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REVISION LOG		
Revision Number	Description of Changes	Pages Affected
0	Intent Change. Changed numbers and headings to define the beginning point of Paducah Remediation Services documentation and to establish Document Control as the control point for tracking document numbers. This document replaces BJC-PQ-1020, <i>Control and Calibration of Measuring and Test Equipment</i> .	All
AC-1	Add examples of M&TE Calibration Tag and Defective Equipment Tag. (I/CATS 60414)	8, 20, 21

CAUTION

This document implements DSA, TSR, SMP, or other Safety Basis Requirements. Specific requirements **and/or** other commitments are noted in the document by **<Source Document Number and Section>**. Sections so marked shall not be modified or removed without the approval of PRS Nuclear/Facility Safety.

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1.0 PURPOSE

This procedure defines the quality assurance requirements and associated processes for identification and control of devices or equipment that requires calibration services, in support of 10 CFR 830 Subpart A, *Quality Assurance Requirements*. Part I of this procedure addresses the general strategy for implementation of Paducah Remediation Services, LLC (PRS) Calibration Quality Assurance (QA). Part II of this procedure establishes the responsibilities and describes the general requirements of the various processes necessary to effectively control and calibrate Measuring and Test Equipment (M&TE). Attachment B provides a flow chart which depicts the major elements of the PRS M&TE Calibration Program.

2.0 SCOPE

The PRS Calibration QA requirements apply to:

- PRS self-performed work involving personnel with either direct or oversight responsibility for calibration, control, and use of equipment or devices which perform essential measurements.
- Calibration services used by a supplier of a product procured by PRS, where specified by the subcontract with PRS.
- PRS self-performed work involving field-installed M&TE and permanently installed equipment, including calibrated equipment/instrumentation to calibrate those items.

This procedure may be used by PRS personnel as guidance for basic M&TE program elements when reviewing subcontractor QA Programs.

Exception: This program does not apply to radiological control M&TE. Calibration requirements for radiological control instruments are addressed by the PRS Radiological Control Program and associated PRS procedures.

Equipment, devices, and systems used for essential measurement shall be calibrated whenever their use is related, but not limited to, the following:

- Operational safety requirements,
- Health, safety, or environmental management evaluations,
- Security, safety, and environmental permits,
- Accountability of materials,
- Conformance to customer requirements,
- Monitoring of processes,
- Inspections and tests,
- Research and development.

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M&TE typically includes instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment, and are identified in written procedures. The Calibration QA Program shall be applied to stand-alone instruments and devices, instruments and devices installed within processes or equipment, and permanently installed instrumentation and or components that perform essential measurements. At a minimum this consists of: plant process instrumentation and control devices, environmental monitoring instrumentation, chemical measuring devices and standards, selected experimental use instrumentation, and M&TE used to calibrate, measure, gauge, or test other instruments or devices. Instruments and equipment will be officially designated as M&TE, or M&TE Systems as determined by the owner/user, based on the end use of the data gathered by the instrument.

The inherent requirements and configuration of field-installed M&TE and permanently installed instruments and devices may require unique calibration program controls that shall be documented for the application. However, the basic QA elements of calibration program requirements shall be maintained.

Some equipment used for research or operations that fall outside of the applications above, or permanently installed instrumentation and components identified by the responsible user as non-essential to the applications above, are not in the scope of this program.

3.0 OTHER DOCUMENTS NEEDED

- PRS-DOC-1009, *Documents and Records*
- PRS-QAP-1208, *Supplier Quality Program Evaluation*

4.0 TRAINING

Training for this procedure is required reading for PRS managers, line supervisors, and Quality Specialists involved in PRS self-performed calibration and other M&TE activities which are within the scope of this procedure. No other training is required.

<PRS-NFS-1394, Revision 1, Section 10.5>

5.0 PROCEDURE PART I - PROGRAM DESCRIPTION

5.1 Strategy for an Effective Calibration Program

- | | | |
|------------------------|-------|--|
| Quality Assurance (QA) | 5.1.1 | Serve as the lead organization for definition and interpretation of requirements for the PRS MT&E Calibration Program. |
| | 5.1.2 | Provide PRS Calibration Quality Program guidance for implementation of applicable consensus standards related to M&TE. |
| Project M&TE Users | 5.1.3 | Implement the following Calibration Quality Program objectives: |

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- Consolidating requirements in programmatic and operating procedures as required;
- Maintaining the accuracy of M&TE calibration standards to ensure that equipment being calibrated will be within required tolerances
- Standardizing, where practical, equipment procurement and use;
- Ensuring that training is adequate for program compliance;
- Providing management oversight to ensure continuous compliance with requirements; and

5.1.4 Serve as liaison between PRS and external organizations (e.g., suppliers where addressed by subcontract language) which provide or receive calibration services.

5.2 Organization Interfaces and Roles and Responsibilities

QA

5.2.1 Provide guidance to establish and maintain an effective Calibration Quality Program.

5.2.2 Schedule and conduct independent assessments of calibration program implementation in accordance with QA procedures.

5.2.3 Provide interpretative guidance of applicable command media and requirement documents.

5.2.4 Review Project QA Plans for compliance with Calibration Quality Program requirements and 10 CFR 830, Subpart A, *Quality Assurance Requirements*.

5.2.5 Provide periodic oversight of the Calibration Quality Program implementation in accordance with the PRS Assessment Program.

Project M&TE Users

5.2.6 Ensure the following calibration program activities are accomplished in accordance with Quality requirements:

- a. Inform QA and applicable PRS management of M&TE-related problems as well as changes and improvements.
- b. Conduct management assessments of Calibration Quality Program implementation.
- c. Develop and conduct appropriate training and awareness activities when required.
- d. Resolve calibration related findings or deficiencies through the formal corrective action process.
- e. Provide feedback to applicable PRS management concerning implementation of calibration policies, standards, and procedures.
- f. Plan and perform calibration-related activities in accordance with Integrated Safety Management, work control requirements, approved command media, and the approved Quality Program.

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6.0 PROCEDURES PART II - CONTROL AND CALIBRATION OF MEASURING AND TEST EQUIPMENT

6.1 General Requirements

Project M&TE Users

6.1.1 Determine mission essential measurements associated with the Project scope and select M&TE of the proper type with the range, accuracy, and precision to perform the intended task (see *Attachment B*).

6.1.2 Identify and document M&TE equipment and devices to be placed into service in the M&TE Program, including persons responsible for M&TE.

NOTE: Approved equipment/instrumentation under “user organization” control that is used to calibrate field-installed M&TE or permanently installed equipment is subject to the same requirements for control, use, and traceability as any other piece of M&TE.

Project/M&TE Users and Engineering/Technical Authority

6.1.3 Select, maintain, and control measurement standards that provide accuracy, precision, and traceability for the calibration of M&TE to national standards. If no standards exist, the responsible technical authority will identify acceptable alternative standards and any special training requirements that are needed.

Project M&TE Users

6.1.4 Prepare and implement appropriate Command Media addressing the proper handling, use, and storage of M&TE, and describe records that will be generated.

NOTE: For “field-installed M&TE,” the command media should specify requirements when external calibration services must be procured.

6.1.5 Document and implement appropriate training (and/or qualification) requirements for M&TE users and maintain records of training activities.

6.1.6 Ensure M&TE is only used by trained and qualified personnel in accordance with approved command media.

6.2 Quality Assurance Requirements

Project/M&TE Users and QA

6.2.1 Arrange for periodic audits at intervals that will verify that operations comply with applicable technical and quality requirements.

6.2.2 Perform management assessment/surveillance of calibration activities and processes in accordance with Quality Program procedures, organizational command media, and Project QA Plans, as appropriate.

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6.2.3 Document audit and assessment observations, findings, corrective actions, and evidence of completion in accordance with Quality Program requirements.

6.2.4 Prepare and process noncompliance reports in accordance with BJC-PQ-1440 [PRS-QAP-1440], *Control of Non-conforming Items and Services* to document conditions/incidents that are determined not compliant with technical and/or Quality requirements.

6.2.5 Ensure calibration data is properly recorded and maintained

6.3 Calibration Parameters and Controls

Project M&TE
Users

6.3.1 Determine M&TE calibration intervals based on manufacturer's recommendations.

6.3.2 Schedule M&TE calibration intervals to ensure M&TE accuracy is maintained, to ensure the availability of M&TE due the timeframe necessary for the calibration process, and to ensure the availability of M&TE services.

NOTE: Project M&TE User Organizations/Projects have ultimate responsibility for establishing calibration intervals of their M&TE and for scheduling M&TE calibrations, when required. The user organizations should have knowledge of the conditions or environments that M&TE will be exposed to and consult the calibration service provider to formally convey the aforementioned information to ensure that M&TE accuracy and availability will be maintained.

6.3.3 Establish controlled issue points for use of calibration standards, if applicable, (see definition in *Attachment A*) and minimize the period of issue to that necessary to perform the work.

6.3.4 Use approved and controlled calibration command media to calibrate M&TE, control the performance of calibration, provide repeatable calibrations, and define the acceptance criteria.

Project M&TE
Users

6.3.5 Maintain calibration certificates, when applicable, that include unique identification traceable to the instrument, date of calibration, calibration due date, any calibration information needed to determine calibration results, verification of conformance with calibration criteria, and traceable to a national standard or equivalent.

6.3.6 Record M&TE identification on inspection or test documentation.

6.3.7 Retain records of user-verified calibration data.

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NOTE: Calibration Stickers/Labels must include: unique identification number, date of calibration, calibration due date, and any limitations. An example of a calibration sticker/label is provided in Attachment C.

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6.3.8 Apply calibration status and identification labels to M&TE.

6.3.9 Re-evaluate critical measurement processes, on a continuing basis, using statistical process control and/or other methods to determine associated measurement uncertainties.

NOTE: Environmental conditions to be considered include, but are not limited to temperature, humidity, dust, vibration, line voltage, and sound.

6.3.10 Document and maintain appropriate environmental controls based on manufacturer instructions or applicable consensus standards where necessary for measurement and/or calibration activities, and describe actions to be taken when control limits are exceeded.

6.3.11 Adequately label, tag and control M&TE based on calibration status and acceptability and in a manner that allows traceability to calibration and test data. M&TE found to be out of calibration are appropriately tagged and segregated.

NOTE: An example of a DEFECTIVE EQUIPMENT TAG for use in identifying and segregating defective or out-of-calibration M&TE is provided in attachment D.

AC-1

6.3.12 Cease using and segregate M&TE when calibration due date has expired, when calibration seals (where used) are broken, or when the condition of the M&TE or validity/accuracy of its measurements are in question.

6.3.13 Submit M&TE for re-calibration where it may have been invalidated due to a change in location or exposure to unacceptable environments. (Refer to the associated M&TE operating manual and/or consult the appropriate calibration laboratory for guidance.)

6.3.14 Evaluate devices calibrated with out-of-tolerance M&TE in a timely manner for operability.

6.3.15 Document a history of use for calibration equipment determined to not be operating according to specifications or within acceptable tolerances, and promptly notify users of calibration services in writing.

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Project M&TE
Users

NOTE: M&TE and calibration equipment for which the history of use is not maintained through formal work planning documents shall require that other historical records of use be maintained.

6.3.16 Evaluate and document whether M&TE with out-of-tolerance conditions may have resulted in a negative impact on processes, health, safety, environment, or data.

6.3.17 Evaluate M&TE related events and incidents for reporting as a noncompliance in accordance with BJC-PQ-1440 [PRS-QAP-1440], *Control of Nonconforming Items and Services*, or an occurrence in accordance with BJC-PQ-1220 [PRS-QAP-1220], *Occurrence Notification and Reporting*.

6.4 As-found and As-left Calibration Data

Project M&TE
Users

6.4.1 Before calibrating M&TE, record the as-found data, and after calibrating M&TE, record the as-left data.

NOTE: For M&TE that is calibrated before each use, the as-found data does not have to be recorded if a post calibration check is performed. The post calibration check will serve as the as-found data and shall be recorded if the M&TE has an out-of-tolerance condition. M&TE that has been out of service or in surplus storage for an extended period (e.g., one year, depending on item) should always be re-calibrated before use

6.4.2 Ensure that acceptance of abnormal or indeterminate as-found/as-left data is reported, formally evaluated, and documented.

6.4.3 Document a history-of-use for M&TE discovered in operation with expired calibration dates and/or where its measurements are determined to be outside the range of acceptable tolerances.

6.4.4 Ensure calibration data is properly documented and maintained as records.

6.5 Tracking of M&TE

NOTE: Calibration of M&TE will be tracked at the Project level as required using the graded approach to ensure compliance with the requirements of this procedure as applicable to the project scope of work.

Project M&TE
Users

6.5.1 Maintain the following information for each item of MT&E utilized by the project:

- Master list of all instruments and devices designated at M&TE, which includes the description, unique identification number, calibration frequency, equipment range and accuracy, identified calibration procedure or approved

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- command media, responsible organization and contact.
- The status and current location of M&TE.
- M&TE calibration data and a calibration history file of calibration data to trend equipment performance
- The history file of maintenance repairs and modifications
<PRS-NFS-1394, Revision 1, Section 10.5>

6.5.2 Update the project list of M&TE in a timely manner to ensure traceability and accountability of all M&TE.

6.5.3 Monitor calibration due dates so that M&TE devices are removed from service prior to, or at the expiration of their calibration interval.

6.5.4 Implement management action necessary to remove M&TE from service when calibration dates have expired.

6.6 Need For Tamper-Evident Seal

Project M&TE
Users

6.6.1 Determine whether calibrated equipment/devices/systems should require tamper-evident seals as evidence of the integrity of the calibration status.

NOTE: Tamper-evident seals are affixed to operator accessible controls or adjustments on measurement standards or M&TE, which if moved will invalidate the calibration. Evidence that a seal was broken or moved will invalidate the calibration.

6.6.2 Where a tamper-evident seal is to be affixed to M&TE, document its use in the individual project M&TE operating/implementing procedures and in other appropriate documents.

6.6.3 **IF** tamper evident seals are required, **THEN** affix tamper evident seals to controls or adjustments on M&TE following calibration.

6.7 Handling, Transportation, and Storage

Project M&TE
Users

6.7.1 Handle, store, and transport M&TE in accordance with manufacturer's requirements where available, and in a manner that will not adversely affect the integrity, condition, or calibration of the equipment.

6.7.2 Physically segregate calibrated M&TE from defective, out of calibration or other M&TE requiring investigation.

6.7.3 Protect M&TE devices that are relatively easy to damage during handling and transporting, with special packaging or special mountings, as necessary.

6.7.4 Ensure M&TE is re-calibrated before use where its calibration status may have been impacted through improper handling, transportation, or a change in environment. (Refer to M&TE

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operating manual and/or consult with appropriate calibration laboratory as needed.)

- 6.7.5** Minimize contamination of M&TE and keep records of equipment to be used only in contaminated environments.

6.8 Special Requirements for Calibration of Field-Installed M&TE and Permanently Installed Equipment

Project M&TE Users

- 6.8.1** Identify and document facility equipment, devices, processes, etc. located in the field requiring calibration.
- 6.8.2** Maintain a controlled list of “field-installed M&TE and permanently installed equipment” requiring calibration, and track the items to ensure that specified calibrations are performed or checked at required frequencies.
- 6.8.3** At a minimum, the following information should be recorded: equipment/device identification, date of calibration, calibration due date, any calibration information needed to determine calibration results, verification of conformance with calibration criteria, and identification of applicable specifications or engineering drawings, or other source of calibration requirements.
- a. Identify “user controlled” equipment/instrumentation (i.e., calibration standards) and any other items that will be used to perform calibrations on “field-installed M&TE.”
 - b. Develop and implement command media to perform calibrations in the field (or to procure the necessary services if required), in accordance with approved command media and Quality Program requirements.

NOTE: Field calibrations can be performed by user organizations in accordance with this procedure on installed M&TE and permanently installed equipment used for essential measurements.

- 6.8.4** Include M&TE and calibration standards used for field calibrations in the Project M&TE List to ensure those items receive checks or re-calibration on the required frequency.

NOTE: The M&TE or M&TE standards used to calibrate field instruments and systems shall themselves be calibrated by an approved calibration laboratory, and shall be traceable to a national standard.

- 6.8.5** Include identification of approved command media and calibration standards, which are developed and approved for performing field calibrations, in work documentation.

- 6.8.6** Ensure calibration safety limits will bound the variations that may

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be caused by environmental conditions (e.g., radiological environments).

- 6.8.7** Label these devices unless a controlled equipment list and/or other system positively identifies and tracks the equipment/devices.

6.9 Procuring Outside Support for Equipment and Services

Project M&TE
Users

- 6.9.1** Where necessary, purchase calibration equipment and/or services (including calibration laboratory services) from approved suppliers/vendors in accordance with the Quality Program, and ensure their M&TE or service is compliant with applicable requirements.
- 6.9.2** Ensure potential suppliers/vendors are evaluated and approved in accordance with BJC-PQ-1208 [PRS-QAP-1208], *Supplier Quality Program Evaluation*, and the approved Quality Plan (PRS-CDL-0058), before initiating procurement of M&TE and services (i.e., ensure traceability to a nationally recognized standard or equivalent).

NOTE: Evaluation of Calibration Laboratories must address the qualifications, certifications, and capabilities of the lab to provide the requested services.

- 6.9.3** Ensure performance of receipt inspection for M&TE for compliance with procurement specifications and quality requirements.
- 6.9.4** Identify, document, segregate, disposition, and track noncompliances in accordance with BJC-PQ-1440 [PRS-QAP-1440], *Control of Nonconforming Items and Services*,
- 6.9.5** Ensure acceptable M&TE is included in the Calibration Program, labeled with unique identification, date of calibration, calibration due date, any limitations, entered in the appropriate Project tracking system, and properly stored and maintained.

7.0 RECORDS

The following records shall be identified and maintained in accordance with PRS-DOC-1009, *Documents and Records*.

- Calibration data and history records for each calibration of M&TE
- All standards and reference material used in calibration of M&TE
- Procurement documentation for M&TE or vendors/suppliers of related services
- Evidence of vendor/supplier evaluations and an "approved suppliers/vendors" list
- Out-of-tolerance, history-of-use, and nonconformance reports
- Personnel qualification and training and associated records

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- M&TE identification and labeling evidence
- M&TE tracking and recall data, including lists of field installed M&TE and permanently installed equipment which required calibration
- Approved Quality Plans and command media addressing M&TE
- Other records of calibration process, use, assessment, and corrective action addressed by approved Quality Plans, command media, and this procedure.

8.0 SOURCE DOCUMENTS

NOTE: The BJC blue-sheeted PRS procedures referenced in this document are the active procedures as the date of issuance of this procedure. Procedures noted in the parentheses [brackets] will become the reference procedures once these procedures are approved and implemented by Paducah Remediation Services, LLC.

- 10 CFR 830 Subpart A, *Quality Assurance Requirements*
- DOE O 414.1C, *Quality Assurance*
- PRS-CDL-0058, *Quality Assurance Program Plan for the Paducah Environmental Remediation Project Paducah, Kentucky.*
- American National Standard for Calibration, ANSI/NCSL Z540-1, *General Requirements for Calibration Laboratories and Measuring and Test Equipment*
- PRS-QAP-1080, *Inspection and Test Control*
- PRS-QAP-1208, *Supplier Quality Program Evaluation and Receipt Inspection and Testing Requirements*

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Attachment A
DEFINITIONS/ACRONYMS
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DEFINITIONS

Accuracy - Conformity or degree of conformity to a specified value; expressed as an allowable error, range of permissible values or upper/lower limit of uncertainty.

Calibrate/Calibration - Comparison of two instruments or measuring devices, one of which is a standard of known accuracy traceable to national standards, to detect, correlate, report or eliminate by adjustment any discrepancy inaccuracy of the instrument or measuring device being compared with the standard. Field checks, e.g., zero the instrument, do not constitute calibration.

Calibration Data - Recorded measurement data, required by or in support of a customer; used for quality and safety control, development, analysis, measurement system support or to validate product conformance to requirements in the development, evaluation build and final acceptance stages of manufacturing. The “as-found” data is the as found condition of M&TE relative to the calibration specifications. The “as-left” data is the post-calibration condition of the M&TE relative to specification requirements.

Calibration Laboratory - An organization that performs calibrations for PRS at an off-site calibration facility.

Calibration Not Required - A status used to identify instruments that lack significant verifiable specifications. Also used for Defined Physical Constant Standards that require no periodic maintenance or comparison against external standards.

Calibration Report/Calibration Data Report - A report that presents results of tests and measurement uncertainties determined at the time of calibration.

Calibration Standard/Standard – M&TE used to perform a calibration or user verification (see definition for Reference and Working Standard).

Calibration Status - Categorization and labeling of M&TE to document performance capabilities and use limitations.

Certify/Certification - The procedure and action by a duly authorized body which verifies and attests in writing to the qualifications of personnel, processes, procedures, or items in accordance with applicable requirements.

Command Media – Standards, approved quality and work plans, procedures, instructions, guidance, or similar materials that provide requirements that define the characteristics of the M&TE program.

Critical Measurement - A significant measurement that is necessary to ensure a device, a system, or a process is providing accurate data.

Critical M&TE - M&TE for which the failure could cause personal injury, harm the public and/or the environment, or jeopardize security or a vital PRS mission.

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Attachment A
DEFINITIONS/ACRONYMS
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Out-of-tolerance - A calibration error that has been determined to be a deficiency in characteristics significant enough to be reported under this command media.

Traceability - The ability to trace the history, application, or location of an item and like items or activities by means of recorded identifications and applicable records.

Tracking/Recall System - A paper-based or electronic system used to track the calibration status of devices in a calibration program.

Supplier (Vendor, Contractor) - Any individual or organization which furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

User-Verified M&TE - M&TE whose calibration is verified before use by the user.

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ACRONYMS

ANSI – American National Standard Institute

MAP – Measurement Assurance Program

M&TE – measuring and test equipment

NCSL – National Conference of Standards Laboratories

QA – Quality Assurance

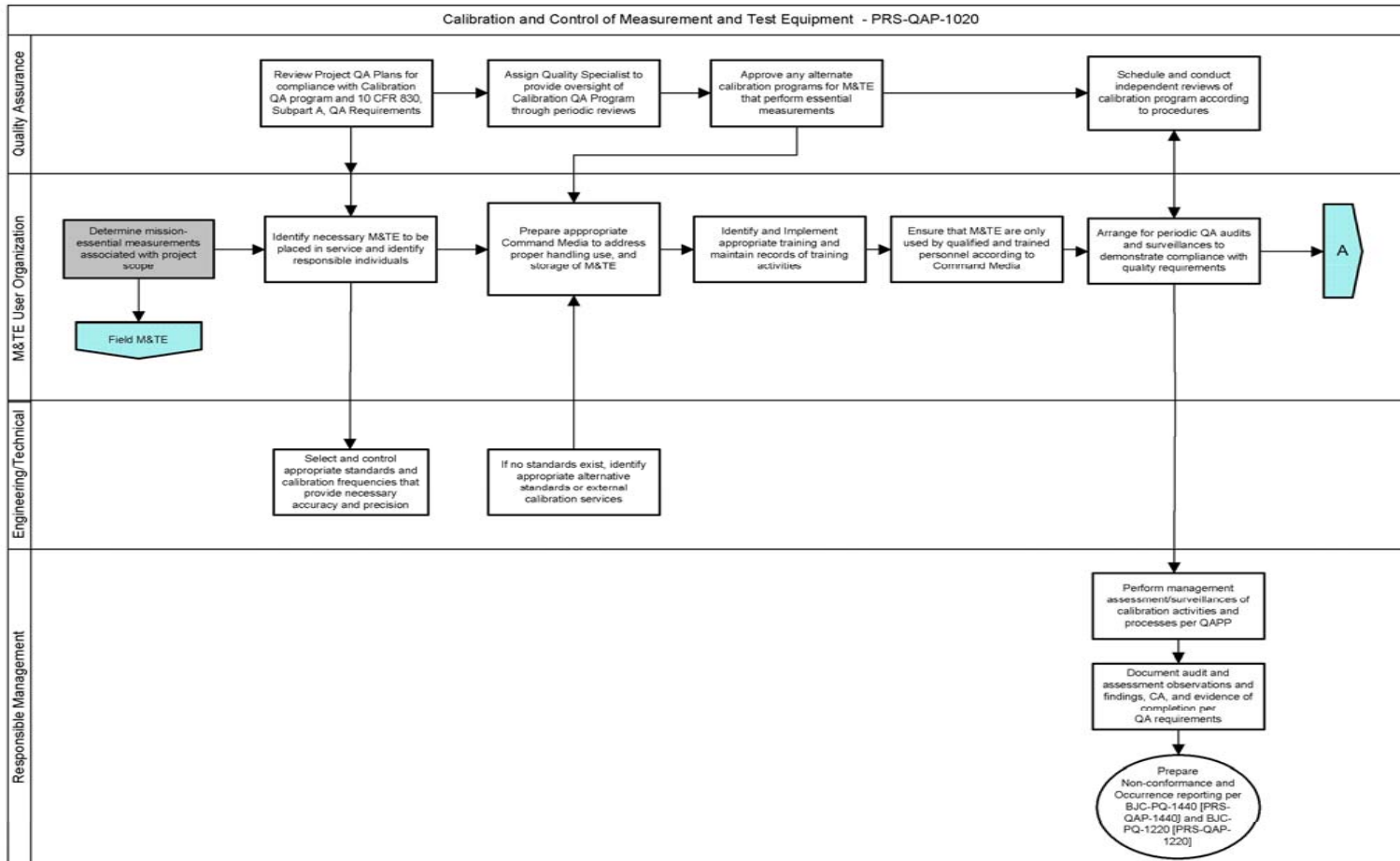
PGDP-DMC – Paducah Gaseous Diffusion Plant Document Management Center

PRS – Paducah Remediation Services, LLC

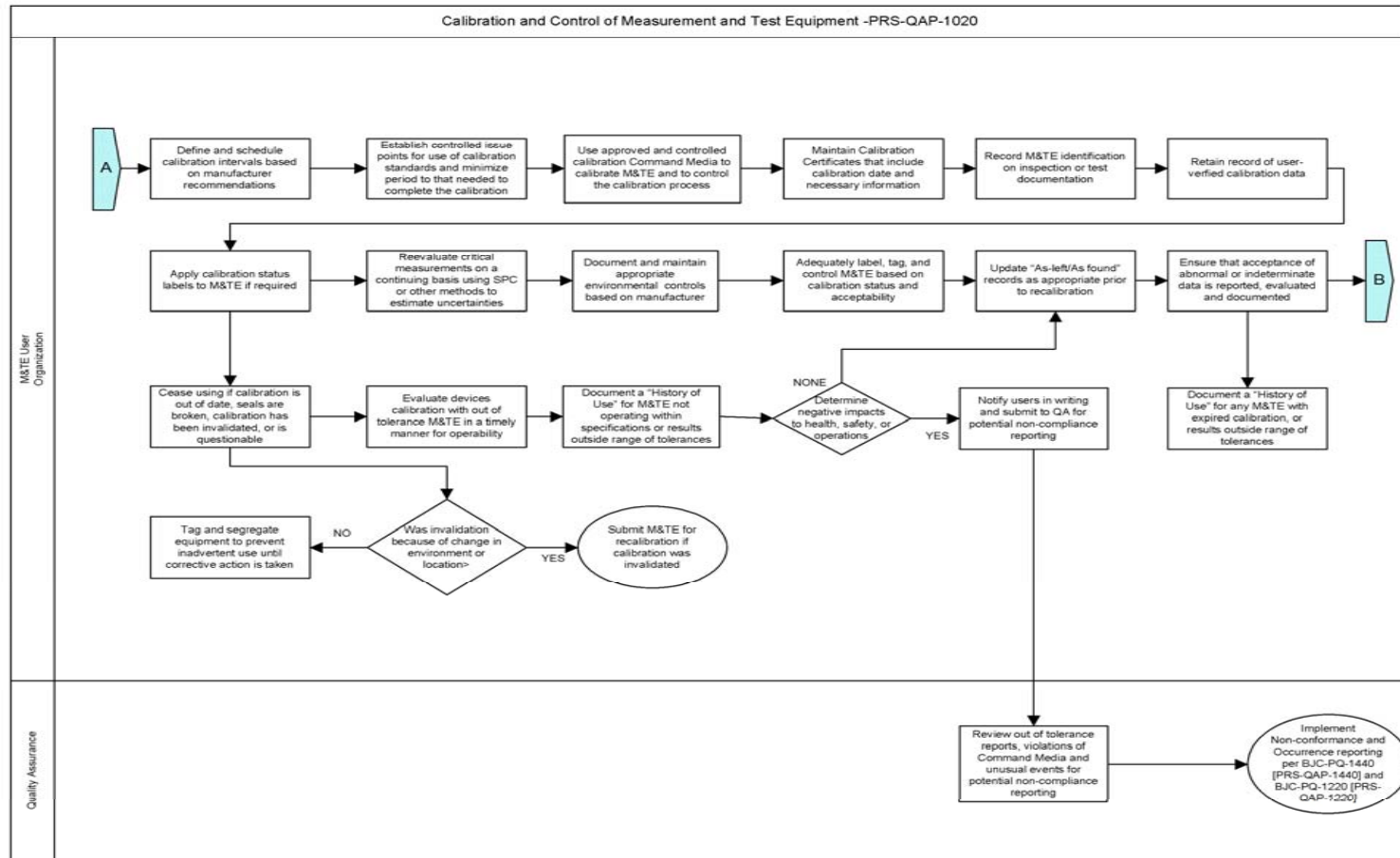
USQD – Unreviewed Safety Question Determination

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Attachment B
Calibration of M&TE Process Flow Chart
Page 1 of 3

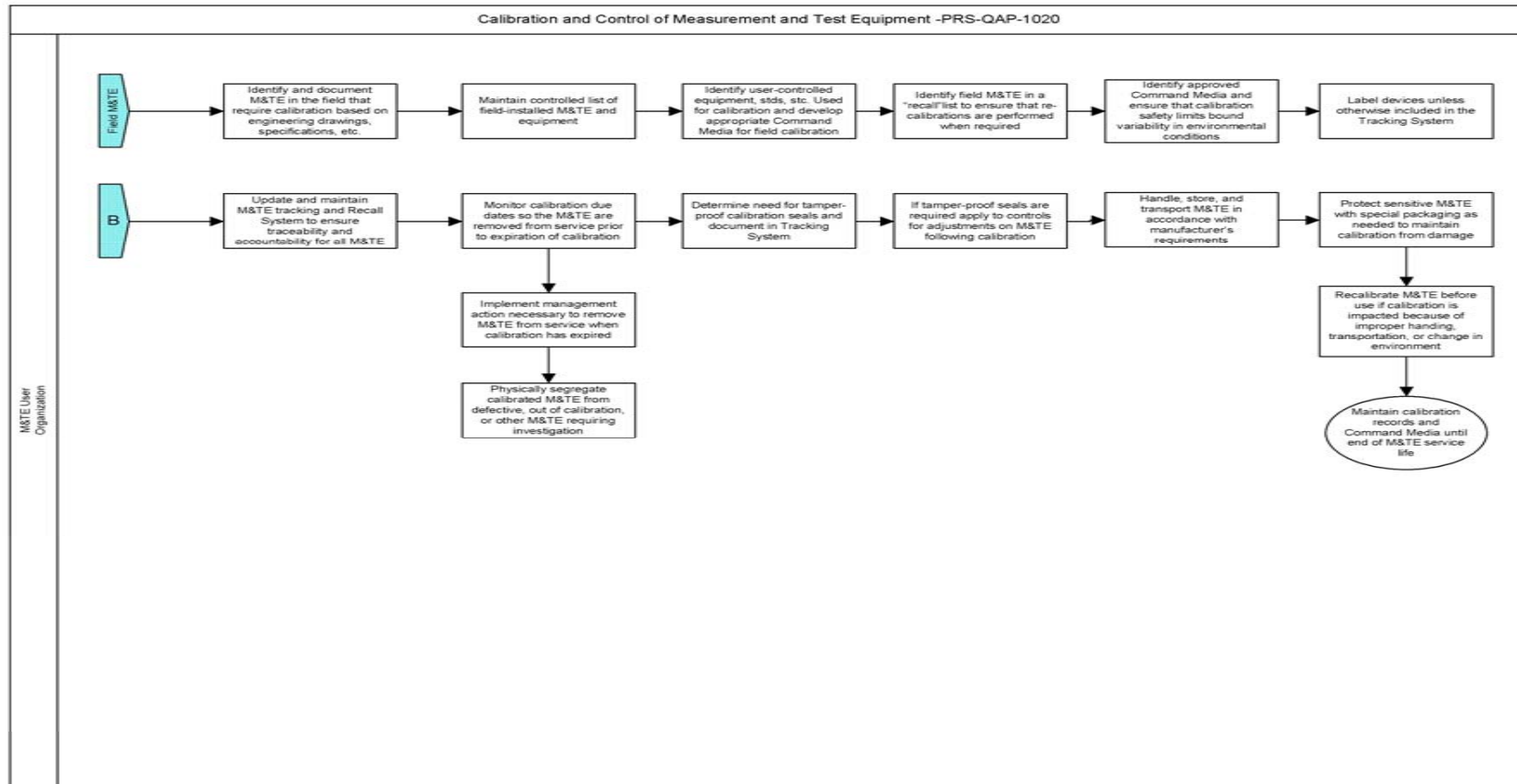


Attachment B
Calibration of M&TE Process Flow Chart
Page 2 of 3



OWNER: Quality	PRS-QAP-1020
TITLE: Control and Calibration of Measuring and Test Equipment	REV. NO. 0, AC-1
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Attachment B
Calibration of M&TE Process Flow Chart
Page 3 of 3



OWNER: Quality	PRS-QAP-1020
TITLE: Control and Calibration of Measuring and Test Equipment	REV. NO. 0, AC-1
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Attachment C
EXAMPLE OF M&TE CALIBRATION STICKER (AC-1)

Identification Number: _____
Date of Calibration: _____
Calibration Due Date: _____
Limitations: _____

Comments: _____

OWNER: Quality	PRS-QAP-1020
TITLE: Control and Calibration of Measuring and Test Equipment	REV. NO. 0, AC-1
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**Attachment D
EXAMPLE OF DEFECTIVE EQUIPMENT TAG (AC-1)**

FRONT SIDE

0

WARNING

DEFECTIVE EQUIPMENT

BACK SIDE

DEFECTIVE EQUIPMENT

TAG NO. _____

ISSUED BY _____ BADGE No. _____

DATE _____ PHONE _____

EQUIP. _____

EQUIP. _____

0 NOT TO BE USED RESTRICTED USE

EQUIPMENT DEFECT _____

EQUIPMENT OWNER _____

SERVICE MGR. _____ DATE _____
