

Guidance on Writing a Quality Assurance Manual

Excerpt from, "Requirements for ASME NQA-1 Certification", Issue No.: 3, Date, February 10, 2014:

3.1 The Quality Assurance Manual shall not be a reiteration of the NQA-1 Standard, but rather, a detailed written document which clearly describes the controls for each element of the Nuclear Quality Assurance Program as to who, what, when, where and how the program is being implemented. The Quality Assurance Manual need not be in the same format or sequential arrangement as in the NQA-1 Standard, as long as all the applicable requirements have been covered. The Manual accepted by ASME is the guide for performing the audits and determining continued compliance with the accepted Quality Assurance Program.

3.1.1 It is not a requirement nor desirable that detailed written technical procedures, work instructions, travelers, and/or forms be a part of the Quality Assurance Manual, but rather, the manual satisfactorily address the controls of the applicable NQA-1 Standard requirements for documents that specify quality requirements or prescribe activities affecting quality.

The following is to clarify paragraph 3.1 & subparagraph 3.1.1, and to provide guidance on the type of Quality Assurance (QA) Manuals ASME Audit Teams will be requiring Applicants to provide.

The purpose of the QA Manual is to provide a detailed written document that describes the QA Program with commitment statements identifying which Requirements of Part I and Part II of the NQA-1 Standard are applicable and which are not applicable. The QA Manual will also:

- 1) describe the organization,
- 2) contain senior management's commitment to establishing and maintaining an adequate and effective QA Program, and
- 3) identify the product (items/services) provided under the QA Program, and
- 4) describe the processes used to supply the product (items/services).

The QA Manual is to clearly identify the product (items/services) being provided under the QA Program and provides an understanding of the processes affecting quality which are implemented under the QA Program to supply the product. To understand the processes, specific activities need to be identified as well as the technique used to implement the process/activity. The processes affecting quality are those elements which are addressed by a Requirement (NQA-1, Part I) or Subpart II work practice (NQA-1, Part II) that is relevant in attaining and verifying quality in the supply of the product. The technique used to implement these processes are the "controls" (who, what, when, where and how) which will be audited by ASME. Completing the QA Manual Checklist will serve as an aid in determining whether the QA Manual is an auditable working document with sufficient and adequate "controls" to retain its functionality as an ASME audited working document while permitting future revisions to sub-tier documents under the QA Program to be made in accordance with the controls specified in the QA Manual without need for additional ASME audits. These sub-tier documents are the drawings, procedures, work instructions, forms, travelers and/or tags used to convey specific detailed instructions/information to either complete or record a specific activity. The QA Manual is to prescribe a process which provides a high level of

confidence that future changes to sub-tier documents are developed, reviewed, and approved by people, who as a collective:

- 1) convey understanding of their employer's QA Program
- 2) convey understanding of the NQA-1 Standard, and
- 3) are knowledgeable of the product's technical requirements (customer specifications, and/or referenced standards).

When a company has attained a NQA-1 Quality Program Certificate, the accepted QA Manual will be used by ASME Audit Teams as the basis for conducting future audits and determining continued compliance with the accepted QA Program.

The terms 'who', 'what', 'when', 'where' and 'how' are defined as follows:

What: The QA Manual identifies the activities which affect quality in the supply of the product (items/services).

When: The QA Manual indicates the point of time the activity is required to be performed.

Where: The QA Manual identifies the location(s) at which the activity is performed. Or indicates if the activity is being subcontracted to an approved supplier/vendor.

Who: The QA Manual identifies the individual by title within the organization, at any level, that is responsible for performing the activity. This includes activities which are being delegated; the title of the delegate is to be identified. (In-lieu of a title, providing a clear description of knowledge, experience, training, and educational requirements of the individual required to perform the activity is permissible.)

How: The QA Manual identifies the technique (planning & accomplishment) used to achieve quality, e.g. drawings, procedures, work instructions, forms, travelers and/or tags.

The described¹ processes, if adequately written, will be able to answer the following questions²:

- 1) What is the activity?
- 2) Who is responsible for the activity?
- 3) When is the activity performed?
- 4) Where is the activity performed?
- 5) How is the activity documented?
 - a) When a sub-tier document (procedure, work instruction) is used to provide specific detailed information on completing the activity, has it been referenced in the QA Manual?
 - b) When forms, travelers and/or tags are used to indicate the status of the activity, are the forms, travelers and/or tags exhibited in the QA Manual and completed as samples?

¹ The description of the process need not be written to address all of the controls in one area of the QA Manual.

² Not all questions may be applicable.