ISM-QAP Template

Incorporating a
Quality Assurance Program (QAP) with an
Integrated Safety Management System (ISMS) Description

Purpose

This is a template for developing a combined QAP and ISMS Description document.

Users of this non-mandatory template will be able to address the requirements for a QAP, as required by DOE Order 414.1D, 10 CFR 830, Subpart A, and an ISM System Description Document, as required by DOE Order 450.2, in a single document.

Only those criteria applicable to the organization need to be addressed. For example, criteria for design or inspection and acceptance testing for a management and/or administrative organization may not be applicable unless oversight of those areas is part of the organization's function.

U.S. Department of Energy
Quality Council
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ISM-QA Template

Summary

The DOE Federal Quality Council formed a working group for the action of developing a Quality Council recommended but non mandatory template that can be followed when establishing Quality Assurance Programs that include Integrated Safety Management System program description requirements in the documented Quality Assurance Program Plan. The Quality Council Task Planning Document, TPD-2009.03, established the action description and action deliverables. The resultant product of the working group is the ISM-QAP template. The final version of the template was concurred upon by the Quality Council for DOE complex wide use.

Questions regarding use of the template can be directed to the working group lead, Robert Blyth, NE-ID, at (208) 526-1181 or Sonya Barnette, DOE-HQ, at (301)903-2068.

A list of Quality Council members can be found at
http://www.hss.doe.gov/nuclearsafety/qa/council/membership_charter.html

I. INTRODUCTION

A. Describe the scope of the work covered by this document. [ISMS Core Function 1]

B. Provide a statement of commitment that the work will be done according to procedure and safely.

C. Describe how a graded approach is applied. This may be accomplished by referencing another section of this document or in a separate document.

D. Indicate how work may be stopped if safety is known to be or suspected to be compromised. This may be accomplished by referencing another organization document.

E. Describe how the document meets the requirements of DOE O 414.1D and DOE P 450.4A.

F. Describe how this Management System is the overall management system for the organization.

II. IMPLEMENTATION[1]

The following sections describe quality assurance requirements and incorporate the integrated safety management guiding principles that can be readily implemented through a quality assurance program. The sections presented below mirror the ten criteria delineated in DOE Order 414.1D and incorporate the guiding principles described in DOE Policy 450.4A. Additional criteria on suspect/counterfeit items (S/CI) prevention and safety software quality assurance (SQA) are also provided.

Describe how QA and ISM requirements are flowed down to supplier or sub tier organizations.

A. MANAGEMENT CRITERIA
Document the chosen consensus QA standard

1. *Management / Program*

1.1   For those managing, performing and assessing work:

1.1.1   Describe the organizational structure, functional responsibilities. [ISMS Guiding Principle 2]

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[1] The applicability of each of these sections is site specific. Some of the descriptions in the following sections may only be applicable to nuclear facilities.

1.1.2   Clearly describe the levels of authority and interfaces for those managing, performing, and assessing work.

1.1.3   Include interface descriptions and controls.

1.2 Describe how work is planned and scheduled and resources allocated.

1.3 Describe how line managers demonstrate their commitment to quality assurance and safety. [ISMS Guiding Principle 1 & 4]

1.4 Describe how the organization has a strong sense of mission and operational goals, including a commitment to highly reliable operations, quality and safety. [ISMS Guiding Principle 4]

References or links to applicable documents
Program Office /Site Office Function, Responsibilities, and Authorities Document
Program Office/Site Office Organizational Chart

2. *Management / Personnel Training and Qualifications*

2.1   Describe how employees are trained and qualified to perform their assigned work, and how this is documented. [ISMS Guiding Principle 3a]

2.2   Describe the requirements for continuous training to maintain job proficiency. [ISMS Guiding Principle 3]

2.4   Describe how line managers provide constructive dialogue and leadership through discussions on the work, safety, and quality assurance. (Ex. Weekly staff meetings, monthly program reviews, safety committees, etc.) [ISMS Guiding Principle 3]

2.5   Describe how the organization maintains a highly knowledgeable workforce to support a broad spectrum of operational and technical decisions. [ISMS Guiding Principle 3]

2.6   Describe how facility personnel maintain awareness of facility activities to ensure compliance with the established safety envelope. [ISMS Guiding Principle 7]

2.7   Describe how the safety envelope is communicated to individuals performing work. [ISMS Guiding Principle 3]

References or links to applicable documents
Training and qualification SOPs
Training materials developed

List of technical qualifications used

3. *__Management / Quality Improvement__*

3.1   Describe how the processes used to detect and prevent quality and safety problems are established and implemented. [ISMS Core Function 5] [ISMS Guiding Principle 1]

3.2   Describe how items, processes, and services that do not meet established quality and safety requirements are identified, controlled and corrected. [ISMS Core Function 5]

3.3   Describe how quality and safety problem causes are identified and how their recurrence is addressed in corrective action planning. [ISMS Guiding Principle 3 &5] [ISMS Core Function 5]

3.4   Describe how item characteristics, process implementation and other quality and safety related information is used to identify items, services and processes needing improvement. [ISMS Core Function 5]

References or links to applicable documents
Applicable SOPs
Corrective action program documents
Lesson learned documents

4. *Management / Documents and Records*

4.1 Describe how controlled documents are: prepared, reviewed, approved, issued, used and revised to prescribe processes, specify requirements or establish design. [ISMS Guiding Principles 1-6] [ISMS Core Functions 1-4]

4.2 Describe how readiness is verified before hazardous operations are authorized. [ISMS Guiding Principle 7]

4.3 Describe how records are prepared, reviewed, approved, and maintained.

References or links to applicable documents
Applicable SOPs

B. PERFORMANCE CRITERIA

5. *Performance / Work Processes*

5.1 Describe how work is performed consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures or other appropriate means. [ISMS Guiding Principles 2, 5, 6 &7] [ISMS Core Function 4]

5.2 Describe how items are identified and controlled to ensure their proper use. [ISMS Core Function 2, 3 & 4]

5.3 Describe how items are maintained to prevent their damage, loss, or deterioration

5.4 Describe how equipment used for process monitoring or data collection is calibrated and maintained.

References or links to applicable documents
Packaging, Handling, Shipping, Storage, or Acceptance SOPs
Safety analyses documents

6. *Performance / Design*

6.1 Describe how items and processes are designed using sound engineering / scientific principles and appropriate standards. [ISMS Guiding Principle 5] [ISMS Core Function 4]

6.2 Describe how applicable requirements and design bases are incorporated into design work and design changes. [ISMS Guiding Principle 5] [ISMS Core Function 4]

6.3 Describe how design interfaces are identified and controlled.

6.4 Describe how design of products is verified or validated by individuals or groups other than those that performed the work. [ISMS Core Function 5]

6.5 Describe how work is verified or validated before approval for implementation [ISMS Guiding Principle 7] [ISMS Core Function 5]

6.6 Describe exemptions or deviations to safety requirements, including how the exemption was authorized and who made the authorization. [ISMS Guiding Principle 5 & 6]

6.7 Describe how personnel at all levels of the organization are held accountable for shortfalls in meeting standards and expectations related to safety and quality. [ISMS Guiding Principles 1 & 2]

6.7 Describe the defense in depth strategy for work processes when selecting engineering controls, administrative processes, and personnel staffing and capabilities. [ISMS Guiding Principals 4 & 6] [ISMS Core Functions 2 & 3]

References or links to applicable documents
Appropriate standards for major items
Design control SOPs

7. *Performance / Procurement*

7.1   Describe how items and services that meet established quality and safety requirements and perform as specified are procured. [ISMS Guiding Principle 5]

7.2   Describe how prospective suppliers are evaluated and selected on the basis of specified criteria. [ISMS Core Function 5]

7.3   Describe how the process that ensures approved suppliers continue to provide acceptable items and services is established and implemented. [ISMS Core Function 5]

7.4   Identify a clearly-defined set of safety requirements and standards invoked in contracts. [ISMS Guiding Principle 5]

7.5   Describe the commercial grade dedication process and how it is implemented. This may be accomplished by referencing another organization document.

References or links to applicable documents
Applicable SOPs
Safety standards invoked in management contracts
Procurement Management Manual (if one exists)
Procurement Specification Manual (if one exists)
Quality Assurance Supplier Surveillance SOPs

8. *Performance / Inspection and Acceptance Testing*

8.1   Describe how specified items, services and processes are inspected and tested using established acceptance and performance criteria. [ISMS Core Function 4]

8.2   Describe how equipment used for inspections and tests is calibrated and maintained. [ISMS Core Function 4]

References or links to applicable documents
Applicable SOPs

C. ASSESSMENT CRITERIA

9. *Assessment / Management Assessment*

9.1 Describe how managers assess their management processes to identify and correct problems that hinder the organization from achieving identified quality and safety objectives. [ISMS Core Function 5]

9.2 Describe the planned management assessment periodicity.

References or links to applicable documents
Assessment manuals
Quality assurance and safety self-inspections

10. *Assessment / Independent Assessment*

10.1 Describe how independent assessments are planned and conducted to measure item and service quality and the adequacy of work performance to promote improvement. [ISMS Core Function 5]

10.2 Describe how independent assessment teams have sufficient authority and autonomy from the line management organization being assessed.

10.3 Describe how persons conducting independent assessment are technically qualified and knowledgeable in the areas to be assessed. [ISMS Guiding Principle 3]

10.4 Describe the planned independent assessment periodicity.

References or links to applicable documents
Qualifications and certification(s) of Independent Inspection Personnel
Quality Assurance and safety audits, self-inspections performed independently on internal programs

D. SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION

Describe how suspect counterfeit item requirements are implemented to achieve quality and safety objectives including who or what organization is the point of contact.

E. SOFTWARE QUALITY ASSURANCE[2]

Using a graded approach, describe how the ten software quality assurance criteria are implemented to achieve quality and safety objectives for all software. For nuclear facilities, the application of safety software requirements should also be addressed.

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[2] This may be a separate document.

III. <u>REFERENCES</u>

The following is a list of references commonly used when developing combined quality assurance and ISM requirements into one management document.

DOE O 414.1D, Quality Assurance
DOE O 450.2, Integrated Safety Management
DOE G 414.1-2B, Quality Assurance Management System Guide
DOE P 450.4, Integrated Safety Management Policy
10 CFR 830, Subpart A, Quality Assurance Requirements
DOE-STD-1189-2008, Integration of Safety into the Design Process
DOE-STD-1073-2003, Configuration Management