



Integrated Safety Management in Quality Assurance Program Planning



2009 DOE Integrated Safety Management (ISM) Conference

Knoxville, TN

August 24-27, 2009

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Bio for Sonya Barnette

- Registered Professional Engineer (PE)
- Department of Energy (DOE) 18 years
 - Had responsibilities in quality assurance (QA) for the last 5 years (primarily the development of quality assurance plans)
 - Recently started in the DOE's QA technical qualification program
 - Certified as NQA-1 lead auditor
 - Previously a lead auditor for the Office of Environmental Management (EM)
- Previous Employment
 - BWXT, Lynchburg , VA
 - Chem-Nuclear, Columbia, SC
 - Westinghouse, West Valley, NY
- Education
 - BS in Chemical Engineering
 - MBA
 - Environmental Management Certification from George Washington University



Integrated Safety Management in Quality Assurance Program Planning Purpose



- Discuss approaches used for integrating Quality Assurance (QA) requirements with Integrated Safety Management (ISM) and associated difficulties and inconsistencies,
- Suggest alternative approach that might be considered to improve consistency and effectiveness of ISM and QA integration.
- Identify tools from DOE and other sources to assist in the integration, and
- Remind you that the Office of Quality Assurance Policy and Assistance is available to assist DOE field elements.



Integrated Safety Management in Quality Assurance Program Planning Typical Approaches



- Some management system document preparers prefer developing Integrated Safety Management (ISM) documentation incorporating Quality Assurance (QA) requirements.
- Some management system document preparers prefer developing a Quality Assurance Program Plan incorporating ISM requirements.
- This is often accomplished through crosswalks because of the overlap of ISM principles and QA criteria.



DOE QUALITY COUNCIL Task Planning Activities



DOE QUALITY COUNCIL TASK PLANNING DOCUMENT

Action Number: TPD-XXXX.YY

**Action Title: Quality Assurance
Program (QAP) Incorporation with
Integrated Safety Management (ISM)**



Potential paths considered

- Requiring a crosswalk of requirements
- Developing a **non-mandatory** DOE template endorsed by the DOE Quality Council in a format similar to that prescribed by some of the Nuclear Regulatory Commission (NRC) Regulatory Guides then eventually consider adopting the template as a DOE Standard.



Examples of Shared Attributes ¹

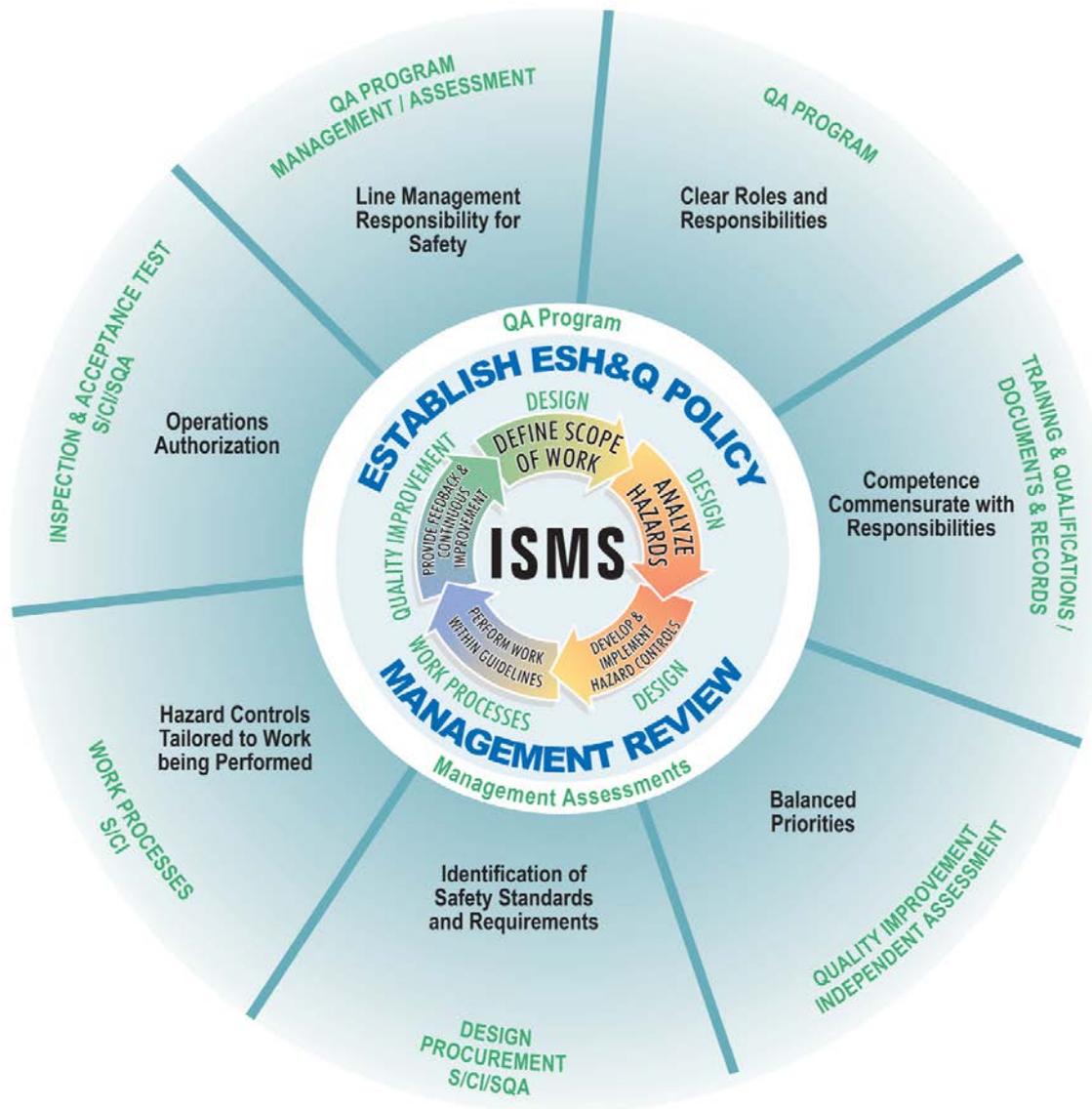


- Expectations for implementation [DEAR 970.5204-2 (c)] (10 CFR 830.121),
- Documentation of the management system (ISMS Principle 7) (10 CFR 830.121),
- Clear roles and responsibilities (ISMS Principle 2) (QA Criterion 1),
- Balanced priorities (resources) (ISMS Principle 4) (QA Criterion 1),
- Feedback and improvement (ISMS Core Function 5) (QA Criteria 3, 8, 9 and 10),
- Line management responsibility (ISMS Principle 1) (QA Criterion 1, General Requirements),
- Competence and qualifications (ISMS Principle 3) (QA Criterion 2)
- Standards and controls for work (ISMS Principle 5 and Core Function 4) (QA Criteria 9 and 5), and
- Graded and tailored controls (ISMS Principle 6) (10 CFR 830.7).

¹DOE G 414.1-2A , *Quality Assurance Management System Guide*



QA Alignment with ISMS





Examples of DOE management system documents with crosswalks



- EM *Quality Assurance Program Plan*
- NNSA, Office of Defense Programs, *Quality Assurance Program*¹
- HSS *Integrated Work Management System*

¹July 2009 draft



Evaluation of NRC Regulatory Guides



- ✓ Many provide standard formats.
- ✓ Many provide direction for content.
- ✓ Most provide expectations.
- ✓ Most provide explanation of requirements.
- ✓ Many provide a level of consistency for documentation.
- ✓ Most provide clarifications in requirements.



DRAFT
**Non-mandatory DOE Quality Council
template¹ presently includes:**



- Outline based on the quality assurance criteria.
- Description of expectations.
- Identification of the specific ISM principles to each expectation/criteria.
- A request for a listing of objective examples for each criteria.
- Language that uses ISM terminology in the text body where practical.

¹Template has only received task team review. Full DOE Quality Council approval is required before endorsement and formal distribution.



EXAMPLE OF DRAFT LANGUAGE



7. Procurement

- Describe how it is ensured that items and services procured meet established requirements.
- Describe how prospective suppliers are evaluated and selected.
- Explain the mechanism used for making a determination for any selected suppliers that continue to provide items and services on an ongoing basis that may not need additional evaluations.
- State whether or not and how safety and quality assurance concerns both receive consideration in procurement decisions. [ISM P 4]
- Identify a clearly-defined set of safety requirements and standards invoked in management contracts. [ISM P 7]



Conclusion



It is difficult to determine how both ISM and QA requirements are fully met if crosswalks are used.

Non-mandatory template may be a useful tool for some Program Offices and some sites during the development of Quality Assurance Program Plans.



Please provide feedback to:

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