|  |
| --- |
| **Calibration and Verification** |
| **Document Number:** | SRF-03-PR-001 | **Effective Date:** | DD Feb 2025 |
| **Revision Number:** | 3 | **Periodic Review Date:** | DD Feb 2028 |
| **Process Owner:** | Larry King | **Department Owner:** | SRF Operations |

# Purpose

The purpose of this procedure is to describe the method SRF Operations uses to control the calibration of monitoring and measuring resources used in the production or testing of superconducting RF cavities, structures, or cryomodules in SRF Operations. This procedure describes the roles and responsibilities of SRF Operations staff, which equipment items will be controlled, and the Calibration Register. The interface between this procedure and existing JLab processes is also described.

This procedure supports the Quality Management System as described in the SRF-01-ML-001 Quality Manual.

# Scope

This procedure applies only to measurement and test equipment used to perform measurements identified by SRF Ops as being critical-to-quality. The use of such “Critical MTE” is commonly prescribed by and recorded in approved, SRF Operations work control documents, including operational procedures and travelers.

This procedure does not apply to M&TE used for non-critical processes or measurements. Such equipment may be controlled as M&TE under JLab QA18kd or other documents.

# Terms and Definitions

A list of general terms and definitions can be found in the SRF-01-ML-001 Quality Manual Quality Manual.

The following terms have specific meanings within this procedure.

|  |  |
| --- | --- |
| **Term** | **Definition** |
| M&TE (Measurement and Test Equipment) | Monitoring or measuring device used to determine the quantitative value of a physical property. |
| Critical MTE (Critical Measurement and Test Equipment) | M&TE identified for use in a critical-to-quality process, requiring measurement traceability in order to provide confidence in the validity of measurement results. |
| Calibration | Operation that establishes the relationship between values indicated by a measuring device and measurement standards traceable to international or national measurement standards. |
| Verification | Operation performed on Critical MTE to confirm the relationship between values indicated and a recognized reference material or standard, or a similar reference or standard. |
| Calibration Register | An electronic log in DocuShare or Pansophy used to track the calibration status of all Critical MTE. |
| Qualifying Calibration Vendor | Vendor performing calibrations traceable to international or national measurement standards and as recognized by the JLab calibration program described in QA18kd, Calibration and Control Procedure for Measurement and Test Equipment (M&TE). |
| Property Tag Number | Unique identifier assigned to an item by the JLab Property Management group. Also known as an F-number, F-tag, or Property number.  |

# Roles and Responsibilities

The following roles have responsibilities described in this document.

|  |  |
| --- | --- |
| **Role** | **Responsibility** |
| Calibration Custodian | Monitors and reports on the condition of Critical MTE assigned to them by their Work Center Lead. Coordinates the performance of required calibrations. Removes from service any Critical MTE failing verification or suspected to be out of tolerance. |
| Work Center Technician | Uses only calibrated and fully functional Critical MTE for measurements that call for Critical MTE. Notifies Work Center Lead if Critical MTE is out of calibration, fails verification, or appears damaged.  |
| Work Center Lead (WCL) | Determines equipment currently needed for critical-to-quality measurements and ensures that it is identified as Critical MTE in the Calibration Register. Assigns Calibration Custodian for Work Center Critical MTE. Notifies Quality Engineer when Critical MTE is found unfit for service. Manages verification program, if implemented for any of their Work Center’s Critical MTE. |
| Work Control Document (WCD) Author | Identifies critical-to-quality measurements and calls out the need to use Critical MTE in work control documents. |
| Project Coordinator | Works with relevant WCLs, WCD authors, and subject matter experts to identify critical-to-quality measurements made in support of their project. |
| Quality Engineer | Determines response after discrepancy is identified.Reviews and approves Calibration Variance requests. |
| Calibration Program Owner | Monitors the program and reports status of the program in Management Review. Participates in internal audits of the Calibration Program. Works with Records Management Program Owner to ensure required records are maintained in compliance with both the Calibration and Records Management Programs. |
| Records Management Program Owner | Works with the Calibration Program Owner and Calibration Custodians to ensure required records are maintained in compliance with both the Calibration Program and Records Management Program requirements. |

# Procedure

## Identifying Critical Measurements

In collaboration with the Project Execution process, each SRF Ops Project Coordinator works with the WCD Author, WCLs/Group Leads, and other subject matter experts to identify critical-to-quality measurements.

### WCD Author

* The Work Control Document (WCD) Author identifies the measurement activities that are critical to quality based on the intended use of the measurement information or project requirements.
* The WCD Author will identify these “Critical Measurements” as such, and specifically state that “the use of Critical MTE is required,” in each relevant step of their travelers or procedures.
* The WCD Author should inform the Work Center Lead(s) of any Critical Measurements, to ensure the proper Critical MTE is available when it is needed for measurement activities.

### Work Center Leads/Group Leads

* Work Center Leads should periodically review the procedures, travelers and WCDs used in their work area and identify any critical-to-quality measurements that require the use of Critical MTE.
* Work Center Leads may designate any piece of M&TE as Critical MTE, with or without critical measurements identified by the WCD Authors.

### SRF Project Coordinators

* The SRF Project Coordinators should review the procedures, travelers and WCDs used by their project to identify any critical-to-quality measurements and work with Work Center Leads and WCD Authors to ensure all Critical Measurements are addressed, as above.

## Selecting Appropriate Critical MTE

Work Center Technicians are responsible for using the Critical MTE that is required by the traveler, procedure or WCD guiding the specific monitoring and measuring activity they are performing. The technician shall ensure the item to be used for a critical-to-quality measurement is labeled as Critical MTE and in good working order.

## Recording the Use of Critical MTE

For each Critical Measurement identified in a WCD, the WCD Author will require the performer of the measurement to record:

1. property tag number (or assigned serial number) of the Critical MTE used
2. calibration DUE Date of the Critical MTE used

## Managing Critical MTE

Work Center Leads determine the types and quantities of Critical MTE needed to support the measurement activities described in the work control documents.

Work Center Leads are responsible for ensuring that adequate quantities of calibrated Critical MTE are available for all critical-to-quality work performed within their work center.

## Calibration Register

The Calibration Register will be created and maintained by the Calibration Custodian for the tracking and recording of Critical MTE and associated calibrations. Each Critical MTE will have a calibration record and be identified in the Calibration Register as "Critical MTE". Measurement equipment not designated as Critical MTE may be entered into the Calibration Register at the discretion of the Calibration Custodian, but it is not subject to the requirements of this procedure.

### Calibration Register Equipment

Each piece of Critical MTE must be listed in the Calibration Register and updated as calibrations are performed. Each Critical MTE listed should contain the following information:

* + Property Tag Number (or unique, assigned serial number, if not tagged by Property)
	+ Current Owner assigned to the Property Tag Number (if applicable)
	+ Calibration Custodian of the equipment
	+ Type (basic function) of equipment
	+ Manufacturer
	+ Model Number
	+ Manufacturer’s Serial Number
	+ Date of Calibration
	+ Calibration Due Date (Expiration)
	+ Location of current Calibration Certificate
	+ Location of Verification Log, if any

### Calibration Certificates

Each piece of Critical MTE in the Calibration Register must identify the most recent Certificate of Calibration's location. Appropriate locations for Certificates include:

* The ESH Calibration Records (Note, these are externally maintained)
	+ An electronically supplied file uploaded to the correct DocuShare location and linked in the Register
	+ The clearly stated location of the physical document. Note, any physical documents must be held in a secure location, safe from reasonable environmental hazards. Furthermore, any physical document should be scanned and uploaded to DocuShare

### Unique Identifier and protection for each Critical MTE

Critical MTE will be installed, located, or otherwise protected in a manner that safeguards the equipment from damage and abuse. Critical MTE must be labeled with either the Property Tag number or the assigned serial number that is used to identify the item in the Calibration Register.

Calibration Custodians must also label, or otherwise clearly identify, all Critical MTE listed on their Calibration Registers to inform users that:

* + The item is “Critical MTE.”
	+ Opening or attempting repairs on the unit is not permitted
	+ Calibration sticker and seals must not be altered.

Calibration Custodians must remove such Critical MTE labels from any M&TE that is no longer identified as Critical MTE.

## Calibrations

Critical MTE will be calibrated against reference standards traceable to international or national measurement standards, using methods appropriate to its use. If reference standards are not available, the equipment owner must secure evidence from the equipment supplier to support an alternate calibration reference method. Where feasible, calibrations will be performed using multiple data points that are representative of the range likely to be seen in the device’s actual application in order to ensure the same degree of accuracy across the entire range of measurements.

### Calibration Intervals

The schedule of calibrations will be based on one of the following:

* The manufacturer’s specified performance intervals –or-
* The qualified calibration vendor’s specified performance intervals –or-
* An internal procedure, approved by the organization, which documents an interval based on prior history and the level of risk associated with out-of-calibration measurements
* A determination made by the Calibration Process Owner.

### Performance of Accredited Calibrations

Calibrations should be performed by a Qualifying Calibration Vendor. Use of the JLab ESH contract calibration vendor is preferred, and described in QA18kd, Calibration and Control Procedure for Measurement and Test Equipment (M&TE). Other Qualifying Calibration Vendors may include OEMs and on-site calibration services.

### Performance of Non-Accredited Calibrations

Where a traceable calibration standard, procedure, or performance interval does not exist, or cannot be followed, the System Owner or cognizant subject matter expert will propose a performance interval and/or calibration procedure (using SRF-07-FM-005 SRF OPS Procedure Template) which fully documents the basis used. Proposed calibrations should include multiple data points that are representative of the range likely to be seen in the device’s actual application. The procedure must list acceptance criteria for each measurement to be performed and should include a place or method to record the required measurements. The document must be approved and signed by the author(s) and the Calibration Process Owner before use.

Each performance of any such calibration must be recorded on a copy of the approved procedure, which will then be used in lieu of a Calibration Certificate for that piece of Critical MTE. The completed and approved form is uploaded to, linked to by, or identified in, the Calibration Register, as per 5.5.2 Calibration Certificates, in place of the calibration certificate. The piece of Critical MTE’s Date of Calibration and Calibration Due Date in the Calibration Register are advanced to reflect the performance and expiration dates listed on the form.

### Calibration Variance

In the rare case when Critical MTE must be used and cannot be calibrated prior to the expiration of its most recent calibration, the Calibration Custodian uses SRF-03-FM-001 Calibration Variance Form to provide rationale and request permission to continue using the Critical MTE past the calibration expiration date. This should only be used to request a short extension of the calibration interval, not to exceed the duration of the most recent calibration interval. The completed and approved form is then uploaded to the QMS Records area for the Calibration Variance Forms, and linked to by, or identified in, the Calibration Register. The Date of Calibration and Calibration Due Date in the Calibration Register are advanced to reflect the performance and expiration dates listed on the form.

## Verifications

Verifications of equipment calibration are encouraged to minimize the impact of Critical MTE being found later to be out of calibration. Verifications performed for this purpose should be logged at the time of performance and identify the tester and results. The Work Center Lead may request that verifications be performed periodically (e.g. monthly, weekly, etc.) or at intervals related directly to each use of the Critical MTE. The requested frequency of verification of Critical MTE might reflect a manufacturer’s recommendations, environment of use, and the risk associated with a later, “out-of-calibration” result.

It is suggested that Verifications be performed on known conditions or reference standards, or a similar calibrated instrument, and be taken at multiple data points, representative of the range over which the device is used. Verifications may be in either paper or electronic format, and the location of the paper or electronic verification should be entered in the “Verification Log” column of the associated Critical MTE record in the Calibration Register.

## Discrepancy Reporting

Steps must be taken to ensure that unfit equipment is removed from service. The scenarios for how discrepancies are discovered are described below.

1. If Critical MTE is determined by a calibrator to be out of calibration in its “as found” state, but has been returned to a calibrated state, the Calibration Custodian will notify the Work Center Lead.
2. If Critical MTE is determined by a calibrator to be out of calibration in its “as found” state and remains uncalibrated, the Calibration Custodian will retain physical custody of the item, tag it as “Do Not Use,” and notify the Work Center Lead.
3. If Critical MTE is found damaged, or fails a verification step, the Work Center Technician must notify the Work Center Lead, who will then inform the Calibration Custodian.The Calibration Custodian will isolate or take physical custody of the item, tag it as “Do Not Use”, remove the Critical MTE sticker and update the item’s record in the Calibration Register to show that it is not Critical MTE.

*In all cases, the Work Center Lead must send an email to the Quality Engineer requesting that a CAPA be initiated in accordance with the Corrective Action Program.*

## Records

The following records are outputs of this procedure.

* + Calibration Certificate
	+ Calibration Variance Form
	+ Verification Record

# Process Flow

NO

NO

YES

Calibration

Calibrated Critical MTE not available for Critical-To-Quality measurements identified

Project Coordinators, WC Leads and WCD Authors identify Critical-To-Quality measurements

YES

WC Leads assign Calibration Custodian and designate items as Critical MTE in Calibration Register

Critical MTE in calibration and in good condition?

Critical MTE‘s “As Found” and final state is “In Tolerance?”

Remove from service.

Tag Do Not Use.

Update Calibration Register.

Send for calibration/repair.

Contact Quality Engineer

Calibrated Critical MTE available for Critical-To-Quality measurements

WC Leads identify

the M&TE

to be used for Critical-To-Quality measurements

Update Calibration Register

Protect and store Critical MTE properly

Remove from service.

Tag Do Not Use.

Update Calibration Register.

Critical MTE damaged or fails verification

# References

|  |  |
| --- | --- |
| **Document No.** | **Title** |
|  |  |
| SRF-03-FM-001 | Calibration Variance Form |
| SRF-03-FM-002 | Calibration Register Template |
| QA18kd | Calibration and Control Procedure for Measurement and Test Equipment (M&TE) |
| SRF-11-PR-001 | Project Execution Procedure |
| SRF-06-PR-001 | Records Management Procedure |

# Release and Revision History

|  |  |  |
| --- | --- | --- |
| **Rev #** | **Major Changes** | **Effective Date:** |
| 1 | Initial version | 30 Sep 2021 |
| 2 | 1. Clarified “measurement standards traceable to international or national measurement standards” in Sec. 5.6, and the Sec. 3 definition of Calibration.
2. Clarified that notification email must be sent to Quality Engineer upon discovery of unfit Critical MTE in Sec. 5.10.
3. Added requirement to physically label “Critical MTE” as such in Sec. 5.5.
4. Allowed for use of unique serial number in Sec. 5.1, 5.4.1 and 5.4.3 when Property “F-tag” is not available.
5. Clarified Sec. 5.1 and 5.2 for all WCDs to identify “Critical Measurements,” to require use of “Critical MTE,” and to prescribe recording of the property tag and Cal DUE date.
6. Added focus in Sec. 5.1 on Critical Measurements and collaboration between stakeholders.
7. Removed “Pansophy” from references to the “Calibration Register.”
 | 03 Mar 2023 |
| 3 | 1. Standardized use of “Property Tag Number” to describe the “F” number assigned by JLab Property Group. In Sec.3 and 5.5.3.
2. Added Project Coordinator role to Sec 5.4.
3. Specifically allow Calibration Custodians to uniquely serialize any item without a Property Tag in Sec. 5.5.3.
4. Added requirement that all Critical MTE be labeled with its Property Tag Number or assigned serial number in Sec. 5.6.
5. Clarified how Cal Variance and Non-Accredited calibration forms are use in lieu of vendor cal certs, Sec.5.7.
6. Limited the length of time that a Calibration Variance Form may be used to extend an existing calibration in Sec. 5.7.4.
7. Removed the requirement to perform or record Verifications, adding suggestions for use, Sec.5.8.
8. Added requirement for Calibration Custodians to remove Critical MTE sticker when taking item out of service in 5.9.3.
9. Updated Approval signature block 9.
10. Updated format to SRF-07-FM-002 Procedure Template, R2.
 | DD Feb 2025 |

# Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Approved by:** | **Name:** | **Signature:** | **Date:** |
| Document Owner | Larry King | In DocuShare |
| Quality Representative | Ashley Mitchell | In DocuShare |
| SRF Department Head  | Tony Reilly | In DocuShare |