Attachment 20

Analytical Instrument and Laboratory Equipment Qualification Process

Table of Contents

1.0 Overview

1.1 Purpose

Analytical instrument and lab equipment qualification must follow the requirements of ABC Analytical Instrument and Lab Equipment Qualification Policy.

This document describes the process to be followed for qualifying analytical instruments and lab equipment.

1.2 Scope

The scope of this document is defined in the scope section of ABC, Validation Policy.

1.3 Implementation

Implementation is in accordance with Effective Date.

Analytical instrument and lab equipment qualification prior to the effective date of this policy may be executed according to the documents in effect at that time.

1.4 Responsibility

The owner organizations of the qualified analytical instruments and lab equipment in the scope of this document and the associated Validation Review

Boards (VRBs) are responsible for assuring compliance with xyz's qualification policy and process document requirements.

2.0 Requirements

2.1 Change Control

2.1.1 Determination of Qualification Approach

Qualification of analytical instruments and lab equipment is based on the concept that electronics, analytical operations and samples to be analyzed constitute an integral system that can be evaluated as such.

Determination of the level of qualification for analytical instruments and lab equipment is based on the Analytical Instrument/Lab Equipment Qualification Process Flow Chart, see Section 2.1.3.
Where no measurement is required by the intended use, no qualification is required.

Measurement requirements are generally derived from test methods and operating procedures.
Installation and operation qualification are required when the instrument or equipment has/contains one or more of the following:

- higher complexity instrument (e.g., HPLC, GC, ICP, NMR, Mass Spec)
- data management system connection (e.g., connected to LIMS system)
- operator modifiable software (e.g., dilutors, robotics)
- calculations performed by software
- physical installation requirements (e.g., analytical balances), and
- laboratory equipment with critical requirements (e.g., refrigerators used to store reference standards).

All other instruments where a measurement is required, may be registered by entry into one or more of the following quality systems, based on corporate or divisional procedure:

- calibration
- user standardization, and
- preventive maintenance.

Reference: See Attachment A for additional typical examples.

The VRB may amend the qualification requirements based on the specific intended use. Any changes will be documented through a VCR.

2.1.2 Vendor Provided Qualification Services

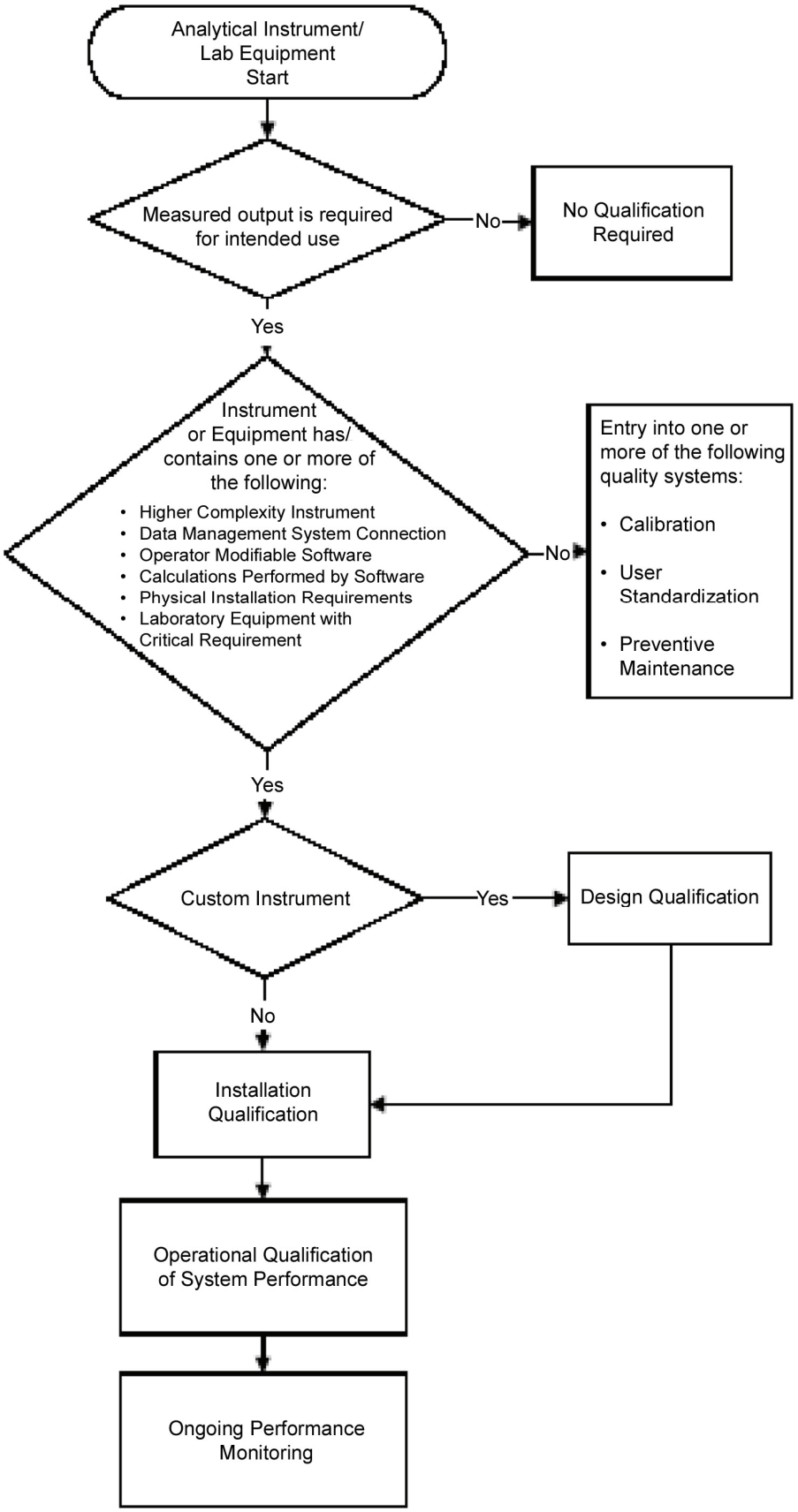
The owner is responsible for verifying the credentials of the vendor before purchasing qualification services. The vendor must supply information demonstrating that they are technically capable of performing the work for which they are contracted. This information is to be retained with the qualification package.

All work provided by the contractor (vendor) must be accompanied by an approved VCR before placing the analytical instrument or lab equipment into operational use. The minimum requirements for XYZ approvers when reviewing or approving qualification documentation is to ensure:

Validation Change Control is followed
Completeness of record
All acceptance criteria have been achieved
Technical accuracy
Compliance to division/site operating procedures

2.1.3 Analytical Instrument/Lab Equipment Qualification Process Flow Chart

This flowchart describes the analytical instrument and lab equipment qualification process.


Analytical Instrument/ Lab Equipment Start
Measured output is required for intended use
No
No Qualification Required
Yes
Instrument or Equipment has/ contains one or more of the following:
• Higher Complexity Instrument
• Data Management System Connection
• Operator Modifiable Software
• Calculations Performed by Software
• Physical Installation Requirements
• Laboratory Equipment with Critical Requirement
No
Entry into one or more of the following quality systems:
• Calibration
• User Standardization
• Preventive Maintenance
Yes
Custom Instrument
Yes
Design Qualification
No
Installation Qualification
Operational Qualification of System Performance
Ongoing Performance Monitoring

2.1.4 Change Impact Level

The VRB must approve the category of change impact level as High, Medium, or Low. Qualification requirements based on the change impact level are described in the table below.

When the change impact is…	Then the qualification requirements are…
High	The same as for new instruments, with appropriate IQ and OQ testing
Medium	IQ and OQ testing related to the change, as needed
Low	Determined by the VRB but may require only validation actions, not full protocols

2.2 Validation Master Plan

The VMP schedule for each site must contain a listing of

analytical instruments and lab equipment requiring qualification or requalification
the qualification status for each, and
a review schedule as appropriate for all analytical instruments and lab equipment.

2.3 Design Qualification

Design specifications must be documented and approved in a Design Qualification (DQ) before purchase or installation of custom analytical instrument and lab equipment. A design qualification is not required for analytical instruments and lab equipment purchased as designed by the vendor manufacturer to meet general market use.

The VRB should be consulted early in the acquisition process to determine if a DQ is required. The owner and site quality assurance must approve the DQ, at a minimum.

2.4 Installation Qualification

2.4.1 Purpose

The purpose of the IQ is to establish by objective evidence the instrumentation or equipment as installed or modified.

complies with the manufacturer specifications and approved design qualification, if applicable, and
considers the manufacturer's recommendations.

2.4.2 IQ Minimum Requirements

This table describes the minimum IQ requirements.

Section	Requirement
Purpose	States why the instrument/equipment is being qualified (i.e., required per policy).
Scope	Identification of the instrument/equipment/system boundaries that will be qualified, and States whether the qualification is for the: – installation of new instrumentation/equipment, or – modification of instrumentation/equipment that has been previously qualified
Instrumentation/Equipment Description and Components	Describe the intended use of the instrument/equipment Identification and brief description of each major component of the subject instrumentation/equipment
Software	Description of the: program version identification software master/backup copy (if applicable), and event handling
Utilities Required	Description of the: electrical requirements water and plumbing requirements, and other (e.g., compressed gas)
Site	Address the suitability of facilities/location and environmental requirements
Operating Procedures and Manuals	List of procedures and/or manuals that are used to operate or maintain the subject instrumentation must be listed.
Calibration Status	Documentation that the instrument is set up to be: calibrated user standardized, or not a calibrated instrument (NCI)
Maintenance Program	Definition of the programs (including any documentation or log books that might be required), and A listing of required PM activities
Events and Nonconformities	Justification must be provided for changes to a pre-approved protocol prior to VRB approval of the results with the exceptions of: typographical corrections, or minor informational changes which have been documented in the body of the protocol Changes to pre-approved protocol tests or acceptance criteria that affect the intent of the pre-approved protocol must be pre-approved by the VRB using an amendment. If qualification results for an instrument are non-confirming

	with the protocol acceptance criteria, then the cause should be investigated, a root cause determined, and a corrective action should be implemented and documented Non-conformities must be evaluated by the VRB as to which ones must be reported and tracked to completion in a corrective and preventive action system.
Summary and Conclusion	Summary on how the IQ demonstrated the lab instrument/equipment was installed correctly, and provide a conclusion on whether the installation is acceptable. **Note:** When an IQ/OQ is performed together the summary and conclusion for the IQ and OQ will be combined together.

2.5 Operation Qualification

2.5.1 Purpose

The purpose of the OQ is to establish by objective evidence the instrumentation as installed or modified performs as intended.

2.5.2 OQ Minimum Requirements

Qualification across ranges may not be required for analytical instruments if methods performed on them have system suitability, check samples, user standardization, or control procedures that verify the instrument is functioning at the time of use.

Important: Where there are formulas, data, or records (which are referred to by 21 CFR Part 211.68 as "input to and output from the computer"), the operational qualification must include a verification of the accuracy of the formulas, data, or records.

This table describes the minimum OQ requirements.

Section	Requirement
Purpose	States why the instrument/equipment is being qualified (i.e., required per policy).
Scope	Identification of the boundaries/functions that will be qualified, and States whether the qualification is for the: - installation of new instrumentation/equipment, or - modification of instrumentation/equipment that has been previously qualified
Operating Procedures and	List of operating procedures and/or manuals for the subject

Manuals	instrumentation/equipment. **Note:** If procedures/manuals are listed in the IQ; a reference to the IQ is acceptable.
Software	Description and testing of the: restart/recovery procedure (if applicable) security procedure(s), and calculations and algorithms
Operating Parameters and Testing	Definition of the operating parameters and test point(s), and Definition of the test procedure. OQ testing must be designed to confirm that the instrumentation meets the predetermined acceptance criteria. **Note:** The number of test runs and the quantity of test data can vary depending on the type of instrumentation, its complexity, and its use. The VRB has the discretion to determine what the extent of testing shall be. Rationale must be documented.
Acceptance Criteria	Definition of acceptance criteria for each operating parameter/test point.
Events and Nonconformities	Justification must be provided for changes to a pre-approved protocol prior to VRB approval of the results with the exceptions of: typographical corrections, or minor informational changes which have been documented in the body of the protocol Changes to pre-approved protocol tests or acceptance criteria that affect the intent of the pre-approved protocol must be pre-approved by the VRB using an amendment. If qualification results for an instrument are non-confirming with the protocol acceptance criteria, then the cause should be investigated, a root cause determined, and a corrective action should be implemented and documented Non-conformities must be evaluated by the VRB as to which ones must be reported and tracked to completion in a corrective and preventive action system.
Summary and Conclusion	Summary of the results of the OQ testing and the extent to which the OQ confirms that the instrumentation performs as intended, and met acceptance criteria.

2.6 Software Requirements

Standard lab instrumentation software that is supplied with the instrument, integral to the instrument operation, and cannot be altered, will be qualified as

part of/in conjunction with the instrument installation and operational qualification. Configuration should be limited to establishing the runtime environment of the instrument (e.g., network and printer connections). Process parameters may be input into the application.

Lab instrument software that is supplied with the instrument where code can be altered will be qualified according to the requirements described in Policy ABC, Automated Process Control System Validation.

Data management software, such as LIMS will be validated and meet computer system validation requirements as described in Policy ABC, Computerized System Quality Assurance and Validation.

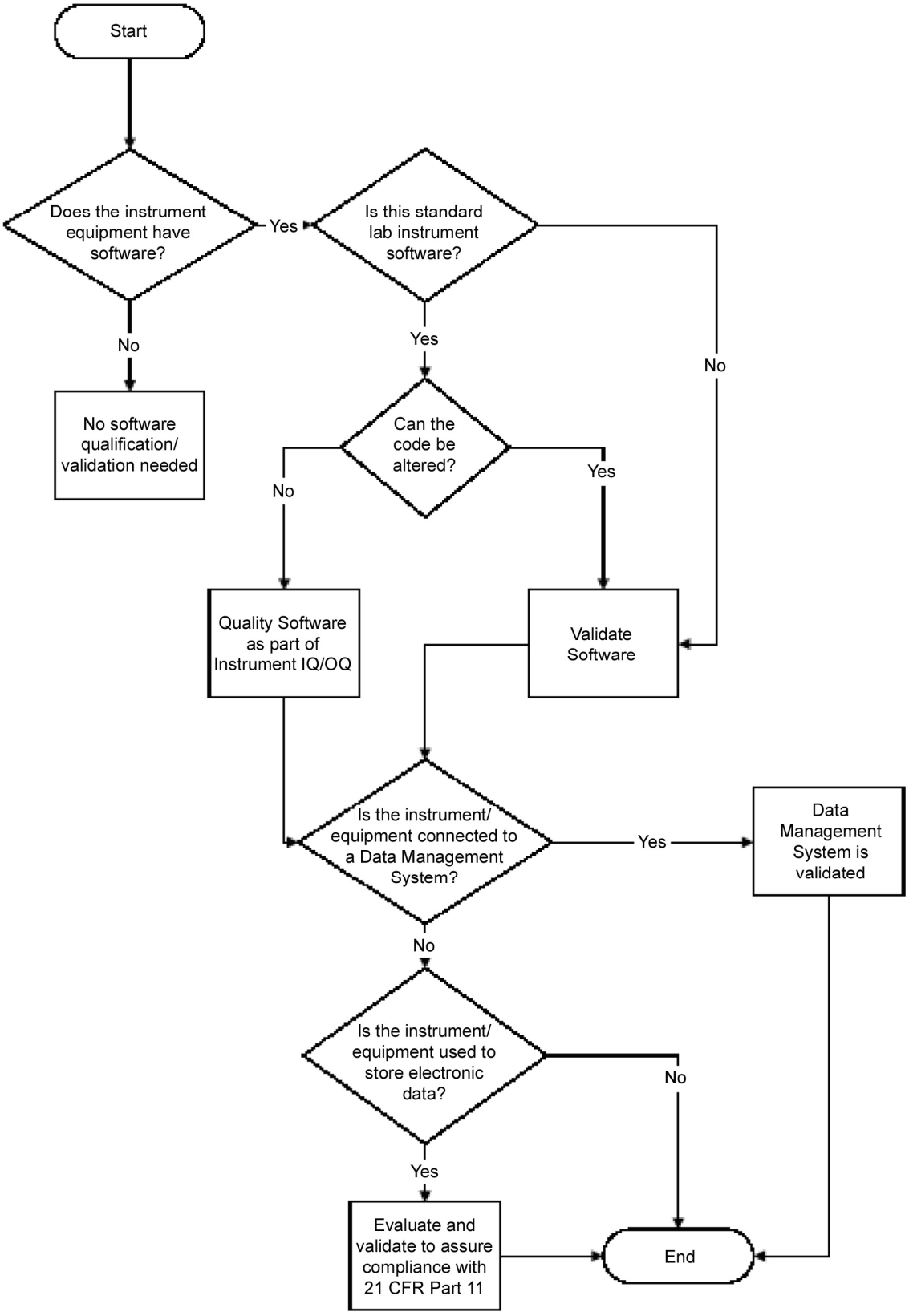
Verification of the continued accuracy of input to and output from the computer of formulas, records, or data that had previously been verified as part of the initial qualification may be required. The frequency of the verification shall be based on complexity and reliability of the system, and other checks that may be in place to assure the accuracy of the formula, data, or records. The frequency will be included in the site validation master plan.

2.6.1 Part 11 Requirements

If the laboratory instrument will be used to store electronic data, the instrument will be evaluated and validated, as appropriate, to assure compliance with 21 CFR Part 11.

2.6.2 Software Flow Chart

This flowchart can be used as a guide to determine qualifications/ validation requirements for the analytical instrument/lab equipment software.


Start
Does the instrument equipment have software?
Yes
Is this standard lab instrument software?
No
No software qualification/ validation needed
Yes
No
Can the code be altered?
No
Yes
Quality Software as part of Instrument IQ/OQ
Validate Software
Is the instrument/ equipment connected to a Data Management System?
Yes
Data Management System is validated
No
Is the instrument/ equipment used to store electronic data?
No
Yes
Evaluate and validate to assure compliance with 21 CFR Part 11
End

2.7 Routine Performance Monitoring

Routine performance monitoring is accomplished through one or more of the following:

system suitability
check samples
user standardization, or
operating procedures.

2.8 Decommissioning

A VCR must be initiated for VRB review to determine actions to be completed for decommissioning.

Qualified analytical instruments or lab equipment that are calibrated, must be end calibrated before removing from service to confirm that the instrument has been in calibration and that the data generated for product release or process decisions is accurate.

Examples of other actions that may be required for decommissioning include:

removing instrument from laboratory information system
deleting operating procedures from documentation system, and
deleting PM/calibration requests from system.

ATTACHMENT A

Typical Analytical Instrument/Lab Equipment Classification

Instrument/Equipment	No Qualification Required	Qualification Required	Entry in applicable quality systems
HPLC Chromatographic Systems		X	
Gas Chromatographic Systems		X	
Preparative Liquid Chromatographic Systems	X		
Chromatography Gas Generators	X		
Sat/IN A/D Converters		X	
Flow Meters			X
Spectrophotometers			
UV/Vis		X	
FTIR		X	
Polarimeter		X	
NMR		X	
Mass Spec		X	
AA		X	
ICP		X	
Colorimeters		X	
Turbidimeter		X	
LAL Instruments		X	
X-Ray Diffractometer		X	
Amino Acid Analyzer		X	
Lysis system		X	
XYZ Autoanalyzer		X	
CHN Analyzer		X	
TOC Analyzer		X	
Volume Delivery Devices			
Potentiometric Titrator		X	
XYZ Titrator		X	
Aquatitrator		X	
XYZ Aquatest		X	
Auto Dilutors		X	
Pipetors	X	Where volume is critical	
Dispensers			X
Auto Analyzer		X	

Instrument/Equipment	No Qualification Required	Qualification Required	Entry in applicable quality systems
Constant Temperature Devices			
Liquid-In-Glass Thermometers Thermocouples Electronic Thermometers			X X X
Temperature/Humidity Recorders			X
Barometer/Manometer			X
Bactometer		X	
Particle/Cell Counters			
Particle Size Instruments		X	
Surface Area Instruments		X	
Granulometer		X	
Sieves (manual & automatic)			X
General Lab Equipment			
Thermal Sample Digestor			X
Centrifugal Air Sampler			X
Centrifuges			X
Conductivity Meter			
Refrigerator / Freezer	X	Where temperature is critical	
Water Baths	X	Where temperature is critical	
Stir plates	X		
Heating Plates	X		
Ovens	X		
Oven Components Temperature Devices Pressure Devices			 X X
Vacuum	X	Where pressure is critical	
Convection	X		
Muffle Furnace			X
Microwave			X
Mixers	X		Where mixing is critical
Regulator Gauges	X		
Steam Baths	X		
Lab Timers			X
Shakers	X		
Sonicators	X		
Cameras	X		

Instrument/Equipment	No Qualification Required	Qualification Required	Entry in applicable quality systems
Micro Plate Readers, Pourers		X	
Densitometers			X
Spotter, TLC	X		
Fume Hood		See XYZ	
Glove Box/Isolators		See XYZ	
Biosafety Cabinet		See XYZ	
Sterilizer/Autoclaves	X	Where sterilization is critical	
pH Meter			X
Melting Point Apparatus			X
Viscometer			X
Incubator	X	Where temperature is critical	
Dissolution Bath			X
Depyrogenation Oven		X	
Physical/Mechanical Testing for Devices			
XYZ company/XYZ company		X	
Calipers (Digital and Analog)			X
Micrometers (Digital and Analog)			X
Pressure Gauges			X
Force Gauges			X
Oscilloscopes			X
Leak Detectors	X	Where measurement is critical	
Torque	Meters		X

The VRB may amend the qualification requirements based on the specific intended use. Any changes will be documented through a VCR.

END OF DOCUMENT