



## 2.0 Implementation Actions

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Refer to the process flow charts included in this procedure.

### 2.1 Use of M&TE

**2.1.1 Prior to first-time use of M&TE**, the custodian/user shall ensure that the M&TE has:

- a unique identification - serial number or unique identifier,
- been entered into the calibration recall system with an established calibration interval (unless it is a calibrate-prior-to-use device, or one which will be destroyed/damaged in use and rendered incapable of being re-calibrated),
- been calibrated, or has been submitted for calibration
- been labeled per requirements in section 2.3.1

### 2.1.2 Prior to Each Use

Prior to each use of M&TE, the user shall:

- examine the calibration label for the item, and determine whether the calibration expiration date has passed, and
- determine whether the device appears to exhibit any condition that could affect its operability or accuracy, (e.g., damage, corrosion).

If either of these conditions is noted, the device must not be used. The user shall tag, segregate, or otherwise control the M&TE item to prevent its use until it has been calibrated. See section 2.1.5 for further instruction.

### 2.1.3 One-time-only-use M&TE

Users shall obtain a calibration of the item both before and after the one-time use (except for M&TE destroyed-in-use, or otherwise rendered not capable of being re-calibrated).

### 2.1.4 Recording the Use of M&TE

Users shall document each use (date, device ID) of M&TE in a use log for the device or a Scientific Notebook, in a manner which will allow for easy retrieval. This documentation will include any M&TE maintenance performed, M&TE anomalies, or analytical problems encountered during data collection activities. Additionally, the actions taken to resolve the problems will be documented accordingly. This will aid in the investigation and evaluation of the impact on data if M&TE is found out-of-tolerance. This documentation shall be performed in addition to recording the actual data in a Scientific Notebook or on data sheets.

### 2.1.5 M&TE Calibration/Accuracy Suspect

If any of the conditions listed below are noted, the user shall tag, segregate, or otherwise control the M&TE item to prevent its use until it has been calibrated, and document the condition in the use-log for the device or the Scientific Notebook.

- The item has exceeded its calibration due date.
- The accuracy of the item is suspect because of mishandling, misuse, or unusual results.
- The item has broken calibration seals.
- The item has been modified or repaired, had components replaced, or operating software updated.

### **2.1.6 Lost/Damaged/Destroyed M&TE**

If M&TE is lost, damaged beyond repair, or inadvertently destroyed, the validity of data obtained from use of that device since its last valid calibration shall be evaluated, and that evaluation documented using the CAR process (see section 2.6).

### **2.1.7 Temporary Extension of Calibration Interval**

If, during use of M&TE, it becomes necessary to temporarily extend the calibration due date for a limited period of time, such as for the completion of an experiment in progress, the user shall document the situation using the CAR process (see section 2.6).

### **2.1.8 Calibration Recall System**

Upon return of M&TE from calibration, the custodian/user shall ensure that the calibration recall system is updated, verify the calibration label contains the appropriate information (Section 2.3.1), and review the calibration report to determine if the item is within specified tolerance(s). If the item is not within tolerance(s), and had been used for data collection or measurement in WIPP activities, the user shall initiate a CAR (see section 2.6).

## **2.2 Control of M&TE**

### **2.2.1 Environment**

M&TE and calibration standards shall be used and stored in environments that support the accuracy requirements of the equipment. Users shall monitor and record any environmental factors which might affect measurements, such as temperature, humidity, lighting, vibration, dust, cleanliness, electromagnetic interference, or other unique factors. When appropriate for accuracy purposes, correcting compensations shall be applied to the measurement results.

### **2.2.2 Storage, Operation, Handling, Transportation, and Maintenance**

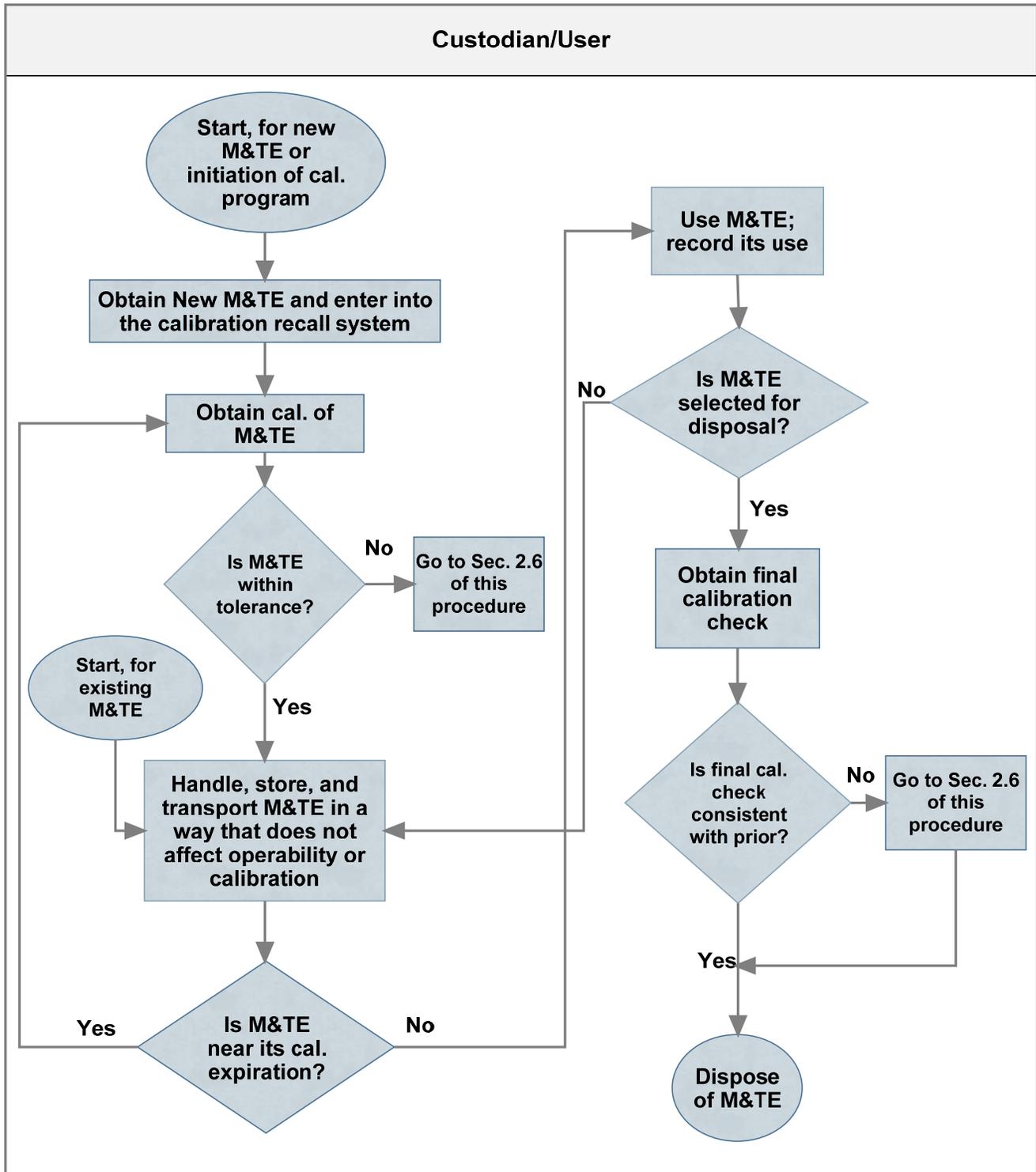
Custodians/Users shall ensure that storage, operation, handling, transportation, and maintenance activities are performed in a manner that does not adversely affect the operation or calibration of the M&TE. The following considerations apply:

- Storage and use areas shall provide acceptable conditions of temperature, humidity, and other pertinent factors to preclude deterioration.
- Handling of equipment during transportation or use shall follow manufacturer's recommendations.
- Tamper-resistant seals shall be affixed to operator accessible controls or adjustments which, if moved, would invalidate the calibration of M&TE. M&TE found with damaged or broken seals shall be removed from service and submitted for recalibration.

### **2.2.3 Maintenance of M&TE**

Any maintenance activity performed on M&TE (routine, corrective, or preventative), will include a determination of the effect of the maintenance activity on the calibration. This determination will be documented in the use-log for the device or Scientific Notebook. If the custodian/user determines that the maintenance activity affects the calibration, the M&TE must not be used and re-submitted for calibration or performance verification.

Figure 1. M&TE Control: Use of M&TE



## 2.3 Obtaining Calibration Services

Custodians/Users shall submit M&TE items to an approved provider of calibration services in the following situations:

- Upon procuring new M&TE, if the item is not received with a current, valid calibration.
- Prior to expiration of the M&TE calibration interval, or
- When the accuracy of M&TE is suspect.

### 2.3.1 Calibration Service Provider Responsibilities

Whether the calibration is performed by a commercial source, the SNL-PSL or SNL-CPG, the Calibration Service Provider will be instructed to perform calibrations in accordance with the following requirements:

#### Calibration or Reference Standards

Calibration or reference standards used by Calibration Service Providers shall be traceable to nationally recognized standards. If nationally recognized standards do not exist, the bases for use of these standards shall be documented.

#### Calibration Procedures

Calibration Service Providers shall have written approved procedures specifying the method of calibration for each M&TE item. If the use of a non-standard method is required then a technical and QA review must be performed to validate the calibration method to ensure the requirements of the test have been achieved, and the acceptance of this approach will be documented in a scientific notebook and a DRC in accordance with NP 6-1, *Document Review Process*.

#### Environmental Conditions

Calibration Service Providers shall control environmental factors such as temperature, humidity, vibration, or electromagnetic interference, to ensure the validity of the calibration; or they must isolate M&TE items from these sources of contamination.

#### Labeling of M&TE

Upon completion of calibration of an M&TE item, Calibration Services Providers will affix a "calibration label" to the item which indicates that the item is operational and within tolerance(s). The calibration label shall contain the following information:

- date calibrated,
- calibration due date, and
- identification of any limitations on the device.

**Note:** When it is impractical to apply a label directly to the M&TE item, the label may be affixed to the instrument container; or some other suitable means may be used to indicate the calibration status.

#### Calibration Report

Calibration Service Providers shall provide the following for each item calibrated. External service providers shall provide this information in the form of a calibration report. Internal service providers shall record this information in a use-log, Scientific Notebook or other suitable record (i.e. a calibration form per applicable SP).

- the unique identification of the M&TE item,
- identification of the calibration standard(s) used for the calibration,

- identification of the calibration procedure, including revision, used in performing the calibration,
- identification of the individual(s) performing the calibration,
- calibration data (as-found data and post-adjustment data, if applicable),
- any calibration action taken (e.g., adjusted, repaired),
- calibration date and next calibration due date (or calibration interval) except for prior to use M&TE,
- statement of acceptability of the device for use,
- If the device was found to be out-of-tolerance (regardless of whether it was adjusted into tolerance), a clear statement of that fact.

### **Inoperative or Out-of-Tolerance M&TE**

When M&TE is found inoperative or out-of-tolerance and cannot be adjusted into tolerance, the Calibration Services Provider will return the device to the user, with a calibration report that clearly reports the inoperative or out-of-tolerance condition. The M&TE Custodian/User shall tag the device to clearly indicate its out-of-tolerance, out-of-service condition.

The M&TE custodian/user shall initiate a Corrective Action Request as the means to document, evaluate, and resolve all out-of-tolerance conditions (see Section 2.6).

### **Calibration Intervals**

External Calibration Service Providers shall assign a calibration interval (a time interval since last calibration) for each M&TE item, based on the type of equipment, its stability characteristics, required accuracy, intended use, and other considerations which will provide a high probability that the items will remain in-tolerance throughout the interval.

Internal Calibration Service Providers will assign calibration intervals (a time interval since last calibration) for each M&TE item, based on the manufacturer's recommendations. This interval may be adjusted based upon the calibration history of the equipment.

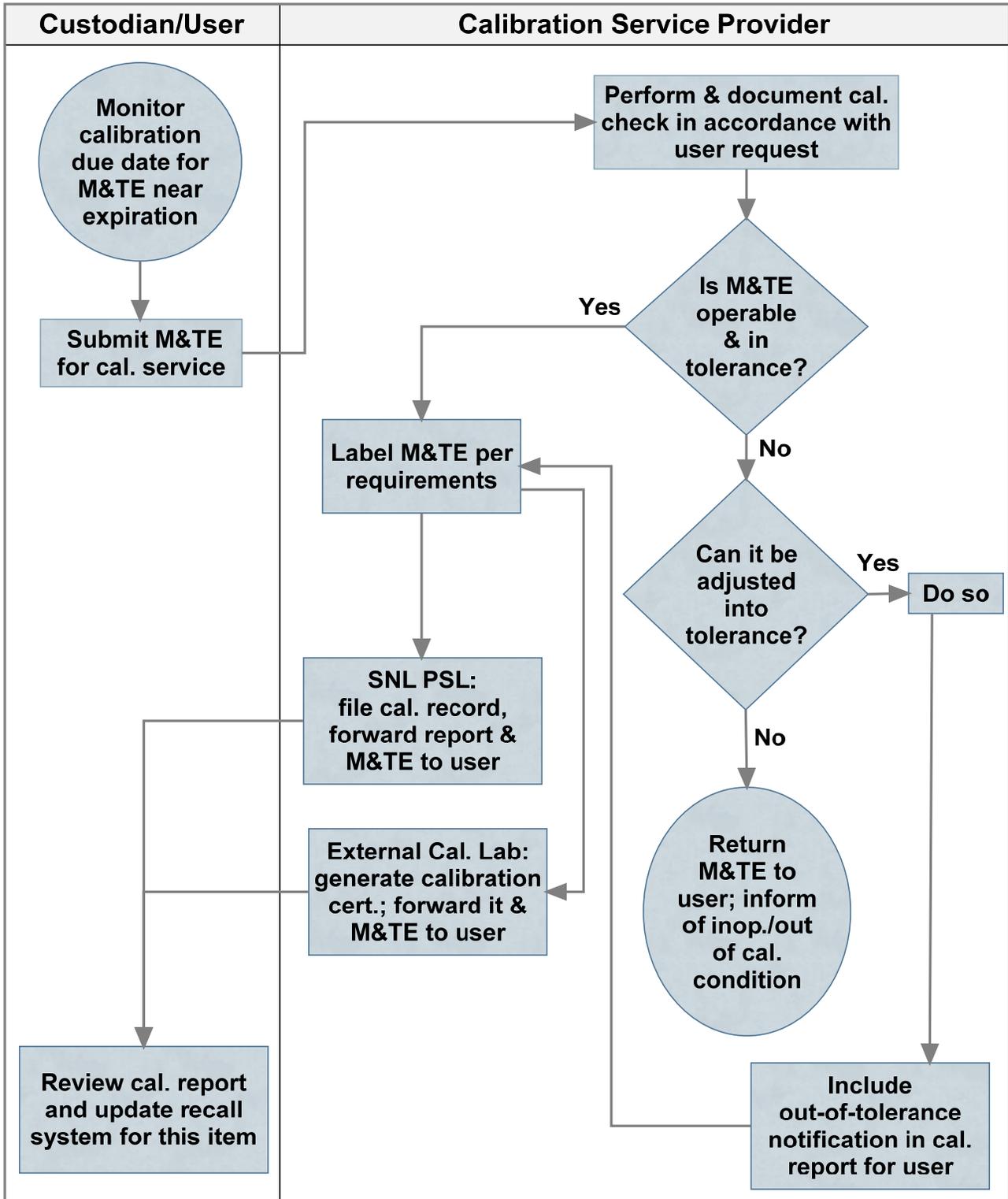
A calibration interval is not needed for M&TE intended for one-time-use (see section 2.1.3).

## **2.4 Check Standard**

If the M&TE cannot be calibrated it must be verified that the instrument is properly functioning by the use of a check standard. For these items, the user shall check the required accuracy of the item prior to the first time it is used, and then according to the interval established by the M&TE custodian/user. The normal interval for such devices is on the day of use, prior to use. These check standards must be documented in a Scientific Notebook to include the check standard ID, results, the applicable procedure and revision, and an acceptability statement.

Check Standards shall be traceable to nationally or internationally recognized standards or natural physical constants. If such standards or physical constants do not exist, the basis for acceptance of this condition must be documented. Prepared Check Standards shall include documentation of the standard preparation, and must be traceable to the materials used to create the Check Standard. Refer to NP 13-1, Control of Samples and Standards, section 2.4 for a more detailed discussion of the use of Calibration Standards, and the controls of those Standards.

Figure 2. Obtaining Calibration Service



## 2.5 Establishing Calibration Service

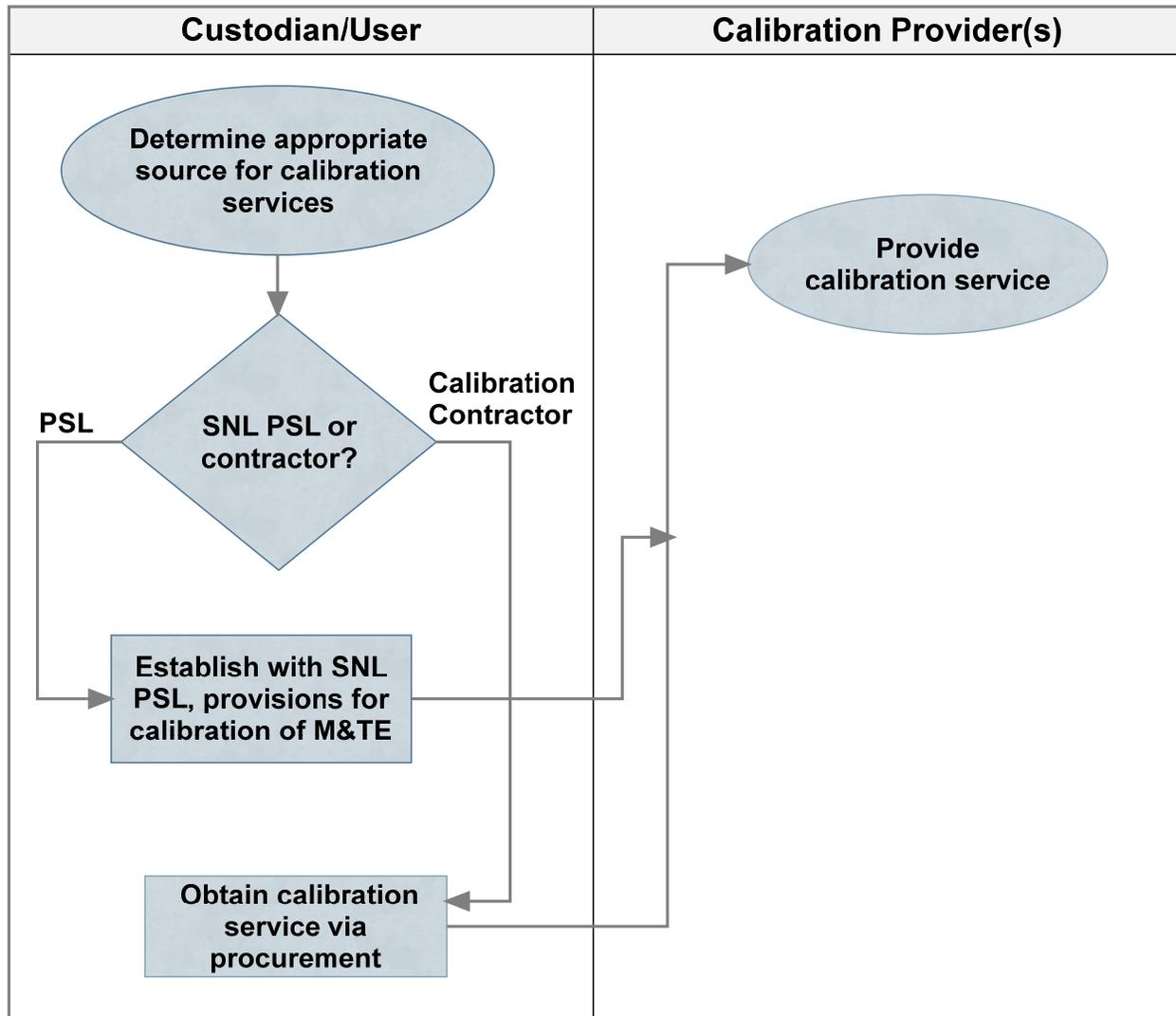
When an external calibration service is used, users shall ensure that proper calibration services for the item have been established, or they shall take steps necessary to obtain proper calibration services, unless it is a one-time use item. Calibration services may be obtained through procurement of contractor services in accordance with NP 4-1, *Procurement*.

M&TE users shall ensure that procurement documents related to establishing external calibration services contain the following requirements:

- Calibration services shall conform to the requirements of DOE-CBFO-94-1012, "U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document," which specifies that calibrations shall be made against certified equipment having known relationships to nationally recognized standards and which outlines the process by which calibration records are to be generated and maintained. If no nationally recognized standards exist, the basis for calibration shall be documented.
- Calibration Service Providers shall assign a calibration interval (a time interval since last calibration) for each M&TE item, based on the type of equipment, its stability characteristics, required accuracy, intended use, and other considerations which will provide a high probability that the items will remain in-tolerance throughout the interval. The system for setting those intervals must be systematically applied to the M&TE items, shall have stated reliability goals, and shall include a method of verifying that those reliability goals are attained (reliability, in this requirement, is defined as the probability of the device remaining in-tolerance throughout its calibration interval).
- Calibration or reference standards used by Calibration Service Providers shall be traceable to nationally recognized standards. If nationally recognized standards do not exist, the bases for use of these standards shall be documented.
- Calibration Service Providers shall have written approved procedures specifying the method of calibration for each M&TE item.
- Calibration Service Providers shall control environmental factors such as temperature, humidity, vibration, or electromagnetic interference, to ensure the validity of the calibration; or they must isolate M&TE items from these sources of contamination.
- A calibration label shall be affixed to M&TE items indicating the status of the item. For items that are in-tolerance, the label must include the date calibrated, the next calibration due date, and any limitations on the device.
- Calibration Service Providers including Sandia internal calibration service providers shall provide a report for each item calibrated. This report shall include the following information:
  - the unique identification of the M&TE item,
  - identification of the calibration standard(s) used for the calibration,
  - identification of the calibration procedure, including revision, used in performing the calibration,
  - identification of the individual(s) performing the calibration,
  - calibration data (as-found data and post-adjustment data, if applicable),
  - any calibration action taken (e.g., adjusted, repaired),
  - calibration date and next calibration due date (or calibration interval),
  - statement of acceptability of the device for use,
  - If the device was found to be out-of-tolerance (regardless of whether it was adjusted into tolerance), a clear statement of that fact, for the user's information.

**Note:** See records section of this procedure for records that may be maintained at the service provider's location.

**Figure 3. Establishing Calibration Service**



**2.6 M&TE Nonconformances**

**2.6.1 Identifying and Processing Nonconformances**

The following conditions shall be identified, by the user of the M&TE, and resolved by initiating and processing a Corrective Action Request (CAR) in accordance with NP 16-1:

- M&TE found to be out-of-tolerance during a calibration check or as-found check, regardless of whether the device was or could be adjusted into tolerance (unless otherwise specifically described in the M&TE specific SP what corrective actions will be taken).
- M&TE that produces results known to be in error.
- M&TE that requires a temporary extended calibration interval.

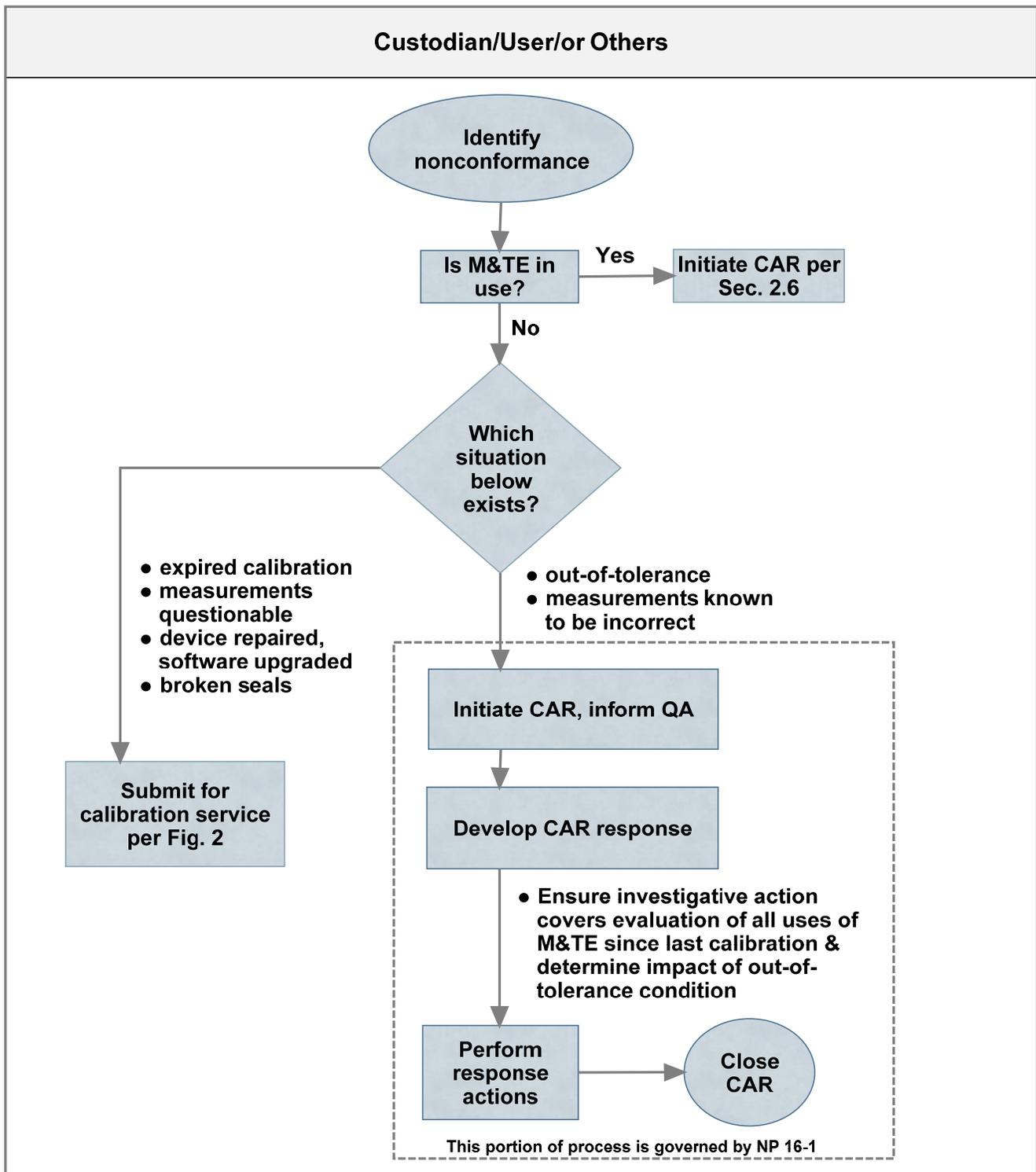
The custodian/user shall ensure that the cognizant QA staff is notified in such cases, in a documented manner.

The actions specified and taken in response to such a CAR shall include:

- immediate remedial action to tag, segregate, or otherwise control the device to prevent the further use of M&TE that could not be adjusted into tolerance during calibration,
- investigative action to identify all of the uses of the subject M&TE item since its last calibration, including notification to any other users of the equipment, and to evaluate the impact of the out-of-tolerance condition with regard to the validity of previous inspection, test, or data-collection efforts, including the acceptability of items, data collected, processes monitored, or conclusions reached.

**Note:** If any M&TE is consistently found to be out-of-tolerance during calibration, the user shall have it replaced or repaired, unless a reduced calibration interval is expected to correct the situation.

**Figure 4. Nonconformance Situations**



### 3.0 Records

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The following QA records generated as a result of implementing this NP, shall be prepared and submitted to the WIPP Records Center in accordance with NP 17-1 (Records):

#### QA Record

- Use-log for the device, the Scientific Notebook, calibration forms
- Calibration Reports
- Corrective Action Requests, if any, and associated documentation

**Note:** Documents that may be maintained at the calibration provider's facility include:

- Calibration facility quality manuals
- Calibration procedures
- Calibration personnel qualification and training documents
- Recall system documentation
- Documentation of calibration standards traceability

### 4.0 Appendices

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Not applicable – there are no appendices to this procedure

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