Quality Assurance at Hazardous Waste-Only facilities

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Quality Assurance Management

Radiological vs Hazardous Waste Quality Management

- **What Standards Exist**
- **What Standards Apply**
- **Customer Expectations**

Radiological Hazardous Waste Quality Management Standards

- ISO 9001

- NQA-1

- DOE O 414.1D

These Facilities will have the standards cited in Quality Assurance Statements and Manuals

DOECAP

Hazardous Waste Quality Assurance

What are the QA Management Requirements?

- Can vary between TSDFs

- Environmental Management System?

- Contractual Elements

- Permits

- A TSDF may not have any Quality Manual outside of RCRA permitted screening or Finger Printing Laboratory

ISO 14001 Non-Mandatory Requirements

- **Environmental management system manual**
- **Procedure for determining Organizational Context and interested party requirements**
- **Procedure for identifying environmental aspects**
- **Procedure for addressing risks and opportunities**
- **Procedure for competence, training and awareness**
- **Procedure for identifying and monitoring compliance obligations**
- **Procedure for managing infrastructure and use of natural resources**
- **Procedure for controlling documented information**
- **Procedure for environmental objectives, targets and programmes**
- **Procedure for emergency environmental preparedness**
- **Procedure for managing nonconformities and corrective actions**
- **Procedure for internal auditing**
- **Procedure for management reviews**
- **Internal audit checklists and process audit checklists**
- **Process maps that describe the sequence of actions**
- **Turtle diagrams that describe processes**
- **Matrices and registers**

The DOECAP QA Goal

- **The DOECAP quality assurance goal is to ensure that the audit process is controlled by an efficient and effective organizational structure with management processes in place for planning, scheduling, and providing resources to support the program effectively.**

Pre-Audit Evaluation

Review the Site Information Sheet

Search for Corporate Quality Policy

Does the facility identify a Quality Manager

What are the Quality Management Aspects

Is Environmental Management System (EMS) a Quality Management System (QMS)?

- **EMS is environmentally driven (ISO 14001)**

- **QMS is Customer driven (ISO 9001)**

THE DIFFERENCES BETWEEN
ISO 9001 AND ISO 14001

ISO 9001 2015 QMS	ISO 14001 2015 EMS
Customer-driven	Environmentally driven
More documented procedures	Less documented procedures
Defined standards	No defined standards
Requires quality manual	No quality manual

QA Elements for Hazardous Waste Facilities

What we look to review?

- **Documents**
- **Records**
- **Training**
- **Corrective Action**

Documents

A document is a piece of written, printed, or electronic matter that provides information. It can contain information in a structured or unstructured format. Documents can usually be changed and revised as needed.

The focus is on:

Document Control (Reviewed for adequacy and completeness, revised, prepared and approved by appropriate personnel, controlled distribution and are correct documents being used)

Records

A record is a piece of evidence about the past, especially an account kept in writing or some other permanent form. Many records start out as documents and then become records when they are used as evidence.

The focus here is on: (The process for identifying, generating, authenticating, maintaining and disposal of records.

Key is record retention schedules, proper storage and protection from loss. Are they retrievable?

Training

- Should be a written training program that defines job qualifications and required training based on job function.

- Personnel performing or managing activities shall understand general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.

- Verify that training records are complete, current, and maintained in a formal record keeping system.

Corrective action

Looking for a corrective action process. (can include quality, health and safety, Regulatory compliance.

Actions need to be documented, reviewed and approved

There should be a mechanism to track actions to closure

What is a finding?

DURING AN AUDIT, FINDINGS ARE OFTEN IDENTIFIED WHICH CONTAIN THE FACTUAL INFORMATION COLLECTED OR OBSERVED DURING THE PERFORMANCE OF THE AUDIT.

THE AUDIT CRITERIA ARE THE STANDARDS, PROCEDURES, REGULATIONS, OR OBJECTIVES THE ORGANIZATION WAS AUDITED AGAINST.

THE CRITERIA REPRESENT REQUIREMENTS THE ORGANIZATION MUST COMPLY INCLUDING THEIR OWN PROCEDURES.

IT IS CRITICAL IN MAINTAINING CONTINUITY IN AN AUDIT PROGRAM, TO FACTUAL CONNECT THE FINDING TO THE REQUIREMENT.

QA Findings We Have Seen

Since 2019........ There has been one Hazardous waste finding. It was based on a facility Document process not reviewing, approving and controlling procedures.

Audit Findings

What is an observation?

A factual statement issued by DOECAP to document a deviation from best management practices, a non-requirement-based issue(s), or an opportunity for improvement that might warrant attention by the audited facility

Observations we have seen

Since 2019......16 observations

- 5 Best Management practices for a Quality Assurance program
- 5 Documents and Records
- 3 Corrective action tracking
- 1 training
- 1 Inspection
- 1 M&TE

Where do we go from Here?

Preaudit information should include information if a Quality Management system is in place at a facility

Should a Quality Management system be a requirement? (Or specifically, what elements should be required)

Do other QA elements need to be audited.

Does QA need to be evaluated for a Hazardous Waste Facility

Are Remote Audits Sufficient?

Questions?

Thank You