

All-In-One Quality Programs

Supplier perspective on auditing 10CFR50
Appendix B and Commercial Grade Programs

Brett McGlone, Quality Systems Program Manager
brett.mcglone@swagelok.com
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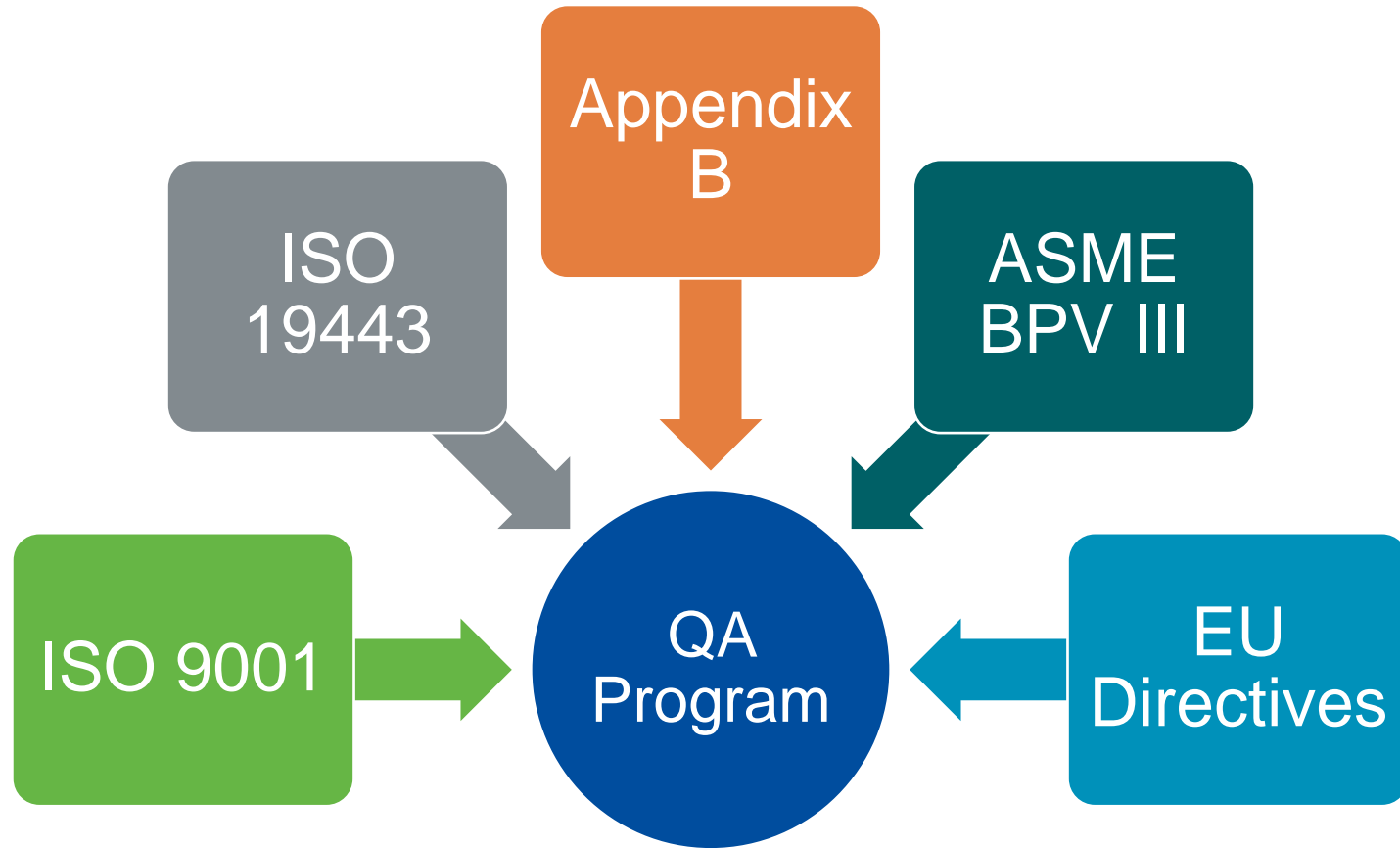


All-In-One Programs

- Requirements suppliers are required to meet
- How an all-in-one quality program is implemented
- Documentation of an all-in-one program
- Audit and survey of an all-in-one program

All-In-One Programs

- Suppliers are required to meet several quality standards depending on the scope of items and services they provide.

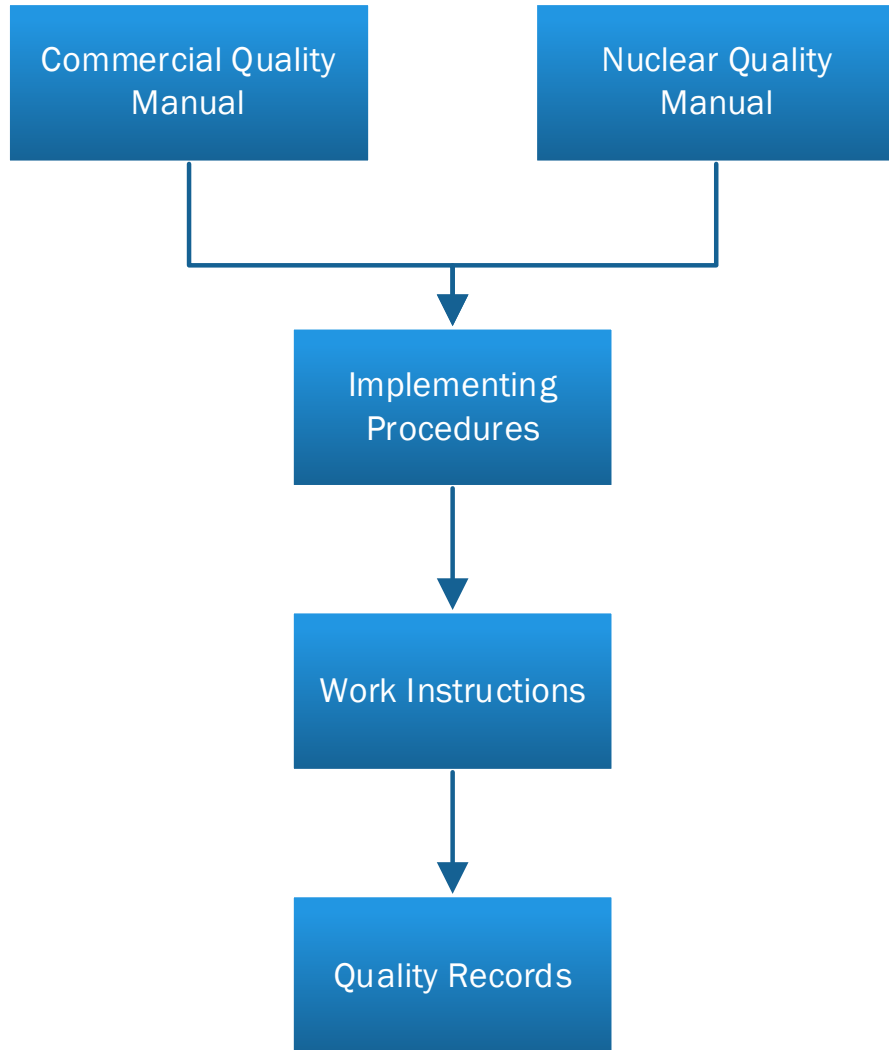


Implementation of All-In-One Programs

- Swagelok implements one system for requirements common to all our products.
 - Training and qualification
 - Document control
 - Procurement
 - Material traceability
 - Inspection
 - Calibration
 - Nonconformances
 - Corrective Actions
 - Audits



Documentation of All-In-One Programs



- Commercial and nuclear quality programs may be in separate manuals or combined into one.
- Same implementing procedures for both programs.
- May have specific procedures for unique safety-related / Code activities, for example design reports.

Audit vs. Survey (NQA-1-2015)

- Audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation...
- Survey: a documented evaluation of an organization's ability to perform activities as verified by a determination of the adequacy of the organization's
 - (a) quality program and/or
 - (b) ability to meet specified requirements

Audit vs. Survey Checklist

- Audit checklist records how a suppliers complies with the specified requirements.

Verify that measures are established and implemented to assure the identification and traceability of items (i.e., materials, parts, weld filler material, etc.) is maintained throughout processing operations.

Note:

Figure 6B, column 2, requires Identification and Traceability. As an example, a tag or stamp (identification) identifying heat number, serial number (traceability).

References:

Appendix B Criteria VIII, XIV

ANSI N45.2 Section 9, 15

ASME Section III

NQA-1 Requirement 8

- Survey checklist records the supplier's controls implemented for the specified critical characteristics.

COMMERCIAL GRADE QUALITY CONTROLS

Describe the controls the supplier implements to maintain lot/material identification throughout manufacturing operations.

(a) Describe how the supplier defines "lot" or "batch" control.

(b) Identify any unique coding system or practices used by the supplier to identify lots/batches.

All-In-One Programs

- Many suppliers are required to implement a wide array of quality requirements.
- Performing an audit and a commercial grade survey at the same time is possible if planned and documented correctly.
- An effective all-in-one program can be documented to meet 10CFR50 Appendix B and control the prescribed critical characteristics.

