

**QUALITY SYSTEM PROGRAM  
SURVEY/AUDIT CHECKLIST - 16**

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
1.0	<p><b><u>ORGANIZATION</u></b></p> <p>1.1 Responsibility and authority established for personnel (NCA 3851.3) (10CFR50 B-1) (NQA-1 100/1)                      a. Described in the quality manual</p> <p>1.2 Verify those responsible for defining and measuring the overall effectiveness of the Program: (NCA 3851.3)(10CFR50 B-1)(NQA-1 200/1/1S-1)                      a. are designated,                      b. are sufficiently independent from the pressures of production,                      c. have direct access to responsible management at a level where appropriate action can be initiated,                      d. report regularly on the effectiveness of the Program</p> <p>1.3 Verify defined authority and organizational freedom to: (NCA 3851.3) (10CFR50 B-1)(NQA-1 200/1/1S-1)                      a. Identify Quality Problems                      b. Initiate actions which result in actions                      c. Verify implementation of solutions to those problems                      d. Assure further processing is controlled</p> <p>1.4 Independence of personnel performing verification actions (NCA 3851.3) (10CFR50 B-1)( NQA-1 200/1/1S-1)                      a. Review with individuals assigned responsibilities for checking, auditing, or otherwise verifying that quality control or production activities are performed independent of the individual/organization directly responsible for performing the specific activity.</p> <p>1.5 Delegation of Work (NQA-1 202/1/1S-1)                      a. Verify direct control of all delegated work performed by others by individuals or organization(s) responsible for establishing and executing the Quality Assurance Program.</p> <p>1.6 Interface control (NQA-1 300/1/1S-1)                      a. Determine more than single organization involvement in the execution of activities, the responsibilities, and interfaces, and the authority of each involved organization                      b. Verify external and internal interfaces between organizations are identified for the execution of program activities, where applicable.</p> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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<p><b>2.0</b></p>	<p><b><u>QUALITY ASSURANCE PROGRAM</u></b></p> <p>2.1 Scope of work defined which describe operations performed per (3851.2) (10CFR50 B-II)</p> <p>2.2 Program documentation (NCA 3853) (10CFR50 B-II)(NQA-1 100/2)</p> <ul style="list-style-type: none"> <li>a. Described in a Quality Systems Manual</li> <li>b. Implemented by written procedures</li> <li>c. Method established for customer notification of changes to the program (as required).</li> </ul> <p>2.3 Management review of the status and adequacy of the program (3851.3 (4) (10CFR50 B-I)(NQA-1 100/2)</p> <ul style="list-style-type: none"> <li>a. Review method of reporting of the program effectiveness.</li> </ul> <p>2.4 Indoctrination, Training and Qualification (NCA 3852)(10CFR50 B-II)(NQA-1 200/2/2S-4) Measures are established to assure:</p> <ul style="list-style-type: none"> <li>a. Personnel performing or managing activities affecting quality are indoctrinated or trained.</li> <li>b. The extent of indoctrination and training is commensurate with the activity</li> <li>c. Indoctrination in the general criteria, applicable codes, standards, company procedures, Quality System Program requirements, job responsibilities.</li> <li>d. Training is ongoing</li> </ul> <p>2.5 Qualification of Inspection and Test personnel(NQA-1 302/2/2S-1)</p> <ul style="list-style-type: none"> <li>a. Identify and verify Inspection and Test personnel qualification records are documented and maintained; and include activities covered, objective evidence of education, experience, audit training, examination, basis for qualification, and expiration date</li> </ul> <p>2.6 Qualification of personnel who lead audits. (NCA 3852.2)(NQA-1 303/2/2S-3)</p> <ul style="list-style-type: none"> <li>a. Identify and verify Lead auditor qualification records are documented and maintained; and include objective evidence of education, experience, audit training, examination, and audit participation.</li> </ul> <p>2.7 Certifications of Qualification (NQA-1 400/2/2S-1/2S-3)</p> <ul style="list-style-type: none"> <li>a. Verify certifications for test, inspection, and Lead Auditors are in writing and provide required information in accordance with requirements</li> </ul> <p>2.8 Personnel Records (NCA-3852.2)(NQA-1 500/2/2S-1/2S-3/2S-4)</p> <ul style="list-style-type: none"> <li>a. Maintained for the training and indoctrination of personnel</li> <li>b. Training and Indoctrination records description i.e. logs, records, attendance sheets, etc.</li> </ul> <p>See Section "Process Control" for investigation of personnel qualifications associated with special processes and control of processes.</p> <p><b>(see also ANSI n45.2 &amp; ASME NQA-1)</b></p>		

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3.0	<p><b><u>PROCUREMENT DOCUMENT CONTROL</u></b></p> <p>3.1 Documents for procurement of materials and subcontracted services shall assure their compliance to the applicable requirements of the program (NCA 3855.4)(10CFR50 B-IV)(NQA-1 200/4/4S-1)</p> <ul style="list-style-type: none"> <li>a. Applicable quality program requirements are in procurement documents, and directed to sub tier suppliers</li> <li>b. Technical requirements - standards, drawings, specifications listed</li> <li>c. Special requirements passed (example 10CFR Part 21) as applicable</li> <li>d. Statement of the scope of work to be performed</li> <li>e. identify documents required as well as retention time</li> </ul> <p>3.2 Right of Access (NQA-1 204/4/4S-1)</p> <ul style="list-style-type: none"> <li>a. Procurement documents provide for access to records, and for audit and surveillance at the supplier's facility</li> </ul> <p>3.3 Nonconformances (NQA-1 206/4/4S-1)</p> <ul style="list-style-type: none"> <li>a. Purchase documents describe requirements for participation in the reporting and disposition of non conformances</li> </ul> <p>3.4 Spare and Replacement Parts (NQA-1 207/4/4S-1)</p> <ul style="list-style-type: none"> <li>a. When applicable, procurement documents identify requirements for spare and replacement parts with the order or separately</li> </ul> <p>3.5 Verify the following:</p> <ul style="list-style-type: none"> <li>a. Procurement documents reviewed for adequacy and approved for release by authorized personnel (NCA 3855.4 (d) (10CFR50 B-IV)(NQA-1 300 &amp; 400)</li> <li>b. Revisions and changes controlled (NCA 3853.3)(10CFR50 B-IV)                             <ul style="list-style-type: none"> <li>(1) Approved and reviewed under the same conditions as the original releases</li> </ul> </li> </ul> <p>3.6 Procurement Documents for Subcontracted materials and services (NCA 3855.4)(10CFR50 B-IV)(NQA-1 200/4/4S-1)</p> <ul style="list-style-type: none"> <li>a. Approved sources used:</li> <li>b. Directed to reference the accepted Quality System or controls on documentation that accompanies (and identified to) the source material or service furnished.</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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6.0	<p><b><u>CONTROL OF PURCHASED MATERIALS AND SERVICES</u></b></p> <p>6.1 Measures are established to assure purchased material, source material and subcontracted services conform to the requirements. (NCA 3855.2, 3855.3) (10CFR50 B-VII)(NQA-1 100/7)</p> <p>6.2 AVL in use and current for purchase order dates listed</p> <p>6.3 Source evaluation and approval of Material Organizations, and suppliers of source materials and subcontracted services includes: (NCA 3855.2,3855.3)(NQA-1 100/7/7S-1)</p> <ul style="list-style-type: none"> <li>a. Evaluation of objective evidence of quality</li> <li>b. Audit scope of qualified sources commensurate with procurement</li> <li>c. Audit procedure or checklist including verification of corrective action. (NCA 3859.1)</li> <li>e. Audits of Material Organizations or Supplier shall be conducted triennially and supplemented by either annual audits or performance assessments or annual evaluations of the Supplier's Quality System including conditions adverse to quality, nonconformances and corrective actions or having the supplier perform the activities in accordance with controls established</li> <li>f. Assessments shall include a review of the Material Organizations quality performance and may include periodic testing. Such testing shall be conducted during the period since the last assessment by the party performing the evaluation. (NCA 3842.2.(i).</li> <li>g. Audits or testing performed when using ASME certificate holder providing 10CFR50 "B" materials. (10CFR50 "B" Crti. VII)</li> </ul> <p>6.4 Alternate to surveys of Calibration Laboratories. accredited to ANSI/ISO/IEC 17025:2005 ( NCA-3855.3(c) Verify:</p> <ul style="list-style-type: none"> <li>a. Calibration Laboratory Scope of Accreditation covers the needed measurement parameters, ranges, and uncertainties.</li> <li>b. Review of objective evidence for conformance to the procurement documents when utilizing Accredited Laboratories</li> <li>c. This activity is documented in the Quality Program Manual</li> <li>d. Procurement documents require that calibration certificates/reports include: <ul style="list-style-type: none"> <li>- Identification of the laboratory equipment/standards used</li> <li>- As Found data</li> <li>- As Left data</li> </ul> </li> </ul> <p>6.5 Control of Supplier Generated Documents (NQA-1 400/7/7S-1)</p> <ul style="list-style-type: none"> <li>a. Verify submittal and evaluation of supplier generated documents is in accordance with the procurement documents</li> </ul> <p>6.6 Inspection of purchased materials on receipt or evaluations of services performed are from approved sources. (NCA 3855.3)(10CFR50 B-VII)NQA-1</p> <ul style="list-style-type: none"> <li>a. Verification of materials and services to meet requirements of the purchase order (NCA 3855.3) and (NCA 3858.4))(10CFR50 B-VII)NQA-1) <ul style="list-style-type: none"> <li>(1) Review of documentation and certifications</li> <li>(2) Required statements and/or other contractual documentation req'mts</li> </ul> </li> <li>b. Accepted and rejected material is identified and separated as practicable</li> <li>c. Reports of inspections documented and reviewed, and traceable to the controlling document and revisions level.</li> </ul> <p>6.7 Control of Supplier Nonconformances Discussed under Section 15</p> <p>6.8 Commercial Grade Items Discussed under Section 10)</p> <p><b>(see also ANSI N45.2 &amp; ASME NQA-1)</b></p>		

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7.0	<p><b><u>IDENTIFICATION, MARKING, AND MATERIAL CONTROL</u></b></p> <p>7.1 Establishment and maintenance of material identification procedures or instructions (NCA 3856)(10CFR50 B-VIII)(NQA-1 100/8) Verify controls at:</p> <ul style="list-style-type: none"> <li>a. Receiving</li> <li>b. Storage</li> <li>c. Shipping</li> </ul> <p>7.2 Verify identification of material maintained throughout manufacturing, processing, testing or examination (NCA 3856.1)(10CFR50 B-VIII)(NQA-1 200/8/8S-1)</p> <ul style="list-style-type: none"> <li>a. Maintained on materials or documents traceable to the materials</li> <li>b. The status of acceptance of the material can be determined at all times while under the supplier's control (NCA 3858.4)(10CFR50 B-XIII)</li> </ul> <p>7.3 Materials and source material marking (NCA 3856.2)(10CFR50 B-VIII)(NQA-1 202/8/8S-1)</p> <ul style="list-style-type: none"> <li>a. Method of marking will not cause contamination or discontinuities and is traceable to the material specification or controlling document.</li> </ul> <p>7.4 Transfer of identification for divided pieces (NCA 3856.1(c) )(NQA-1 202/8/8S-1)</p> <ul style="list-style-type: none"> <li>a. Cut piece markings or tagging are identifiable to the parent material</li> </ul> <p>7.5 Identification of completed material (NCA 3856.3)(10CFR50 B-VIII)(NQA-1 300/8/8S-1)</p> <ul style="list-style-type: none"> <li>a. Material marking traceable to reports of applicable tests and examination</li> <li>b. Verify size excluded material traceable to documentation via tags, packaging or containers (NCA 3856.3(f))</li> <li>c. Identification of items is protected</li> <li>d. Status of acceptance of items is known</li> <li>e. Environmental conditions evaluated to safeguard against deterioration and loss of identification</li> </ul> <p>7.6 Welding and Brazing Material Identification (NCA 3856.4)</p> <ul style="list-style-type: none"> <li>a. Weld materials identified on packages with: <ul style="list-style-type: none"> <li>(1) Heat Number or Lot Number</li> <li>(2) Code identifiable to the Certified Material Test Report</li> <li>(3) Specification</li> <li>(4) Grade and Classification Number</li> <li>(5) Material Organization name and trade designation</li> </ul> </li> </ul> <p>7.7 Limited Life Items (NQA-1 302/8/8S-1)</p> <ul style="list-style-type: none"> <li>a. Identified and controlled for shelf or operating life</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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8.0	<p><b><u>PROCESS CONTROL</u></b></p> <p>8.1 Manufacturing controlled under system of process sheets, checklists, travelers, or equivalent procedures: (NCA 3857.1)(10CFR50 B-IX)(NQA-1 100/9)</p> <ul style="list-style-type: none"> <li>a. Traceable to the materials being processed (represented)</li> <li>b. Process sheets released under system of control and approval</li> <li>c. Describe or detail sequence of operations for processing materials</li> <li>d. Contains acceptance criteria</li> </ul> <p>8.2 Welding (NCA 3857.3)(10CFR50 B-IX)(NQA-1 300/9/9S-1)</p> <ul style="list-style-type: none"> <li>a. By qualified procedures (ASME Section IX or specified)</li> <li>b. By qualified personnel or operators</li> <li>c. Weld materials controlled</li> </ul> <p>8.3 Heat treating (NCA 3857.2)(10CFR50 B-IX)(NQA-1 200/9/9S-1)</p> <ul style="list-style-type: none"> <li>a. Controlled by procedure or specification</li> <li>b. Calibration and qualification records maintained and current</li> <li>c. When contracted, method used for demonstration of direct control and supervision of this activity</li> <li>d. Heat treat charts reviewed and traceable to heat, material and ovens</li> </ul> <p>8.4 Nondestructive Examination (NCA 3857)(10CFR50 B-IX)(NQA-1 200/9/9S-1,2S-2)(Tables NCA-7100)</p> <ul style="list-style-type: none"> <li>a. Controlled by qualified procedure.</li> <li>b. Personnel are qualified in accordance with ASME Sections Paragraph NB, NC, ND, NE, NF, and NG-5520 (SNT-TC-1a 2011) &amp; procedure.</li> <li>c. Qualification records of nondestructive examination personnel are documented and maintained.</li> <li>d. When subcontracted, records of subcontractor's procedures (reviewed and approved) and personnel qualifications are verified to current reports of NDE                             <ul style="list-style-type: none"> <li>(1) Delegation and approval of Level III authority where appropriate.</li> </ul> </li> </ul> <p>8.5 Control of contracted services for processing materials (From Section 7(NQA-1 507/7/7S-1)</p> <ul style="list-style-type: none"> <li>a. Verify subcontracted services are from approved sources</li> <li>b. Verify subcontracted procedures and processes reviewed and approved by the supplier</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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<p><b>9.0</b></p>	<p><b><u>INSPECTION and EXAMINATION</u></b></p> <p>9.1 Inspections and examinations controlled by written procedure referenced standard or material specification. (NCA 3858.1)(10CFR50 B-X)(NQA-1 100/10)</p> <p>9.2 Final inspection and examinations conducted to material specification (NQA-1 600/10/10S-1)</p> <ul style="list-style-type: none"> <li>a. Examinations conducted with calibrated or standardized equipment</li> <li>b. Materials traceable to records of inspection and examination</li> <li>c. Inspection and examinations traceable to the controlling document and revision level.</li> </ul> <p>9.3 Inspection and hold points (NCA 3858.4)(10CFR50 B-X)(NQA-1 300/10/10S-1)</p> <ul style="list-style-type: none"> <li>a. Hold points for inspection and/or examinations listed on process sheets</li> <li>b. Customer witness/hold points accommodated by the system</li> </ul> <p>9.4 Records of inspection and examination (NCA 3853.5, NCA 3858.4)(10CFR50 B-X)(NQA-1 602/10/10S-1)</p> <ul style="list-style-type: none"> <li>a. Measures taken to assure the status and results of any required inspection can be determined at any time</li> </ul> <p>9.5 Inspection and Test Status (NCA-3855.4)(NQA-1 100/14)</p> <p>Basic (100) Inspection and test status indicators</p> <ul style="list-style-type: none"> <li>a. Verify the use of tags, markings, shop travelers, stamps or inspection records identifiable to the material inspected or tested to provide verification of item status and acceptability</li> <li>b. Verify operation sequence followed to preclude inadvertent use, installation or operation of items prior to completion of all activities</li> <li>c. Authority for placement or removal of indicating tags, labels and the sign off of sequentially assigned operations shall be indicated by procedure or traveler notation</li> </ul> <p>9.6 Verify qualifications of personnel conducting tests and examinations as required</p> <p>9.7 Sampling (NQA-1 402/10/10S-1)</p> <ul style="list-style-type: none"> <li>a. Sampling inspections based on recognized standard practices and provide for validity for their selection</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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10.0	<p><b><u>TEST CONTROL</u></b></p> <p>10.1 Tests controlled by written procedure, referenced standard or material specification. (NCA 3858.1)(10CFR50 B-XI)(NQA-1 200/11/11S-1)</p> <p>a. As required by the material specification</p> <ol style="list-style-type: none"> <li>1 Chemistry</li> <li>2 Mechanical</li> <li>3 Heat Treat Data</li> <li>4 Impact Data</li> </ol> <p>10.2 Records of tests (NCA 3853.5, NCA 3858.4)(10CFR50 B-XI)(NQA-1 600/11/11S-1)</p> <p>a. Results of required tests are recorded, reviewed, and are traceable to the controlling document and revision level. Records indicate Tested Item identification Date test performed, Type of observation, Results, Test Equipment identification ,Action taken in connection with any deviations noted and Person(s) evaluating the results</p> <p>10.3 Computer Program Test Procedures (NQA-1 400/11/11S-2)</p> <p>a. Review computer program validation to provide evaluating technical adequacy of programs used for tests</p> <p><b><u>UTILIZATION OF UNQUALIFIED SOURCE material</u></b></p> <p>10.4 Unqualified source material (NCA 3855.5) Included in the Program Scope of Activities</p> <ol style="list-style-type: none"> <li>a. Procedure in use to detail such qualification activities.</li> <li>b. No weld with filler metal/weld repair.</li> <li>c. Unqualified source material manufacturer's melt process is known</li> <li>d. Performs chemical analysis on each piece of stock material</li> <li>e. Performs or subcontracts all other requirements of the material specification on each piece of unqualified source material. Alternatively, perform or subcontract all other requirements by each heat and lot provided:             <ol style="list-style-type: none"> <li>(1) A CMTR is provided with the unqualified source material.</li> <li>(2) The unqualified source material is traceable to the CMTR</li> <li>(3) Procurement documents require that suppliers establish written procedures for identifying source materials in a manner that provides traceability to the CMTR.</li> <li>(4) The Material Organization reviews, accepts, and performs an onsite verification of the supplier's identification and traceability procedures at a frequency commensurate with the schedule of production or procurement, but at least once triennially</li> <li>(5)The Material Organization shall perform receipt inspection activities to verify that the requirements of the Material Organization's purchase Order have been met.</li> </ol> </li> </ol> <p><b><u>DEDICATION OF COMMERCIAL GRADE MATERIALS (NQA-1 700/7/7S-1)</u></b></p> <p><b><u>Part II 2.14</u></b></p> <p>10.5 Identified in an approved design output document</p> <ol style="list-style-type: none"> <li>a Alternate Commercial Grade Item may be used if the intended function is verified</li> <li>b. Source evaluation and selection in accordance with (200) of this section</li> <li>c. Methods are applied and identified to provide reasonable assurance that the item meets the acceptance criteria identified</li> </ol> <p><b>(see also ANSI N45.2 &amp; ASME NQA-1)</b></p>		

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11.0	<p><b><u>CONTROL of MEASURING and TEST EQUIPMENT</u></b></p> <p>11.1 Verify procedures or standards available to assure tools, gages and instruments are checked and properly adjusted. (NCA 3858.2)(10CFR50 B-XII)(NQA-1 300/12/12/S-1)</p> <ul style="list-style-type: none"> <li>a. Frequency established for calibration of instruments</li> <li>b. Accuracy (tolerance) established for instruments</li> </ul> <p>11.2 Calibration records or logs (NCA 3858.2)(10CFR50 B-XII)(NQA-1400/12S-1)</p> <ul style="list-style-type: none"> <li>a. Traceable to standards or procedures used</li> </ul> <p>11.3 Equipment identification (NCA 3858.2)(10CFR50 B-XII)(NQA-1 300/12S-1)</p> <ul style="list-style-type: none"> <li>a. Instruments carry identification traceable to records of calibration</li> <li>b. Status of calibration identified on instruments (stickers, color code, tags, etc.)</li> </ul> <p>11.4 Measurement standards (NCA 3858.2(b))(10CFR50B-XII)(NQA-1300/12S-1)</p> <ul style="list-style-type: none"> <li>a. Instrument calibrations traceable to nationally recognized standards or documented basis for calibration were no national standard exist.</li> <li>b. Calibration services are audited. (NCA 3855.2) or ISO 17025 accredited as contained in section 7.</li> </ul> <p>11.5 Discrepancies in Measuring or Test Equipment (NCA 3858.3) (10CFR50 B-XII)(NQA-1 302/12S-1)</p> <ul style="list-style-type: none"> <li>a. Determine system used to identify materials accepted by equipment found to be out of calibration</li> <li>b. Examine System used for reporting measuring and test equipment deficiencies:                             <ul style="list-style-type: none"> <li>(1) Internally</li> <li>(2) To customers</li> </ul> </li> </ul> <p>11.6 Handling and Storage (NQA-1 302.2/12/12S-1)</p> <ul style="list-style-type: none"> <li>a. Verify handling and storage activities are adequate to insure maintenance of accuracy</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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12.0	<p><b><u>HANDLING, STORAGE, and SHIPPING</u></b></p> <p>12.1 Instructions or procedures established to prevent damage loss of identification, and deterioration of materials during: (NCA 3857.4) (10CFR50 B-III)(NQA-1 300/13S-1)</p> <ul style="list-style-type: none"> <li>a. Handling</li> <li>b. Storage</li> <li>c. Shipping</li> </ul> <p>12.2 Preservation of products (NCA 3857.4)(10CFR50 B-XIII)(NQA-1 400/13/13S-1)</p> <ul style="list-style-type: none"> <li>a. Shelf life during storage</li> <li>b. Protection from contamination</li> <li>c. Status of acceptance of products known at all times</li> </ul> <p>12.3 Customer required special provisions for packaging and shipping(NQA-1 200/13/13S-1)</p> <ul style="list-style-type: none"> <li>a. As applicable by customer purchase order</li> </ul> <p>12.4 Operators (NQA-1 500/13/13S-1)</p> <ul style="list-style-type: none"> <li>a. Supplier determination for training and experience in the use of special handling and lifting equipment</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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13.0	<p><b><u>NONCONFORMING MATERIAL</u></b></p> <p>13.1 Control of nonconforming items, processes and activities established by procedure (NCA 3858.5)(10CFR50 B-XV) NQA-1 100/15)                      a. Nonconforming material identified (NCA 3858.5)                      b. Segregated (as practicable)</p> <p>13.2 Documentation of Nonconformances (NCA 3858.5)(10CFR50 B-XV)(NQA-1 200/15S-1)                      a. Nonconformances described by reports identified to the material or service                      b. Nonconforming material disposition responsibility and authority defined</p> <p>13.3 Re-examination of repaired or reworked items (NCA 3858.5)(10CFR50 B-XV)(NQA-1 405/15/15S-1)                      a. Repaired items reexamined in accordance with applicable procedures</p> <p>13.4 Control measures established (NCA 3858.5)(10CFR50 B-XV)(NQA-1 400/15/15S-1)                      a. To prevent further processing of nonconforming materials or source materials                      b. Notification to customers for participation in acceptance evaluation of nonconforming material</p> <p>13.5 Nonconforming item disposition documented (NCA 3858.5)(10CFR50 B-XV):(NQA-1 400/15S-1)                      a. Verify a disposition is made and documented for nonconforming items such as Use-as-is, reject, repair or rework                      b. Verify technical justification for the acceptability of nonconforming items dispositioned as repair or rework                      c. Design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design                      d. Notification to customers for participation in evaluations for "Use-as-is" or "Rework" dispositions when required by purchase agreement</p> <p>13.6 Authority established for the placement and removal of tags denoting the acceptability of items (NCA 3858.4)(10CFR50 B-XIV)(NQA-1 300/15/15S-1)</p> <p>13.7 Controls of supplier nonconformances.</p> <p>Note: Reports of nonconformance require verification of dispositions</p> <p>13.7 10 CFR 21 condition are evaluated as part of the nonconformance.</p> <p><b>(see also ANSI N45.2 &amp; ASME NQA-1)</b></p>		

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**QUALITY SYSTEM PROGRAM  
SURVEY/AUDIT CHECKLIST - 16**

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
14.0	<p><b><u>CORRECTIVE ACTION</u></b></p> <p>14.1 The cause of conditions adverse to established quality levels shall be determined and corrected. (NCA 3859.2)(10CFR50 B-XVI)(NQA-1 100/16)</p> <p>a. Reporting method used by supplier</p> <p>14.2 Documentation (NCA 3859.2)(10CFR50 B-XVI)(NQA-1 100/16)</p> <p>a. Description of condition adverse to established quality levels</p> <p>b. Corrective action taken to prevent recurrence described</p> <p>c. Evaluation and approval of completed corrective action</p> <p>d. Evaluation of 10 CFR 21 applicability</p> <p>14.3 Subcontractor corrective action performance (NCA 3859.2(c)) (10CFR50 B-XVI)(NQA-1 100/16)</p> <p>a. Quality program extends to subcontractor corrective actions</p> <p><b><u>CAR SUPPLEMENT - REPORTING OF DEFECTS AND NONCONFORMANCES - 10 CFR PART 21</u></b></p> <p>The following will be reported as an observation when required by the scope of the audit</p> <ol style="list-style-type: none"> <li>1. Procedure for implementation and reporting</li> <li>2. Posted for personnel</li> <li>3. Personnel awareness through training programs</li> </ol> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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**QUALITY SYSTEM PROGRAM  
SURVEY/AUDIT CHECKLIST - 16**

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
15.0	<p><b><u>QUALITY ASSURANCE RECORDS</u></b></p> <p>15.1 Procedure for the preparation and maintenance of quality records provides: (NCA 3853.4)(10CFR50 B-XVII)(NQA-1 100/17)</p> <ul style="list-style-type: none"> <li>a. Duration of record retention and disposition indicated</li> <li>b. Identification of types of records maintained</li> <li>c. Transmittal and distribution as applicable</li> </ul> <p>15.2 Identification and traceability(NCA 3853.4)(10CFR50 B-XVII)(NQA-1 200/17S-1)</p> <ul style="list-style-type: none"> <li>a. Records traceable to procedures, specifications, materials and instruments used for acceptance</li> <li>b. Records identify the status and the results of all required tests and examinations.</li> </ul> <p>15.3 Retrievalability of records (NCA 3853.4)(10CFR50 B-XVII)(NQA-1 200/17S-1)</p> <ul style="list-style-type: none"> <li>a. Quality records are retrievable and available so that errors and results of any required test or examination can be determined for materials</li> </ul> <p>15.4 Authentication of Records (NQA-1 300/17S-1)</p> <ul style="list-style-type: none"> <li>a. Validation of documents prior to entry into record maintenance system</li> <li>b. Records shall stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated</li> </ul> <p>15.5 Classification (NQA-1 400/17S-1)</p> <p>When applicable, and detailed by customer purchase orders, Classification and maintenance of records for other than nonpermanent shall be defined. Retention in fire rated cabinets or dual storage as applicable.</p> <p>15.7 Maintenance of records (NQA-1 800/17S-1)</p> <ul style="list-style-type: none"> <li>a. Records indexed</li> <li>b. Quality records are retrievable and available for review</li> <li>c. Corrections to records made in accordance with procedures</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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QUALITY SYSTEM PROGRAM  
SURVEY/AUDIT CHECKLIST - 16

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
16.0	<p><b><u>CERTIFICATION REQUIREMENTS (NCA3860)</u></b></p> <p>16.1 Certification Requirements for Material Organizations                      (a) The Material Organization shall provide a CMTR or C of C as applicable, for the material. (3861.a)                      (1) The certification affirms that contents of the report are correct and accurate and that all test results are in compliance.                      (2) Results of analyses, tests, examinations, and heat treatments required by the material specification not performed are included on the CMTR or C of C or identified attachments.                      (3) including certification to dimensional requirements for product form conversion                      (b) transmit all certifications required by NCA-3862.1(b), received from other Material Organizations or approved suppliers at the time of shipment. (3861.b)                      (c) The Certificate Holder shall complete all operations not completed by the Material Organization and shall provide a CMTR for all operations performed by him or his approved suppliers. The Certificate Holder shall certify that the contents of the report are correct and accurate and that all test results and operations performed by the Certificate Holder or his approved suppliers are in compliance with the requirements (3861.c)</p> <p><b><u>CERTIFICATION OF MATERIALS</u></b></p> <p>16.2 The Material Organization's Material Test Report shall include (NCA-3862)                      a. The results of all required chemical and mechanical tests, examinations analysis required by the Material Specification (NCA 3862.1(a) &amp; (b)) except as provided for weld material in lieu of a Mill Test Report.                      b. Specific time and temperatures when required to be reported (NCA 3862.1(d))                      c. The Material Organization Quality System Certificate (materials) number and expiration date shall be indicated or (NCA 3862.2)                      d. When qualified by other than the Society, the Revision and Date of the written program to which the material was manufactured (May be on accompanying documentation) (NCA 3862.2)                      e. The approved supplier's certification for the operations performed (NCA 3862.1(b))                      f. Certifications for Non ASME materials as required by order.</p> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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SURVEY/AUDIT CHECKLIST - 16**

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
17.0	<p><b><u>AUDITS</u></b></p> <p>17.1 Verify program of planned, scheduled periodic audits to assure compliance and evaluation of all aspects of the Quality System(NCA 3859.1) (10CFR50 B-XVIII)(NQA-1 100 &amp; 300/18S-1)</p> <ul style="list-style-type: none"> <li>a. Procedures available to establish schedules and frequency</li> <li>b. Previous audits available for review</li> <li>c. Preparation of Audit Plans</li> </ul> <p>17.2 Audit performance and responsibilities (NCA 3859.1)(10CFR50 B-XVIII)(NQA-1 302/18S-1)</p> <ul style="list-style-type: none"> <li>a. Audits conducted using written procedures or checklists</li> <li>b. Auditors independent of areas investigated</li> </ul> <p>17.3 Qualification of Lead Auditors (NCA 3852.2(c))(10CFR50 B-XVIII)(NQA-1 200/2S-3)</p> <ul style="list-style-type: none"> <li>a. Based on education, experience, audit training, and examination and audit participation</li> <li>b. Review records of qualification</li> </ul> <p>17.4 Deficiencies (NCA 3859.1)(10CFR50 B-XVIII)(NQA-1 600 &amp; 700/18S-1)</p> <ul style="list-style-type: none"> <li>a. Follow-up action taken in areas of deficiencies continued to provide final resolution</li> <li>b. Follow-up actions, including reaudits, are documented</li> </ul> <p>17.5 Documentation of Audits and reports (NCA 3859.1)(10CFR50 B-XVIII)(NQA-1 500/18S-1)</p> <ul style="list-style-type: none"> <li>a. Results of audits, investigations, reaudits are reviewed and approved</li> <li>b. Reviewed by management having responsibility in areas audited</li> </ul> <p>(see also ANSI N45.2 &amp; ASME NQA-1)</p>		

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