

Whited Paper in response Query for Frequency & Qualifications for CG Surveys and ASME Surveys April 2025 Rev. 1

Prepared by Sham Beri

Request from a Client

1. Qualification for those performing commercial grade survey – help us understand where ASME NQA-1 is specifying the requirements for those performing a commercial grade survey.

Note Added question about the potential use of Technical Specialists to lead the surveys and frequency of the surveys.

2. ASME Section III survey versus a commercial grade survey – help us to understand the specific differences between these two activities

References considered for this paper:

- 1. 10 CFR 50 App. B
- 2. ANSI N45.2 12
- 3. ANSI N45.2.23
- 4. NQA-1: 2008/2009a
- 5. 10 CFR Part 21
- 6. EPRI # 3002002982, NP-5652 Rev. 1
- 7. EPRI # 1003105: Dedicating CGI Procured from ISO 9000 Suppliers
- 8. NRC Inspection Manual #43004 dated 02/10/23
- 9. Email with Kerri Kavanagh at Kerri.kavanagh@nrc.gov
- 10. ASME experts ASME Sec. III surveys

Discussion:

1. 10 CFR 50 App. B Criteria 18 states in part "A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by *appropriately trained personnel* not having direct responsibilities in the areas being audited."

Conclusion: CGI Surveys are not in App. B which addresses only "audits."

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2. ANSI N45.2.12 section 2.2 states in part that "*The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to assist in the auditing of the quality assurance programs.*"

Note: Differentiates between "Audit Personnel and Technical Specialists."

3. ANSI N45.2.12 section 5.3 states in part that "Personnel Records - Records shall include documentary evidence of the qualifications and training of auditors and shall be retained."

Conclusion: No mention of Technical Specialists in personnel records.

4. ANSI N45.2.23 section 1.1 states in part that "This Standard also provides requirements and guidance for the qualifications of individuals, henceforth referred to as "Auditor", who participate in an audit, such as **technical specialists**, management representatives, and auditors-in-training."

Conclusion: This has always been interpreted as that a Lead Auditor can also be a Technical Specialist (TS) but not vice versa. This is not uncommon when there is a team of one.

5. NQA-1: 2008/2009a Subpart 2.14 section 603 (h) states in part that "Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys." Section 603 (i) states in part that "The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls. The survey frequency interval may be the same used or supplier audits but shall not exceed the frequency interval for supplier audits."

Conclusion: There is no definitive statement on the qualification of Lead Surveyor. However, there is clear implication that frequency of CG Surveys should be three years or less i.e., same as App. B/NQA-1 audits.

6. EPRI # 3002002982 NP-5652 Rev.1 section 8.4.2 page 8-6 states in part that "In addition, the survey team should include personnel familiar with performance-based evaluations (see EPRI NP-6630 [85]). Technically qualified or trained personnel often can provide valuable input by participating in survey plan development and/or participating as part of the survey team. Personnel qualifications should be delineated in procedures and documented."

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Conclusion: The implication is that the Technically Qualified personnel i.e., TS can participate in the survey. The language in this document does not and is not intended to convey that a technical specialist cannot lead a survey. The technical specialist develops the CC's but may not always be familiar with manufacturing processes and associated quality activities, so its common sense to have someone who is, like a lead auditor, present to assist.

7. EPRI NP-5652 Rev.1 section C page C-1 states in part that "*Technical specialists* should be active participants in the survey planning process. In addition to assembling technical information, <u>technical specialists should work with the survey</u> <u>team leader</u> and supplier as appropriate to identify manufacturing processes and quality activities that are important to ensuring that the items possess the identified critical characteristics. These are the processes and activities that will be observed during conduct of the survey."

Conclusion: Here is implies that TS is a distinct entity & should work with the survey team leader but not replace him/her.

8. EPRI # 1003105: Dedicating CGI Procured from ISO 9000 Suppliers Table A-1 states in part that "Qualification of QA Program Audit Personnel for Nuclear facilities - ANSI N45.2.23 - Some auditor certification practices described in this implementing standard have been adapted for personnel performing commercial-grade supplier surveys."

Conclusion: This seems to indicate that CG Surveys are performed by ANSI N45.2.23 certified auditors.

9. NRC Inspection Manual #43004 dated 02/10/23 states in part that "*The survey should* be conducted by an individual(s) that is also trained in auditing and knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified."

Conclusion: This section requires the survey team is trained in "auditing" thus qualified as an auditor which a typical TS is not.

10. Email from Ms. Kerri Kavanagh at Kerri.kavanagh@nrc.gov is as follows:

Kerri Kavanagh From:kerri.kavanagh@nrc.gov To: Sham Beri Fri, Apr 18 at 10:08 AM

Hi Sham –

So nice to hear from you. Current plan is for me to be in Austin, but lately, that is subject to change.

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There doesn't appear to be one spot that states that the NRC approves/requires lead auditors to be qualified to N45 or NQA-1 and that surveys should be done on a triennial basis. However, it can be pieced together.

RG 1.28 Rev 3 endorses NQA-1-1983. This is the first RG with the regulatory position that suppliers shall be audited on a triennial basis. I am assuming that NQA-1-1983 requires these audits to be performed by qualified lead auditors, but I don't have a copy of 1983.

The next edition that the NRC endorsed via safety evaluation is NQA-1-1994. This was the first edition of NQA-1 to mention commercial grade dedication in 7S-1:

1 O COMMERCIAL GRADE ITEMS Where the design utilizes commercial grade items, the following requirements are an acceptable alter[1]nate to other requirements of this Supplement, *ex*[1]*cept as noted in (b) below and the requirements of* Supplement 4s-1. (a) The commercial grade item is identified in an approved design output document. An alternate com[1]mercial grade item may be applied, provided the cog[1]nizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its appli[1]cation. (b) Source evaluation and selection, where deter[1]mined necessary by the Purchaser based on com[1]plexity and importance to safety, shall be in accordance with para. 3.1 of this Supplement. (cl Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number). *id) After receipt of a commercial grade item, the* Purchaser shall determine that: (7) damage was not sustained during shipment; (2) the item received was the item ordered; (3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements; (41 documentation, as applicable to the item, was received and is acceptable.

The NRC did not find this section to be acceptable (though not documented in a RG) but had the licensees that adopted NQA-1-1994 commit to the following:

NQA-1-1994, Supplement 7S-1, "Supplementary Requirements for Control of Purchased Items and Services," Section 10 addresses requirements for Commercial Grade Items. Based on NRC Generic Letter 89-02 and its endorsement of Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications," the licensees will use the guidance contained in EPRI NP-5652 instead of the NQA-1-1994 requirements.

The next NRC endorsed edition was NQA-1-2008 as endorsed by RG 1.28 revision 4. The NRC worked with NQA-1 to correct section 7 on commercial grade dedication such that a regulatory position was not necessary. I believe this was the first appearance of Subpart 2.14 as well.

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So long winded circular answer is yes – lead auditors can used to conduct commercial grade surveys consistent with NQA-1-1994 and those auditors shall be qualified per the requirements in NQA-1-1994. Since commercial grade survey is part of the acceptance process to make a commercial item safety related, the surveys shall be treated like audits with regard to frequency as discussed in the regulatory positions in RG 1.28 rev 3, 4, 5, and 6.

Hope this helps.

Kerri

Conclusion: Please see Ms. Kerri Kavanagh's the last paragraph of her email.

ASME Surveys

- 1. NCA-4255.3 Approval and Control of Suppliers of Source Material and Services
- (a) The Material Organization or Certificate Holder shall be responsible for the approval of and control of activities performed by suppliers of source materials and subcontracted services. Such control shall provide for source evaluation and selection, evaluation of objective evidence of quality, survey, audit, and examination of items and services upon delivery, as applicable, in accordance with requirements documented in the Material Organization's or Certificate Holder's Program.
- (b) The Material Organization or Certificate Holder shall be responsible for establishing and verifying that the supplier's controls applicable to the activities performed are adequate by:
 - (1) performing a survey of the supplier's quality system, and performing triennial audits covering applicable elements of the approved supplier's established quality system that is consistent with the requirements of this sub article supplemented by annual valuations of the approved supplier's quality system, including a review of the history of conditions adverse to quality, nonconformances, and corrective actions, or
 - (2) having the supplier perform the activities in accordance with controls established by the Material Organization's or Certificate Holder's Program.

NCA-4255.5 Utilization of Unqualified Source Material

(a) As an alternative to NCA-4255.2(b), when included in its scope of activities as permitted by the provisions of this sub-article, a Material Organization may accept certification of the requirements of the material specification that must be performed

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during the melting, heat analysis, and heat treatment of the material, and may use or furnish unqualified source material, provided the requirements of (1) through (5) below are met.

(1) No welding with filler metal has been performed on the unqualified source material. The organization that establishes the material form and issues the source material test report shall not perform any welding with filler metal and shall confirm that no welding with filler metal has been performed.

(2) The Material Organization performs or subcontracts a product analysis to verify the chemical composition of each piece of unqualified source material.

(3) The Material Organization performs or subcontracts all other testing and examination requirements of the material specification on each piece of unqualified source material. Alternatively, the Material Organization may perform or subcontract all other testing and examination requirements of the material specification on each heat and lot of unqualified source material provided

(-a) a source material test report is provided with the unqualified source material that attests that the material is in accordance with the requirements of the material specification that must be performed during the melting, heat analysis, and heat treatment of the material, including the actual results of all required chemical analyses, tests, and examinations as applicable to the product form.

(-b) the unqualified source material is traceable to the source material test report (-c) procurement documents require that suppliers of unqualified source material establish written procedures for identifying source materials in a manner that provides traceability to the source material test report

(-d) the Material Organization reviews and accepts the supplier's identification and traceability procedures and performs an on-site verification for compliance with the procedures at a frequency commensurate with the schedule of production or procurement, but at least once triennially

(-e) upon receipt, the Material Organization shall verify by review of objective evidence, that the requirements of the procurement document have been met

(4) If Certificates of Compliance [see NCA-1225.1(g), NF-2130(b)] are acceptable, in lieu of (3) above, the Material Organization may perform or subcontract all other requirements of the material specification on each heat and lot of unqualified source material.

(5) The provisions of (1) through (4) above are performed in accordance with the Material Organization's Quality System Program.

(b) The provisions of (a)(1) through (a)(4) above may be performed by the Certificate Holder in accordance with its Quality Assurance Program. NCA-4256 Identification, Marking, and Material

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Based upon the above for ASME the testing of each piece of material by chemical analysis is required for all pieces of unqualified source material.

Conclusion:

- 1. Based upon the requirements testing of all other requirements of the material specification i.e. tensile or hardness, can be reduced by performing a survey of the suppliers written program on site. The use of personnel to perform this survey is assumed to be Auditors/Lead auditors.
- 2. The Commercial grade dedication process must identify the critical characteristics of the material being dedicated where these characteristics are identified in ASME III. However, it must be noted that dedication cannot be used to establish unqualified source materials as qualified source material under ASME Section III. It either meets all the requirements of Section III (design requirements) or it does not.
- **3.** Based upon this there are no essential difference between NQA-1 and ASME surveys for Dedication and qualification of unqualified source material.

= End of the Report =