

# NRC Workshop on Vendor Oversight June 2020

## How to Qualify a Supplier using ASME Section III

Jay Gardiner

Senior QA Manager, Curtiss-Wright EMD

Chair, ASME Section III, SubGroup General Requirements

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# How to Qualify a Supplier - Agenda

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## Introduction

This presentation focuses on requirements in ASME Code, Section III, Subsection NCA

If your organization is subject to NRC regulations, compliance with 10CFR50 Appendix B and 10CFR Part 21 is an important additional consideration when procuring safety related material or services

## Definitions (1)

Defined in ASME Subsection NCA-9100

Supplier:

Any individual or organization that furnishes materials or services in accordance with a procurement document.

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## Definitions (2)

Defined in ASME Subsection NCA-9100

Material Organization, Qualified:

an organization surveyed and qualified to provide materials or services in accordance with the requirements of Section III, NCA-3800 or NCA-3900 to the certified Material Organization or Certificate Holder that performed the qualification

## Definitions (3)

Material Organization, Certified:

an organization certified by holding a Quality System Certificate issued by the Society (*ASME*) to provide materials or services in accordance with the requirements of Section III, NCA-3800 or NCA-3900

In other words, the certified Material Organization is the Quality System Certificate holder

## Definitions (4)

### Certificate Holder:

an organization holding a Certificate of Authorization, Certificate of Authorization (Corporate), or Quality Assurance Program Certificate issued by the Society (*ASME*). This does not include the holder of a Quality System Certificate or an Owner's Certificate.

In other words, an organization that holds an N, NPT, NS, NA, or NV Certificate

## Definitions (5)

Survey:

a documented evaluation of an organization's ability to perform Code activities as verified by a determination of the adequacy of the organization's quality program and by a review of the implementation of that program at the location of the work.

In other words, the initial qualification of the subcontractor



## Definitions (6)

Audit:

a documented evaluation performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality program have been developed, documented, and implemented in accordance with specified requirements. An audit does not include surveillance or inspection for the purpose of process control or acceptance of material or items.

In other words, requalification subsequent to a survey

# Authority to Subcontract

## NCA-3125 Subcontracted Services

NCA-3125(a) Allows subcontracting for both Code and non-Code products and services

NCA-3125(b) Allows subcontracting for stress analysis or complete design

NCA-3125(c) Requires the organizations QA Manual to address subcontracting controls and accept responsibility for subcontracted activities

# Responsibilities for Subcontracting

Where do I find my Responsibilities for Subcontracting?

|  | Division | Responsibility                                      | Implementation               | Limitations                  |
|--|----------|---|------------------------------|------------------------------|
| Owner  |          | Not addressed                                       | Not addressed                |                              |
| Designer   | 2        | Not addressed                                       | Not addressed                |                              |
| N Certificate Holder                             | 2        | NCA-3420(c)<br>NCA-3420(d)                          | NCA-3461(a)<br>NCA-4134.18   | NCA-3820(b)<br>NCA-3842.1(a) |
| N Certificate Holder                             | 1        | NCA-3520(e)   | NCA-3561(a)<br>NCA-4134.18   | NCA-3820(b)<br>NCA-3842.1(a) |
| NPT Certificate Holder                           | 1        | NCA-3620(c)   | NCA-3661(a)<br>NCA-4134.18   | NCA-3820(b)<br>NCA-3842.1(a) |
| NS Certificate Holder                            | 1        | NCA-3681(c)   | NCA-3684(a)<br>NCA-4137.18   | NCA-3820(b)<br>NCA-3842.1(a) |
| NA Certificate Holder                            | 1        | NCA-3720(c)   | NCA-3761(a)<br>NCA-4134.18   | NCA-3820(b)<br>NCA-3842.1(a) |
| NV Certificate Holder                            | 1        | NCA-3781(e)   | NCA-3785.1(a)<br>NCA-4134.18 | NCA-3820(b)<br>NCA-3842.1(a) |
| Metallic Material Organization                   | 1        | NCA-3830(c)<br>NCA-4251.2(a)(4)<br>NCA-4251.2(a)(5) | NCA-4255                     | NCA-3820(b)<br>NCA-3842.1(a) |
| Nonmetallic (Concrete) Material Organization     | 2        | NCA-4351.1(a)(3)                                    | NCA-4354                     | NCA-3820(b)<br>NCA-3842.1(a) |
| Nonmetallic (Polyethylene) Material Organization | 2        | NCA-4471.1(c)<br>NCA-4471.5(f)<br>NCA-4471.7(c)     | NCA-4472.3<br>NCA-4472.4     | NCA-3820(b)<br>NCA-3842.1(a) |

## Your Organization's Program (1)

As the Certificate Holder / Certified Material Organization, you shall include the following in your Quality System Program Manual:

- Supplier audit frequency
  - audits shall be conducted at least triennially,
  - audits shall cover all elements of the previously approved(surveyed) Quality System Program
- Annually, between triennial audits, conduct either:
  - an annual audit, or
  - annual performance assessment

## Your Organization's Program (2)

As the Certificate Holder / Certified Material Organization, you are responsible for controls on:

- Source evaluation and selection
- Evaluation of objective evidence of quality
- Survey
- Audit
- Examination of items and services upon delivery

## Initial Qualification

A Survey is the initial qualification tool:

- The survey shall be performed using written procedures or checklists
- Results shall be documented
- Results shall be reviewed by responsible management
- Procedures shall include provisions for:
  - documenting corrective action taken on deficiencies
  - follow-up action to verify corrective action implementation
  - re-audit of deficient areas, when indicated

## Triennial Re-Qualification (1)

An Audit is the appropriate re-qualification tool:

- The audit shall be performed using written procedures or checklists
- Results shall be documented
- Results shall be reviewed by responsible management
- Procedures shall include provisions for
  - documenting corrective action taken on deficiencies
  - follow-up action to verify corrective action implementation
  - re-audit of deficient areas, when indicated

## Triennial Re-Qualification (2)

Audits shall be:

- Conducted at least triennially
- Between triennial audits, conduct an:
  - annual audit, or
  - annual performance assessment



# Performance Assessments

Supplement triennial audits

- Perform a documented review of the suppliers:
  - history of conditions adverse to quality
  - non-conformances
  - corrective actions
- Perform periodic material testing since the last assessment to demonstrate material samples conformance to selected material specification requirements

## Your Supplier's Program (1)

NCA-3842 requires your supplier to have a manual which addresses their Quality System Program. Their manual shall address:

- Section III material requirements
- NCA-4200, NCA-4300 or NCA-4400 (dependent upon material type provided)
- Providing a controlled copy for your organization's use during survey / audit
- Notifying you of changes to their manual

## Your Supplier's Program (2)

- Notifying you of changes to their manual
- Utilization of unqualified source material (if implemented and used)
- Approval and control of suppliers (if implemented and used)
- Shipment of material to parties other than your organization (if implemented and used)

## Your Supplier's Program (3)

### Example:

- Your organization needs the services of an organization that provides a unique service
- The service will be provided on pressure boundary material
- The supplier has an ISO-9001:2015 Certificate but no ISO-9001 program manual
- Their existing program does not address ASME Section III requirements
- ❖ The supplier is required to prepare, approve, and use a Quality System Program Manual to address the program which controls the services they provide as a Qualified Material Organization

## Commercial Grade Dedication

ASME Section III does NOT recognize commercial grade dedication, with two exceptions:

- NCA-3126 allows use of ISO-17025 Certification as a means to qualify calibration suppliers {see also, NCA-4255.3(c) and NCA-4354.3(c)}
- NCA-3127 allows use of ISO-17025 Certification as a means to qualify testing laboratories {see also, NCA-4255.3(d) and NCA-4354.3(d)}

## Exception

When supply of materials or services is dormant:

- The Certificate Holder or Certified Material Organization is not required to perform annual audits / performance assessments in the 1<sup>st</sup> or 2<sup>nd</sup> year after the triennial audit
- The Certificate Holder or Certified Material Organization is required to perform an audit or performance assessment to requalify the supplier before continued use after the supply of materials or services has been dormant

## Other Considerations

If the nuclear power facility is in the United States:

- NRC regulations apply regardless of the supplier's location (domestic or international)
- 10CFR Part 50 Appendix B also needs to be considered
- 10CFR Part 21 also needs to be considered

# Questions?