

**Request for Additional Information Perma-Fix Environmental Services, Inc.**

**Docket No. 71-0970**

**Perma-Fix Quality Management System, PF-Q-1, Rev. 8**

By submittal dated April 28, 2022, Perma-Fix Environmental Services, Inc. (Perma-Fix) requested approval of Perma-Fix Quality Management System (QMS), PF-Q-1, Rev. 8. This request for additional information (RAI) identifies information needed by the U.S. Nuclear Regulatory Commission (NRC) staff in connection with its review of the Perma-Fix QMS. The requested information is listed by chapter number and title in the applicant's QMS. NUREG 2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," was used by the staff in its review of the application.

Each RAI describes the information needed by the staff for it to complete its review of the submittal and to determine whether the applicant has demonstrated compliance with the regulatory requirements.

**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).

- 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.

### **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.

### **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.

## 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.

## 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, that 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, that 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.

## 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.

## **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.

### **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.

- 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.

## **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.

## **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.