



September 20th, 2022

ATTN: Document Control Desk
Director, Division of Fuel Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

Subject: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE PERMA-FIX
QUALITY ASSURANCE PROGRAM [Docket No. 71-0970]

Please find attached the response to the U.S. Nuclear Regulatory Commission (NRC) request for additional information dated September 1st, 2022.

We trust that this additional information contains the details necessary to continue your review.

We look forward to hearing from you. If you have any questions or require additional information, please contact me at 865-690-0501 or pjones@perma-fix.com.

Respectfully submitted,

Paul Jones, NRRPT
Waste Technical Services Manager

Enclosures:

Perma-Fix Environmental Services, Inc. Quality Management System, Revision 9
Perma-Fix Response to Questions
Revision Log for QMS, Revision 9

Cc:

Darrell Srdoc – Perma-Fix ESH&Q Director

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Q004
NM55

NRC Comment:**Section 4.1 "Organization"**

- 4-1 Explain how Quality Assurance (QA) personnel retain sufficient independence from cost and schedule.

In the organization structure, it is shown that the Facility QA Managers have a direct report to the Facility GM and Project/Instrument Services (IS) QA Representatives (QAR) have a direct report to the Project / IS Managers. This structure presents the appearance that those responsible for production and schedule may have undue influence over QA personnel.

This information is needed to determine compliance with Title 10 of the Code of Federal Regulations (10 CFR), Part 71.103(d).

Perma-Fix Response to 4.1:

Each facility is an individual business entity and therefore the Facility QA Manager (FQAM) reports directly to the highest position in the organization, the General Manager. This is similar to the QA Representative (QAR) for projects who reports to highest position for projects, the Project Manager.

The QAR/Project Quality Assurance Representative (PQAR) will report to the ESHQ Director when participating in quality affecting activities that involve packaging regulated under 10 CFR 71 and their performance in those activities will include input from the ESHQ Director. While "stop work" authority has always been in place from a policy standpoint, it is now represented as a specific responsibility in the QMS.

NRC Comment:**4-2 Define "assessment."**

The term "assessment" is used multiple times throughout the QMS. Is "assessment" meant to be synonymous with an audit as required by 10 CFR 71.103(b)(2) and 10 CFR 71.137 or is the intent to "promote improvement?" Assessment as a general term includes a variety of evaluation methods (i.e., reviewing, evaluating, inspecting, testing, checking, surveillance, auditing, or otherwise determining and documenting).

This information is needed to determine compliance with 10 CFR 71.103(b)(2) and 10 CFR 71.137.

Perma-Fix Response to 4.2:

Perma-Fix conducts independent and management assessments of facilities and projects as a way of evaluating and verifying compliance to the QMS and flow-down QA procedures. It is also a way to promote improvement overall.

As defined in our QA procedure PF-Q-18, Assessments:

Independent Assessment – A generic term encompassing audit, surveillance, evaluation, "for cause," review, or inspection conducted by individuals within the organization or company but independent from the work or process being evaluated, or by individuals from an external organization or company.

Management Assessment – A generic term for evaluations conducted by managers (or designee) of work or processes, for which they are responsible, with the intent to identify the management systems, processes, and programs that affect performance and to make improvements.

PF-Q-18, Assessments, also describes assessments/evaluations of suppliers of items or services specific to safety systems. These assessments are conducted by lead assessors who are evaluated and qualified by the ESHQ Director.

NRC Comment:***Section 4.2.2 “Graded Approach”***

- 4-3 Revise the QMS to establish that, regarding items important to safety, Perma-Fix’s graded quality program will be applied to packages as specified by the package certificate holder.

This section states “The QMS and flow down implementing documents will be implemented using a graded approach and applied primarily to activities, items, or services considered “important to safety and quality.” As defined by Perma-Fix, “important to safety and quality” means an activity that if performed incorrectly, could have an adverse effect on employees, public safety, nuclear safety, or the environment.”

This statement seems to imply that Perma-Fix is the sole entity responsible for determining what is “important to safety.” Per 10 CFR 71.107, the package certificate holder is responsible for “the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.” The Perma-Fix QMS does not acknowledge the role of the package certificate holder in evaluating and determining a packaging component’s importance to safety and the applicable criteria that should be applied in a graded quality program.

This is needed to ensure compliance with 10 CFR 71.107.

Perma-Fix Response to 4.3:

Section 4.2.2, Graded Approach, the QMS has been revised to include the following language:

The application of a graded approach philosophy does not relieve Perma-Fix of its responsibility to maintain compliance with federal, state, or local regulations. In this regard, when Perma-Fix uses packages regulated under 10 CFR 71, the package certificate holder is responsible for determining a packaging’s component’s importance to safety and the applicable criteria that should be applied in a graded approach.

NRC Comment:***Section 4.4 “Design Control”***

- 4-4 Revise the QMS to specify that Perma-fix will not be performing design activities related to radioactive material packages that fall under the requirements of 10 CFR Part 71.

10 CFR 71.107(a) states, “The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall establish measures to assure that applicable regulatory requirements

and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions.”

As Perma-Fix is not a certificate holder or applicant at the current time, Perma-fix cannot engage in design activities for packages that must meet the requirements of 10 CFR 71 except for those designs for which it intends to seek NRC approval.

This is needed to determine compliance with 10 CFR 107.

Perma-Fix Response to 4.4:

Perma-Fix has revised Section 4.4, Design Control, of the QMS with the following language:

“In addition, as Perma-Fix is not a certificate holder, it does not engage in design activities for packages that must meet the requirements of 10CFR71.”

NRC Comment:

Section 4.5 “Procurement Control”

- 4-5 Provide additional information on how a “facility/project equivalent” may be reviewed and approved for establishing the necessary requirements for evaluating suppliers of services or items that are important to safety.

This section states, “PF-P-001, PF-Q-04, Procurement Control, or facility/project equivalent, establishes specific requirements for evaluating suppliers of services and items considered ‘important to safety and quality’.”

This information is necessary to determine compliance with 10 CFR 71.109.

- 4-6 Clarify and provide additional details on how Perma-fix will apply its graded quality program to the procurement process. Specifically:

1) State which personnel is responsible for updating the ASL with suppliers and any applicable quality requirements.

2) Describe the review and approval process for procurement documents.

3) Explain how changes to procurement documents are controlled.

10 CFR 71.109 states, “The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee, certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.”

This information is necessary to determine compliance with 10 CFR 71.109.

- 4-7 State whether Perma-fix intends to engage in commercial grade dedication of items or services important to safety. If so, provide details on how Perma-fix will implement this process.

This information is needed to determine compliance with 10 CFR 71.109.

Perma-Fix Response to 4.5:

In this regard, procurements specific to packaging used for transporting radioactive materials regulated under 10CFR71, will only be procured at the corporate level in which "important to safety" attributes will be established by the certificate holder and captured in related procurement documents. While Facility/Project QA personnel may be involved, they will be trained and qualified to do so.

Perma-Fix Response to 4.6:

As stated in PF-Q-07, Control of Purchased Items and Services, the ESHQ Director is responsible for updating the ASL and establishing requirements for evaluating suppliers. The ESHQ Director is a trained, qualified lead assessor under NQA-1 protocols. Procurement documents such as the purchase requisition, specifications, drawings, and associated terms and conditions for items that are important to quality and safety are reviewed and approved by the ESHQ Director and appropriate subject matter experts (SME). For packaging, the SME will include the Waste Management Representative and Engineering Manager. Personnel involved with the initial review of procurement documents will also be involved in any changes to these documents. Procurement documents will be controlled as a package under the control of Contracts Management (as stated in PF-Q-04, Procurement Document Control). This would include any subcontracts for potential service-related activities. Changes to contract requirements would undergo the same review/approval process as any other procurement document. The quality department would maintain receipt inspection requirements or any source verification / inspection plans.

Perma-Fix Response to 4.7:

As part of a commercial grade dedication process, Perma-Fix will follow the requirements identified in DOE's Commercial Grade Dedication Application Handbook, DOE-HDBK-1230-2019. This will include a technical evaluation of the items/services required and implementation of specific inspections, special tests, source verification, or assessments at the supplier's facility, or when the items are received or services provided at the project site or facility.

NRC Comment:***Section 4.7 "Document Control"***

- 4-8 Provide additional details on the review and approval process for documents considered important to safety. Specifically:
- 1) State the personnel, identified by position or function, who is responsible for reviewing, approving, or issuing documents.
 - 2) Describe the process and personnel responsible for reviewing and approving changes to controlled documents.

10 CFR 71.113, "Document control," states, "The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed."

This information is needed to determine compliance with 10 CFR 71.113.

- 4-9 Describe the processes and personnel responsibilities for verifying the that correct version of a controlled document (printed or electronic) is being used when conducting activities that are important to safety.

This information is needed to determine compliance with 10 CFR 71.113.

Perma-Fix Response to 4.8:

Per PF-Q-06, Document Control:

The Responsible Manager (RM) of the quality affecting document—

- Determines the need for a document,
- Authorizes individuals to prepare documents,
- Identifies individuals for reviewing new documents and subsequent revision to documents,
- Provides final disposition of comments received during document reviews,
- Approves documents that affect activities managed by the RM, and
- Ensures sufficient resources are allocated to prepare and maintain documents.

The ESHQ Director or Quality Assurance Representative (QAR)—

- Assures implementation of the document control process,
- Provides training to individuals involved in the document control process,
- Establishes and approves document naming conventions,
- Approves new documents and subsequent revision to documents related to 10 CFR 71 activities,
- Ensures the document control process is effective, and
- Oversees the Document Center (DC).

The Document Preparer—

- Contacts the Quality Assurance Specialist (QAS) for the proper naming convention,
- Prepares the initial draft document or revision to a current document,
- Ensures format guidelines are incorporated during document preparation,
- Coordinates review and approval of documents and subsequent revisions,
- Facilitates comment resolution between the RM and reviewer, and
- Provides the final Word version of a document to the DC.

Perma-Fix Response to 4.9:

Per PF-Q-06, Document Control:

Current electronic versions of documents are posted to the public DC directory when a signed hard copy or signed electronic version and current Word version of the document are provided to and secured by the QAS.

Personnel can access electronic versions of current documents by using the public DC directory. The site maintains a list of controlled documents to ensure the user has access to the latest version of the document.

Personnel using a document printed from the public DC directory are responsible for ensuring the document is the current version by comparing it to the list of controlled documents. When a document is printed from the public DC directory, the footer states "This document is uncontrolled when printed. Before use, check the Document Inventory List to verify that this is the current version." For projects without internet access, a controlled hard copy will be issued.

NRC Comment:

Section 4.8 "Control of Purchased Material, Equipment, and Services"

- 4-10 Provide additional details on the evaluation methods by which Perma-Fix suppliers are placed on the ASL in accordance with its graded quality program. Specifically, explain if Perma-Fix considers any of the methods of supplier evaluation listed in this section of the Perma-Fix QMS to be acceptable for all items or services considered important to safety. In addition, state the frequency and basis for which Perma-Fix will perform these various supplier evaluations.

This section of the Perma-Fix QMS states, "Perma-Fix procurement controls include measures to ensure items and services considered "important to safety and quality" are procured through suppliers listed on the Perma-Fix ASL. Suppliers listed on the ASL are selected based on a documented evaluation of their past performance, objective evidence of an acceptable QA program or system, customer approval, approved by recognized independent auditing group, certified by an accredited entity, approved by the NRC, and/or other attributes deemed appropriate for the items or services being procured. Suppliers of items or services that may affect safety structures, systems, or components may undergo an additional site evaluation by a Perma-Fix NQA-1 lead auditor based on the complexity of the items or services provided."

This information is needed to determine compliance with 10 CFR 71.115.

- 4-11 State the qualification requirements of Perma-Fix NQA-1 lead auditors.

NRC REGULATORY GUIDE 1.28 provides clarification of necessary lead auditor qualifications as stated in NQA-1-2015

"Prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization."

10 CFR 71.105(d) states, "The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained."

This information is needed to determine compliance with 10 CFR 71.105(d) and 71.137.

Perma-Fix Response to 4.10:

Perma-Fix believes the provisions in PF-Q-07, Control of Purchased Items/Services, are consistent with 10 CFR 71.115 and NQA-1 2015 basic Requirement 7, for evaluating suppliers for items/services important to safety. Perma-Fix recognizes the need to ensure specific requirements for suppliers of packaging need to be well documented in procurement documents and refer to 10 CFR 71 Subpart H QA provisions. Approved suppliers are reviewed at least once a year for renewed third party certification and are re-evaluated at least once every three years.

Perma-Fix Response to 4.11:

Perma-Fix lead assessors (auditors) are qualified consistent with SUBPART 3.1-2.2 of NQA-1 2015 and documented using the form, Lead Assessor Qualification, PF-Q-18-F3.

NRC Comment:

Section 4.10 "Control of Special Processes"

- 4-12 Provide details of how special process activities that must meet the requirements of 10 CFR 71.119 are controlled or excluded from the Perma-Fix QMS. Special processes should only be performed on NRC-approved packages as prescribed by the package certificate holder.

10 CFR 71.119 states: "The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

As Perma-Fix is not a certificate holder of an NRC-approved package, Perma-Fix cannot determine the suitability of special processes that are applicable to a package design.

This information is needed to determine compliance with 10 CFR 71.119.

Perma-Fix Response to 4.12:

Perma-Fix will revise its QMS to state that Section 4.10 "Control of Special Processes" does not apply to items or services regulated under 10 CFR 71.119.

NRC Comment:***Section 4.13 "Control of Special Measuring and Test Equipment"***

- 4-13 Provide additional information on how Perma-Fix intends to adhere to the requirements of 10 CFR 71.125 in each M&TE calibration scenario mentioned in this section of the QMS.

This section of the Perma-Fix QMS states, "Equipment requiring specialized calibration or repair is sent to the original equipment manufacturer (OEM); to an approved supplier qualified under PF-Q-04, Procurement Control or facility/project equivalent; or to a supplier certified by the OEM to perform such services." This statement implies that Perma-Fix intends to impose different quality requirements on the OEM, or an OEM-approved supplier as compared to other calibration suppliers.

This is needed to ensure compliance with 10 CFR 71.125.

Perma-Fix Response to 4.13:

Original equipment manufacturers (OEM) will be evaluated according to Control of Purchased Items and Services, PF-Q-07, and when approved, will be added the Approved Supplier List (ASL). PF-Q-04, Procurement Control, does not establish evaluation requirements for calibration service providers, only that a provider of calibration services is on Perma-Fix's Approved Supplier list. Evaluation requirements specific to M&TE are described in PF-Q-012, Control of Measuring and Test Equipment. These requirements are consistent with requirements in 10 CFR 71.125 and NQA-1, Basic Requirement 12, Control of Measuring and Test Equipment. They include that any calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards.

NRC Comment:

- 4-14 State whether Perma-Fix intends to accept subcontracted calibration services based on the ILAC accreditation process in lieu of a commercial grade survey for calibration services considered important to safety. If so, provide details on how Perma-Fix will control these activities as part of its commercial grade dedication process.

Revision 1 of NEI 14-05A (ADAMS Accession No. ML20259B731) clarifies that the guidance for the use of the ILAC accreditation process developed as part of the commercial-grade dedication process for laboratory calibration and testing services by licensees and suppliers of basic components. Further, staff review and endorsement of Revision 1 of NEI 14-05A (ADAMS Accession No. ML20322A019) provides an updated approach using laboratory accreditation by Accreditation Bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services. Also, to ensure that the calibration and/or testing work is

performed by an ILAC accredited laboratory and reduce the chance of misuse of the ILAC accreditation process and not receive an accredited service, the procurement documents must prohibit the accredited calibration or testing laboratory from subcontracting the service being procured. The procurement document for accredited services must be submitted directly to the entity performing the calibration or testing. Section 3.5 of the NRC endorsement referenced above also lists other limitations and conditions that should be included.

This is needed to ensure compliance with 10 CFR 71.125.

Perma-Fix Response to 4.14:

As part of the Perma-Fix procurement of calibration services, Perma-Fix will ensure procurement documents for accredited services are submitted directly to the entity performing the calibration or testing. Also, procurement documents for calibration services will include QA requirements that would prohibit the accredited calibration or testing laboratory from subcontracting the service being procured. As part of its QA procurement evaluation, Perma-Fix will ensure accreditation is current prior to issuing a purchase order.

NRC Comment:

Section 4.18 "Quality Assurance Records"

- 4-15 List and describe what records relating to 10 CFR 71 activities that Perma-Fix will be creating, how they may be classified, and the periods of time for which they will be maintained.

10 CFR 71.135 "Quality assurance records," states: "The licensee, certificate holder, and applicant for a Certificate of Compliance shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a Certificate of Compliance last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a Certificate of Compliance shall retain the superseded material for 3 years after it is superseded."

NRC Regulatory Guide 1.28, Revision 5 (ADAMS Accession Number No. ML17207A293), provides guidance on the requirements for retention of records that are specified in NQA-1:2015.

This is needed to ensure compliance with 10 CFR 71.135.

- 4-16 Provide additional details on how Perma-Fix will store and protect records (physical & electronic) related to 10 CFR 71 activities.

NRC Regulatory Guide 1.28, Revision 5 (ADAMS Accession Number No. ML17207A293) provides clarifying guidance on the management of records in electronic media that is specified in NQA-1:2015.

This is needed to ensure compliance with 10 CFR 71.135.

Perma-Fix Response to 4.15:

Perma-Fix expects to generate the following records (not inclusive) during its use of packaging regulated under 10 CFR 71: Procurement specifications, purchase order and contracts including amendments, evaluated supplier listings, inspection and test data (when required), nonconformance reports, training and qualification records for current members of the facility-operating staff, surveillance activities, inspections, and calibrations if required by the technical specifications. The records will be classified in accordance with the records inventory index and retained in accordance with established retention times but no less than 3 years from the latest quality affecting activity.

Perma-Fix Response to 4.16:

Perma-Fix will manage and store records in accordance with PF-Q-17, Records Management. PF-Q-17 addresses the protection, deterioration, distribution, retention, maintenance, and disposition of quality affecting records. Perma-Fix will acquire, secure, and store records as they are generated until they are no longer required to support ongoing activities or have met legal retention requirements. Hard copy records will be stored in a fire-rated storage cabinet/safe and may be digitized (minimum 600 dpi) and maintained in a separate storage medium to ensure dual repository management. When hard copy records are no longer required to support ongoing activities, Perma-Fix will transfer them to a long-term, secured storage facility.

NRC Comment:***Section 4.19 "Assessments"***

- 4-17 State whether the "assessments" described in this section are intended to meet the requirements for audits described in 10 CFR 71.137 and NQA-1: 2015, Requirement 18. If so, provide details on how Perma-Fix meets these requirements. Specifically:

- 1) State the required qualifications of personnel performing the assessments (audits)
- 2) Explain how Perma-Fix will establish schedules for internal and external assessments (audits)

This is needed to ensure compliance with 10 CFR 71.137.

Perma-Fix Response to 4.17:

Perma-Fix follows PF-Q-18, Assessments, for scheduling and conducting assessments. Assessments are defined in a previous response which addresses question 1 also. Schedules for assessments will be dictated by "important to safety" activities and overseen by the ESHQ Director. Perma-Fix will revise its QMS in Section 4.19, Assessments with the following:

Perma-Fix conducts independent and management assessments of facilities and projects as a way of evaluating and verifying compliance to the QMS and flow-down QA procedures. As a general term, assessments may include a variety of evaluation methods (i.e., reviewing, evaluating, inspection, testing, checking, surveillance, auditing, or otherwise determining and documenting.

Corporate <input checked="" type="checkbox"/> Facility <input type="checkbox"/> Project <input type="checkbox"/>		Document No:	PF-Q-01
Document Title: Quality Management System		Document SME:	D. Srdoc
REVISION LOG			
Change Number	Description of Changes for: Revision 9	Pages Affected	
1	Updated Figure 1 – Removed EWOC and removed shading to show PF Canada as ISO 9001 certified (also removed PF Canada as being ISO 9001 certified in Section 2).	6-7	
2	Section 4.1.8- Clarified line of authority for PQAR and FQAR - <i>Each has an independent line of authority to from the ESHQD to initiate a "stop work" if operational costs and/or schedule jeopardize achievement of quality or safety requirements.</i> (PQAR and FQAR report to PM or GM for day-to-day activities.)	11	
3	Section 4.1.8 – Clarified role for PQAR and FQAR - <i>Reporting to the ESHQD when participating in quality affecting activities involving packaging regulated under 10 CFR 71</i>	11	
4	Section 4.2 - Added when to use 10 CFR § 71 Subpart H, Quality Assurance – added " <i>when transporting radioactive materials in packages governed under this regulation.</i> "	12	
5	Section 4.2.2 – Added package certificate holder's role in graded approach - <i>In this regard, when Perma-Fix uses packages regulated under 10 CFR 71, the package certificate holder is responsible for determining a packaging's component's importance to safety and the applicable criteria that should be applied in a graded approach.</i>	16	
6	Section 4.4 – Added design control information - <i>In addition, as Perma-Fix is not a certificate holder, it will not engage in design activities for packages that must meet the requirements of 10CFR71.</i>	17-18	
7	Section 4.5 – Added additional procurement controls for packaging used for transporting radioactive materials - <i>In this regard, procurements specific to packaging used for transporting radioactive materials regulated under 10CFR71, will only be procured at the corporate level in which "important to safety" attributes will be established by the certificate holder and captured in related procurement documents. Also added - Suppliers of packaging regulated under 10CFR71 will also be evaluated on their ability to comply with applicable sections of Subpart H, results of any survey of the supplier's facility and QA Program, and review of the supplier's previous record and performance.</i>	18-19	
8	Section 4.5 – Clarified procurement controls - <i>As part of the "dedication process," the supplier may undergo specific inspections, special tests, or source verification...</i> Also added - <i>items "important to safety" will be used only when they have been evaluated under a commercial grade dedication process and approved by a qualified lead auditor... (for suppliers that do not maintain a compliant QA Program).</i>	18	
9	Section 4.7 – Added clarifying information on review of QA documents - <i>Changes to quality affecting documents will always be reviewed by the cognizant QAR and approved by the ESHQD.</i>	19	
10	Section 4.7 – Added clarifying information on document control – the document version should be verified - <i>against the document inventory list each time it is used.</i>	20	
11	Section 4.10 – Added – " <i>Regarding NRC-approved packages, since Perma-Fix is not a certificate holder, special processes are not applicable to items or services regulated under 10 CFR 71.119.</i> "	21	
12	Section 4.19 – Added clarification on assessments - <i>Perma-Fix conducts independent and management assessments of facilities and projects as a way of evaluating and verifying compliance to the QMS and flow-down QA procedures. As a general term, assessments may include a variety of evaluation methods (i.e., reviewing, evaluating, inspection, testing, checking, surveillance, auditing, or otherwise determining and documenting.</i>	25	
13	Added to footer - This document is uncontrolled when printed. Before use, check the Document Inventory List to verify that this is the current version.	3-28	