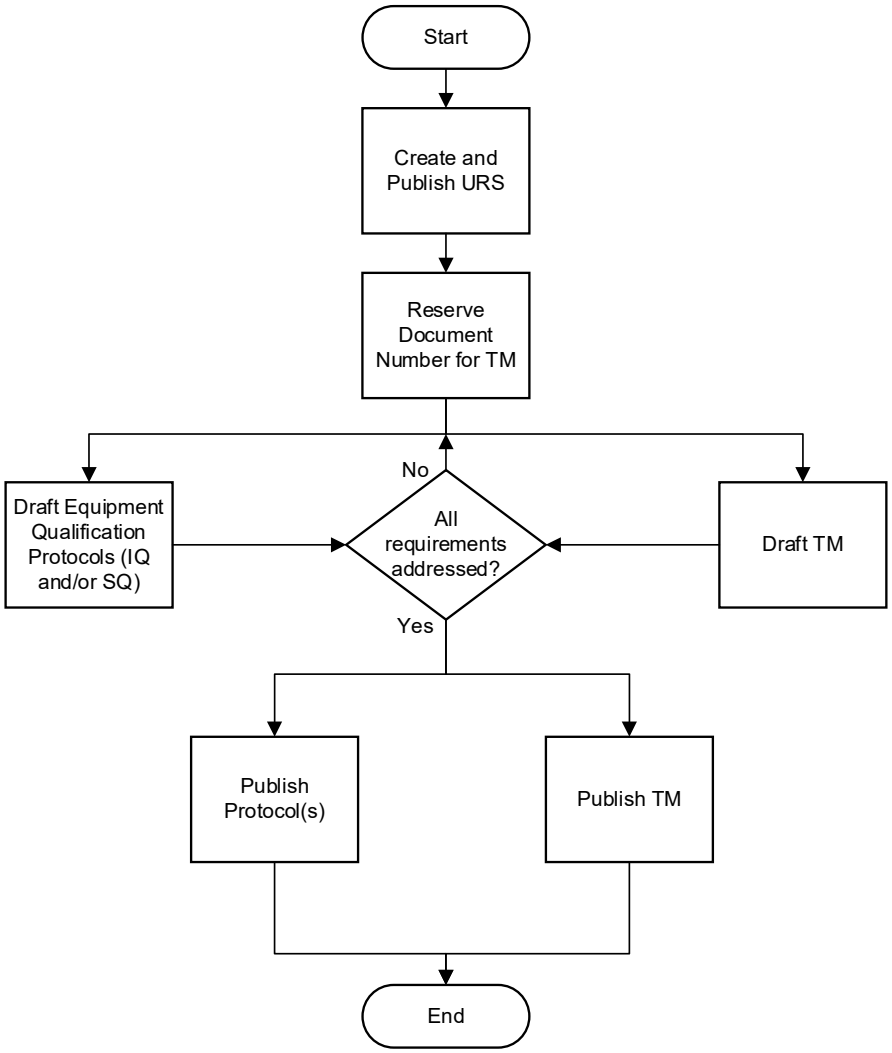
6.4.2.2 The URS is used to establish the requirements for process and test equipment and then document, via the TM, that the requirements have been met.

6.4.2.3 When qualifying Class IV equipment, some requirements may be verified within an SQ protocol while others are in an IQ protocol, so long as all requirements are met.

6.4.2.4 If an alternate approved pathway for documenting user requirements has been approved (e.g. within the IQ protocol only), that pathway shall fully capture requirements and successful execution of the deliverables agreed upon for that pathway shall demonstrate traceability that the user requirements have been met. In these cases, the test cases within the protocol serve as the full definition of the user requirements.

6.4.2.5 When a URS per **D00197459** is not required, a TM is not required.

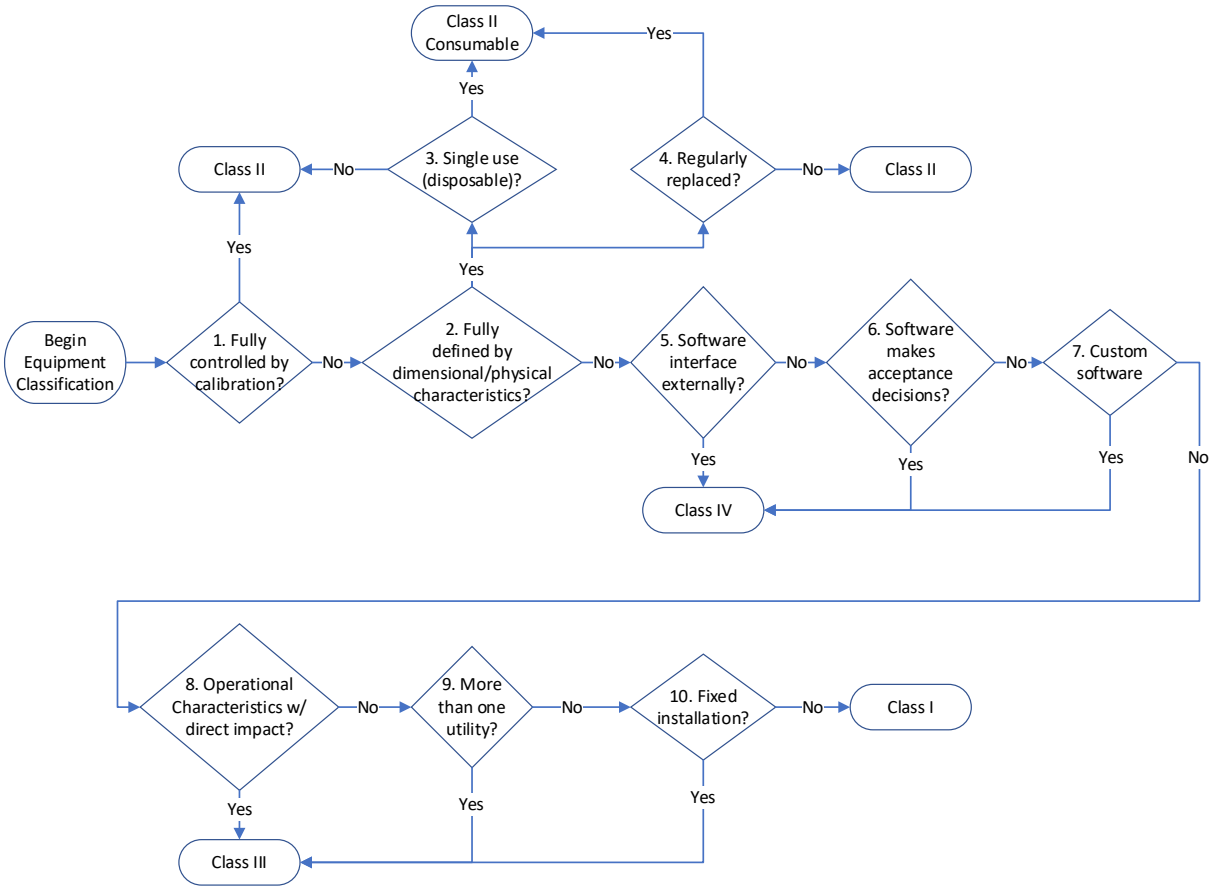
6.4.2.6 The following shows the procedural flow from a high level.



6.4.3 Classification

6.4.3.1 Equipment shall be classified per the following decision tree. Classification aids in determining the equipment qualification pathway. See supporting details below the decision tree.

Classification decision tree:



1. Is the **full functionality** of the equipment controlled through calibration? For example: calipers or pressure gauges enrolled in the calibration program.
2. Is the **full functionality** of the equipment defined by physical (for example: materials, surface finish) and/or dimensional characteristics (defined on a drawing or specification)?
3. Is the equipment one-time use?
4. Must the equipment be replaced regularly because it wears out, breaks, is used up, or is permanently altered in the process of manufacturing?
5. Does the equipment software interface with other equipment or systems?
6. Does the equipment software make acceptance decisions on product quality, such as when the software makes a pass or fail decision?
7. Has the equipment software been customized by Cook Inc. or customized for Cook Inc. by the manufacturer?
8. Does the equipment have operational characteristics, not fully controlled through calibration or dimensional or physical characteristics, that have a direct impact on the results of a process or test method?
    a. Operational characteristics are dynamic (as opposed to static) in nature or involve energy transfer. For example: moving components, heating elements, UV lights, pneumatics.
    b. Direct impact for process equipment:
        i. Causes a change of state of the product. For example: change in length, change from uncoated to coated, change from unbonded to bonded.
        ii. Affects the ability of the process to produce a product meeting its specifications. For example: the heating element (an operational characteristic) on a sealer affects the ability of the process to produce a sealed package meeting the requirements for seal integrity.

c. Direct impact for test method equipment: The operational characteristics affect the ability of the test method to produce repeatable test results.

d. This question does not apply to hand tools (for example, pliers or razor blades)

9. Does the equipment have more than one utility supplying it?

10. Does the equipment require a fixed installation? For example: plumbing or hardwire electric connections.

6.4.4 Portability

6.4.4.1 Portability for Class III and IV equipment is classified by the criteria listed below. All Class II non-calibrated equipment are considered as portable, unless stated otherwise. All Class II calibrated equipment will be handled per QSP14-C (**D00195778**). Class III and IV equipment are considered portable if all of the following are true:

- The equipment can be moved from place to place without dismantling or modification.
- The equipment only uses standard connection types (for example: electrical plugs, quick connect fittings).
- The equipment can be moved, unassisted, by a single person (e.g. equipment small in size, less than 30 lbs) and/or the equipment is designed with the means of transportation (e.g. handles or wheels).

6.4.4.2 Portability is documented in the IQ protocol per template **D00186722**.

6.4.5 Equipment Identification

6.4.5.1 Equipment identification refers to assigning identification to the equipment.

6.4.5.2 Equipment traceability refers to recording the equipment identification in the Device History Record (DHR) or other means of tracing the equipment to the manufactured product. For equipment traceability requirements (recording equipment in the DHR), refer to **D00186716**.

6.4.5.3 Equipment identification is required in the following cases:

- As required by **D00178875** (QSP14)
- As required by **D00184956** (QSP22)
- For qualified equipment or equipment containing qualified software
- When equipment traceability is required

6.4.5.4 An RM CPN must be assigned when required by **D00182901** (QSI28-B-05).

6.4.5.5 Class I equipment does not require traceability to the DHR. A unique Asset ID number is not required. Class I equipment may be purchased and implemented if its intended use is consistent with the manufacturer's commercial intended use.

6.4.5.6 Qualified Class II – IV Equipment shall be entered into the EAM system and labeled with a unique identification number: for example, an Asset ID, Alias, or a Calibration Identification Number (Cal I.D.). Asset IDs are issued according to **D00181021** (QSP22-A). Exception: Asset ID number or other unique identifiers are not required for Class II Consumable equipment. This equipment may be traced with its lot number and drawing or raw material number.

6.4.5.7 Equipment may be labeled by other means (etching, engraving, tagging) when process environments, such as high heat levels or chemical exposure mandate alternate methods of identification. Label(s) may be applied to the equipment storage container when the application of the label would be detrimental to the equipment, or the equipment is too small to accommodate labeling.

6.4.6 Commissioning

Large, complex or sophisticated equipment systems (For example: loom, sterilizer) should be considered for commissioning. Through commissioning, the vendor demonstrates that the equipment fulfills all specifications as defined in the purchase contract. Commissioning is a well-planned, documented, and managed engineering approach to the start-up and turnover of equipment that meets established design requirements and stakeholder expectations. A successful turnover strengthens the likelihood of meeting the next step validation requirements. A documented commissioning approach offers traceable verification and ensures a systematic approach that minimizes commissioning oversights.

6.4.6.1 Documentation for commissioning may be in any format considered appropriate by the system owner and Validation Engineering.

6.4.6.2 Factory Acceptance Testing – Testing the equipment or system at the factory provides a cost-effective means of detecting deficiencies and allows for their correction at the vendors location before the equipment arrives on-site.

6.4.6.3 Site Acceptance Testing – Testing the equipment on-site verifies proper operation at the site and confirms deficiencies were resolved at the vendor’s location and no new deficiencies have been introduced from transportation or the site environment.

6.4.6.4 Setting-to-Work – Adjustments may be needed before energizing or full start-up such as factory representative calibration.

6.4.6.5 Inspection – Process by which the construction and installation is verified as in accordance with the detailed design, specified construction standards and materials and any relevant legal or regulatory demands related to these areas.

6.4.6.6 Testing – Testing is the process by which adjustments to, and regulation of, individual systems are demonstrated as within the required tolerances, system components are demonstrated as delivering the required capacity or duty, the functions of the systems are demonstrated as delivering the required capacity or duty, the functions of the system are demonstrated to be as specified and appropriate.

6.4.6.7 Training – Properly trained staff will be able to safely and efficiently operate and maintain the equipment or system.

6.4.6.8 Project Closeout Documentation – More complex projects may benefit from a formal commissioning plan. All associated documentation should be included on a Commissioning Report. This includes checklist verifications, as-built drawings and specifications, operations and maintenance manuals, test reports, calibration certificates, etc.

6.5 Implementation

6.5.1 During the implementation phase, all equipment shall be labeled with a “Do Not Use” tag (RM CPN: 313134).

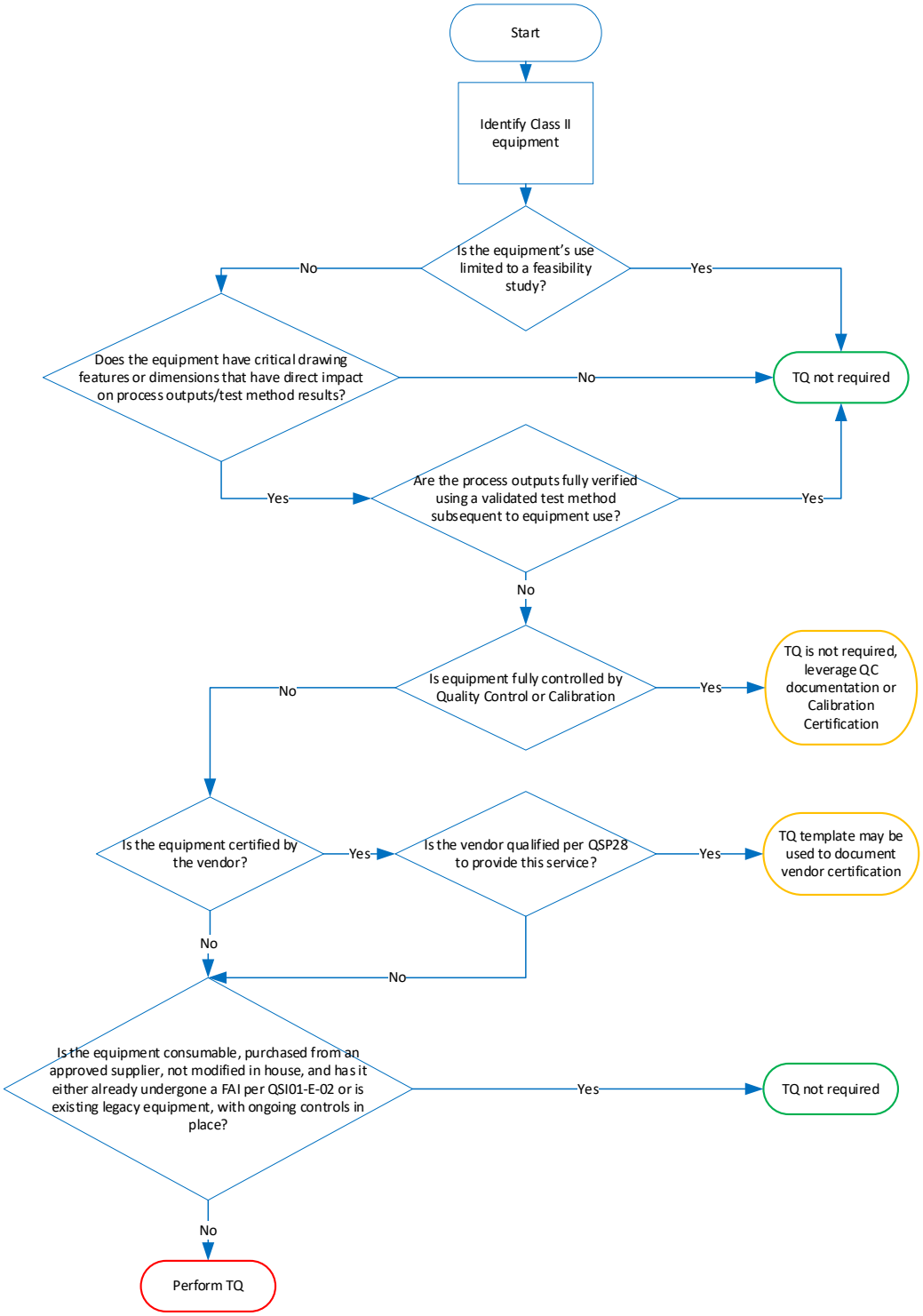
6.5.2 During implementation, process characterization activities may include specific equipment characterization activities, specific product activities, or combined equipment and product interaction activities. These activities may repeat through iterative cycles and they may result in the need for equipment modifications or replacements. These efforts will refine and define Intended Use for the equipment.

6.5.3 Class I Equipment

6.5.3.1 Class I is equipment that does not meet the criteria of any of the higher classes (Class II – IV). Class I equipment is generally commercial off-the-shelf equipment being used for the manufacturer’s intended use (For example: non-calibrated tools such as pliers and razor blades). Class I equipment may be received per **D00186961** and released for use. Class I equipment, like all other classes of equipment, must be added to the EVP per **D00521044**.

6.5.4 Class II Equipment: Tooling Qualification (TQ) Requirements

6.5.4.1 TQ Decision Tree:



6.5.4.2 TQ is used to qualify Class II equipment. TQ will verify that the Class II equipment was built according to its pre-approved specifications.

6.5.4.3 Qualification for Class II equipment where the function is defined solely through calibration shall be demonstrated through a completed and successful calibration.

6.5.4.4 When Class II equipment is used as a part of a system, TQ is performed prior to completion of process characterization (excluding feasibility), TMV, OQ, or PQ.

6.5.4.5 TQ is required for the following (not inclusive):

6.5.4.5.1 Class II equipment used during test or inspection methods that are used for outputs that are not later tested or verified.

- For example: a go/no go gauge used during the process to ensure the correct balloon has been used, and the balloon outer diameter is NOT later measured in final QC.
- For example: Class II equipment used in a process validation test method.

6.5.4.5.2 Class II equipment used during a manufacturing step that has a direct impact on a validated output. For example, a flaring iron tip used to create flared tubing that is not subsequently fully verified.

6.5.4.6 A TQ is not required for the following (not inclusive):

6.5.4.6.1 Class II equipment used for feasibility tests.

6.5.4.6.2 Class II equipment that has no critical drawing features or dimensions (i.e., no features or dimensions that directly impact the product or process).

Section **6.5.4.6.2** *continued*

- In this application, direct impact means the function of the equipment affects the ability of the process to produce a product meeting its specification.
- Example of no direct impact: a tool holding fixture where the function is one of convenience to the operator to aid in the efficiency of processing without having any impact on the process outputs i.e. the process may be successfully performed both with and without the fixture.

6.5.4.6.3 Class II equipment used during in-process verification for attributes that are subsequently measured with a validated test method. For example, go/no-go gauge used during the process to ensure the correct balloon has been used, and the balloon outer diameter is later measured in final QC on a laser micrometer.

6.5.4.6.4 Class II equipment used during a process for which all the process outputs are subsequently fully verified with a validated test method, when a TMV is required per **D00182959**.

- In some cases, the process has a combination of fully verified and validated outputs. If the impact of the equipment is limited to specific process outputs, and those process outputs are fully verified with a validated test method, a TQ is not required.

6.5.4.6.5 Class II equipment that is fully controlled by other documented means which can be leveraged to satisfy the TQ requirement: calibration, Quality Control, or vendor certification. QC documentation or Calibration Certification should be leveraged if applicable. In the case of vendor certification, the TQ template may be used to document vendor certification.

6.5.4.6.5.1 When a vendor certifies the dimensions of the Class II equipment, the vendor must be qualified per **D00186961** (QSP28) to provide this service. Follow the instructions in **D00178655** for documentation and storage of vendor certifications unless vendor certification is documented and stored by other means.

6.5.4.6.6 Class II equipment that is consumable, purchased from an approved supplier, is not modified in-house and has already undergone a First Article Inspection (FAI) per **D00186664** (QSI01-E-02). Ongoing controls shall be in place to ensure the equipment continues to meet specifications (for example: lot acceptance activities via Cook Inc. Quality Control or vendor certifications).

6.5.4.6.7 Equipment identified as Class II Consumable requires only an initial Tooling Qualification with subsequent lot acceptance (e.g. IQC or vendor certification) for duplicates. An initial Tooling Qualification is not required in the case of legacy tooling that has already been in use or if an FAI has been performed.

6.5.4.7 Refer to **D00178655** for inputs and the creation, execution, and reporting of Tooling Qualifications.

6.5.4.8 Instruments and equipment to be used for collecting process data or building parts during the qualification must be identified and have a current calibration and verification that the calibrated range and instrument tolerance are appropriate for their intended use.

6.5.5 Class III Equipment: Installation Qualification

6.5.5.1 The Installation Qualification (IQ) provides documented evidence that the system is installed/built and is operating in accordance with pre-approved specifications and intended use.

6.5.5.2 A URS **D00197459**, shall be completed unless not required as indicated elsewhere in this procedure. When a URS is required, a Traceability Matrix is also required.

6.5.5.3 Installation Qualification shall be executed for Class III and IV equipment, unless rationale is provided. If the Class III equipment has components that require dimensional verification, a test case shall be added to the IQ, unless the dimensions are verified by other documented means.

6.5.5.4 IQ may not be required for equipment used for feasibility tests.

6.5.5.5 For duplicate equipment (same make and model), if IQ was conducted on the original equipment, IQ is required for duplicate equipment.

6.5.5.6 Refer to **D00186722** for inputs and the creation, execution, and reporting of Installation Qualifications.

6.5.5.7 Instructions for Component Criticality Assessments (CCA) are in the IQ template **D00186722**.

6.5.5.8 Instruments and equipment to be used for collecting process data or building parts during the qualification must be identified and have a current calibration and verification that the calibrated range and instrument tolerance are appropriate for their intended use.

6.5.5.9 When components or raw materials are used in the qualification, the components or raw materials are qualified or verified to be within specification. Substitute samples may be used when actual components and raw materials are not available, and substitutes are representative. Adequate justification/rationale must be provided in the qualification when substitutes are used.

6.5.6 Class IV Equipment: Software Qualification

6.5.6.1 Class IV Equipment must meet the requirements for Class III equipment, unless rationale is provided, as well as the requirements in **D00178663**.

6.6 Qualification Documentation

6.6.1 Keep the same Document Object Number (D#) for the report for an individual asset. This means, when re-executing a qualification for an individual asset keep the same report D# and up-rev it in PLM.

6.7 Maintaining A Validated/Qualified State

6.7.1 Once the equipment has been implemented, maintenance and calibration, if applicable, shall be maintained until retirement of the equipment.

6.7.2 Equipment shall be stored in a manner that minimizes the possibility of damage or deterioration.

6.7.3 Refer to **D00184940** to ensure the integrity of the validated state is maintained over time or when changes are made to the equipment, software, or process.

6.7.4 Replacement of components for repair which are not like-for-like require a review to evaluate impact to process and process validation. Evaluation shall be performed per **D00195491** (QSI22-C-02).

6.8 Retirement

Equipment shall be retired according to **D00184956** (QSP22).

7.0 DOCUMENTATION

7.1 Refer to **D00188594** (QPM-Attachment_07) for Cook record retention guidelines.