



Procedure Number: SNS-QA-P06

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Revision: 0

Title: Calibration of Measuring and Test Equipment

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Purpose

To establish the program for calibration of measuring and test equipment for the Spallation Neutron Source (SNS). This procedure implements parts of two criteria in the SNS Quality Assurance Plan, SNS-QA-P01; 5, Work Processes; and 8, Inspection and Acceptance Testing. It provides the details of SNS compliance with ORNL SBMS Subject Area "Calibration," and with ISO 9001:2000 section 7.6 "Control of Measuring and Monitoring Devices."

Scope

This procedure applies to devices and systems, including those with software, that will be used for inspection, test, control, measurement, and data collecting at SNS, or which are incorporated into the SNS. These devices are sometimes referred to as Measuring and Test Equipment. This procedure is only for use at Oak Ridge, whereas the partner labs will continue to use their own calibration programs in compliance with their QA programs.

Implementation

This procedure will be implemented during calendar year 2002, beginning with appointment of coordinators who will do a survey of the applicable devices already received and their manufacturers' calibrations. It will be extended to include devices provided by the AE/CM at the time of beneficial occupancy of the buildings and structures. The AE/CM QA program is responsible for their calibration prior to that time.

Definition

Calibration is a set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards (reference 1).

Responsibilities

Each SNS Group Leader in ASD, XFD, or CFD with authority over applicable devices or systems

- assigns a calibration coordinator(s) who is technically capable of assessing the group's applicable devices, establishing calibration supplier work orders or procurements, and completing the entry of existing and new devices into the tracking database

Calibration Coordinator

- attends coordinator training provided by SNS Quality Assurance and obtains access from SNS Management Information Systems to enter calibration data into the Equipment Tracking Database
- determines the need for calibration of the devices for which the group is responsible, using these general criteria supplemented as needed for the nature of the devices and data. If any of these apply, calibration is needed:
 - data resulting from the use of the device or system is QA level I or II (reference 2),
 - data from the device or system is needed to show compliance with requirements
 - the device or system helps control a process that must meet requirements
 - the data is otherwise required in approved SNS instructions, procedures or plans

Note that when SNS becomes operational, the requirements may include those from the user's home institution if SNS users need data from devices under SNS control.

- ensures equipment tracking bar code numbers are applied to the applicable items using the SNS Equipment Tracking web page (http://snsapp1.sns.ornl.gov:7777/pls/prod/bc_pkg.bc_req_pg) (page requires UCAMS userid and password, established through the SNS IT group)
- adds the last calibration date, recalibration interval if other than calibrate-before-each-use, and calibration supplier (SNS, ORNL, or external) in the Equipment Tracking database for each device
- coordinates recalibration when needed, with users and calibration providers, including updates to the calibration tracking database and application of tags as shown in Appendix B or as determined by the special needs of the device and its use



- when establishing new calibration providers/suppliers or renewing existing ones, coordinates with division QAR to ensure that the contract, purchase order, work order or specification requires suppliers to:
 - do an initial check of calibration before making any adjustments
 - report any out-of-tolerance conditions
 - provide a certificate showing the final accuracy and accuracy tolerances
 - show traceability to national (NIST is preferred) or other appropriate standards
- reports any out-of-tolerance conditions to the primary user or custodian and to the division QAR (out-of-tolerance means reported measurements could have had greater error than certified)
- consults with radiation protection staff if possible internal contamination is suspected, before devices are given to calibration performers

Equipment custodian/primary user

- protects equipment from damage or deterioration, safeguards adjustments that would invalidate the and remains alert to indications that accuracy might have been affected since the calibration was last verified
- checks calibration status systematically to ensure that applicable devices are tagged and not past-due for recalibration
- evaluates impact of out-of-tolerance devices with QAR assistance, when reported by the re-calibrator, and takes action to mitigate the impact
- arranges with the coordinator for proper calibration-supplier arrangements and database entry for any newly-acquired equipment
- alerts the calibration coordinator of any known possibility of internal radioactive contamination or other hazards to the calibration supplier
- when performing calibrations-by-user:
 - maintains capability to meet requirements, such as training, calibration environment, and calibration setup;
 - uses coordinator-approved reference standards and methods (methods may be in procedures, instructions, or user's manuals);
 - records pertinent data and notifies the calibration coordinator and QAR if a device may have been used while out of tolerance

Calibration Performer

- maintains capability to calibrate the assigned devices or systems to requirements including training, calibration environment, procedures, certifications, and calibration setup
- records pre-adjustment and final accuracy data and notifies the calibration coordinator if a device was not working when received or was out of tolerance when received
- provides certification documents as provided by contract or procedure
- applies tags per appendix B or as arranged by the coordinator

SNS Equipment Database Manager

- establishes and maintains a computer database that allows coordinators to enter data, and any SNS/Oak Ridge personnel access to check the status of calibration on a particular device
- provides training aids and assists in training of users as needed
- ensures that applicable computer security and software quality procedures are followed in the construction and operation of the database

The quality assurance representative (QAR)

- oversees the calibration program as required by SNS-QA-P01
- evaluates calibration providers in accordance with SNS-QA-P01 and SNS-QA-P05
- assists the user and custodian to determine impact and mitigating actions when an out-of-tolerance condition is reported
- ensures that the original copies of calibration certificates (and the other items listed under Records below) are maintained in an accessible and indexed file, and makes copies available to those who need them
- processes deviations to this procedure for QA Manager approval when necessary, while maintaining compliance with SNS-QA-P01 Criterion 5, "Work Processes"

Process Flow

Follow the process shown in Appendix A



Records

- Calibration certificates
- Reports from the tracking database
- Out-of-tolerance reports and impact assessments
- QA evaluations and audits of calibration providers

References

- [NIST Handbook 150, National Voluntary Laboratory Accreditation Program](#)
- [SNS-QA-P01, SNS Quality Assurance Plan](#)
- ORNL SBMS Subject Area "Calibration"
- [SNS-QA-P05, Quality in Acquisitions](#)
- ISO 9001:2000 Quality management systems--Requirements

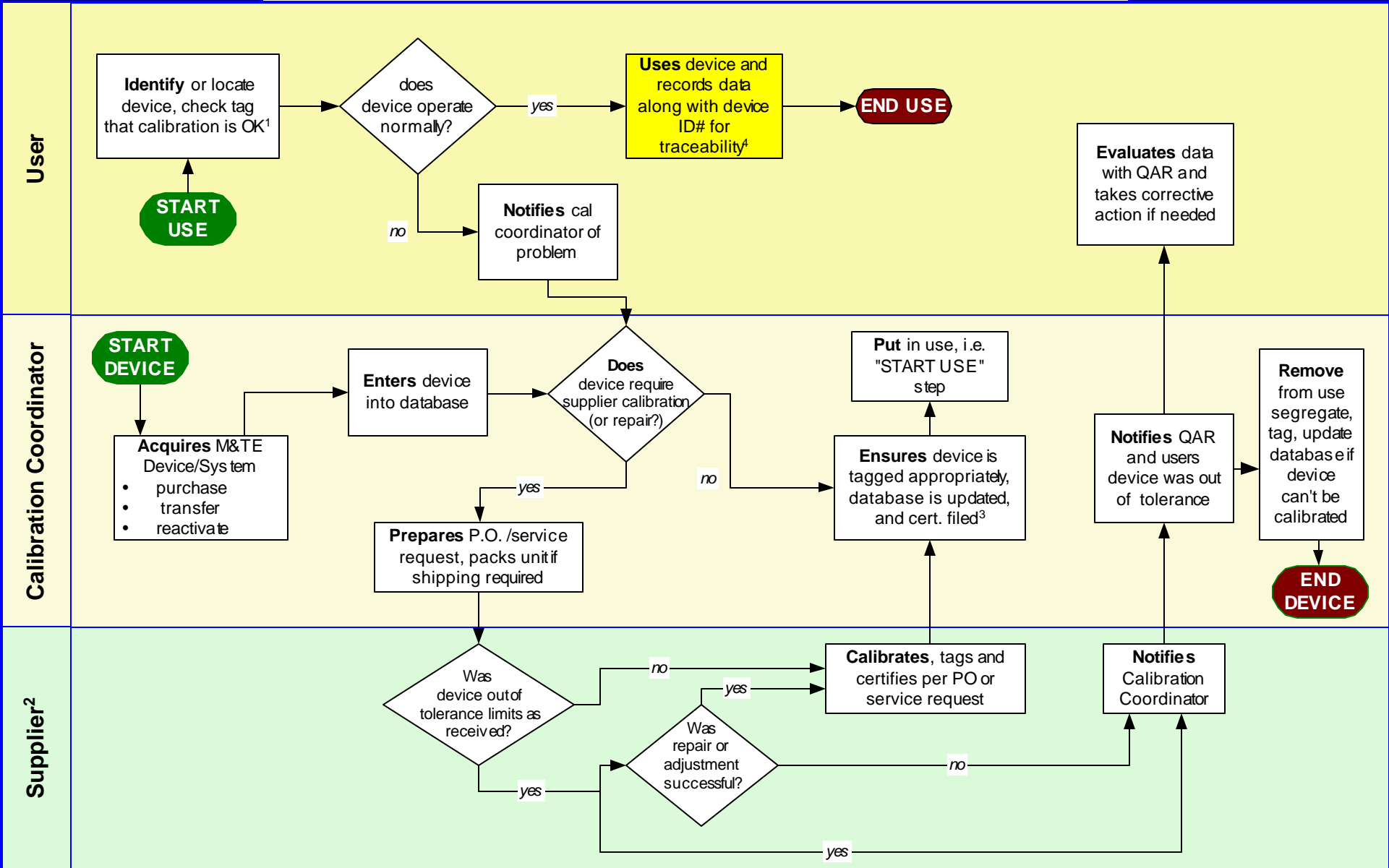
Appendixes

- A: SNS Calibration Coordination
- B: SNS Calibration Tags

Approved by: _____ *M.H. Skonicki* (signed original filed in SNS DCC)
SNS Quality Assurance Manager

SNS CALIBRATION COORDINATION

Oak Ridge process. Partner labs follow their own process.



¹Tags must show equipment number. Where a calibration date is given, it should not be past due. The tag may indicate the user does a calibration

²Supplier may be SNS metrology lab, an ORNL calibration service, a contracted supplier, etc.

³Certificates go to the QAR for filing. See appendix B for appropriate tags

⁴Protects against damage during period of custody, and against contamination if used in a contamination area



Example Tags

Calibrated SNS Device

Calibrated by _____
Last _____
Due _____

Limited Calibration-SNS

Function _____
Range _____
Calibrated by _____
Last _____
Due _____

Calibrate before Use

Instruction _____

Calibration Coordinator

Calibration Not Required

Using SNS-QA-P06 Criteria

Calibration Coordinator