

THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS

GUIDE FOR ASME NUCLEAR SURVEY TEAMS FOR SURVEY OF APPLICANTS FOR QUALITY SYSTEM CERTIFICATE (POLYETHYLENE MATERIAL ORGANIZATION)

INTRODUCTION

This guide is prepared solely for the use of ASME Nuclear Survey Teams when conducting a survey of a Material Organization's Quality System Program. It does not replace or interpret the requirements of the ASME Boiler and Pressure Vessel Code, Section III, Divisions 1 & 2 Subsection NCA, General Requirements

This guide is based on Section III, Divisions 1. It is subject to revisions based on changes in Section III of the ASME Boiler and Pressure Vessel Code.

A survey must cover a Quality System Manual and its implementation. This Guide outlines the requirements of NCA-4470, which establish a Quality System Program. However, Survey Teams are advised that the scope of work, the Quality Assurance Manual, its layout and implementation will vary from Applicant to Applicant; therefore, all aspects of this Guide may not apply and all possible aspects are not necessarily covered. The format of this Guide is not intended to influence the review of the Manual and its implementation. A NCA-4250 Quality System Program is invoked as modified and supplemented in NCA-4400. Therefore, the basis of this Checklist is the use of NCA-4250, and where applicable, modified to meet the additional requirements, restrictions, prohibitions, and terminology under NCA-4400.

Send suggestions for revisions to the Guide to the ASME Director, Accreditation and Certification.

Questions of possible need for Code interpretation raised by Survey Teams shall be submitted to ASME. When an interpretation is to be submitted by an Applicant, the Team Leader shall advise the Applicant that all such inquiries must be submitted to the Secretary, Committee on Construction of Nuclear Facility Components (III).

HOW TO USE THIS GUIDE

Review each checklist item in the "Quality Program Survey Checklist" and note the paragraph number in the QA Program which covers the subject addressed in the column labeled "Q.S. Program References." In the case where an item gives more than one alternative for fulfilling the applicable Code requirement, mark "N/A" in the column labeled "Q.S. Program References" adjacent to those alternatives that do not apply.

The original of this Guide shall be provided to the Team Leader along with sufficient copies for each member of the Survey Team including the Team Leader.

Checklist for Quality System Program Requirements

Company Name: _____

Quality Manual Revision #: _____ **Date:** _____

Applicant for Polyethylene Material Organization	(check if applicable)
Polyethylene Material Manufacturer	☐
Polyethylene Material Supplier	☐
Polyethylene Source Material Manufacturer	☐
Natural Compound Manufacturer	☐
Pigment Concentrate Compound Manufacturer	☐
Polyethylene Compound Manufacturer	☐
Supplier Control (NCA-4472.3, NCA-4472.4)	
Evaluation of Polyethylene Service Suppliers	☐
Nondestructive Examination, Testing & Calibration	☐
Calibration	☐

Checklist for Quality System Program Requirements

Company Name: _____

Quality Manual Revision #: _____ Date: _____

Item No.	Quality Element	Code Reference	Quality System Manual Reference
	NCA-4473 - QUALITY PROGRAM REQUIREMENTS* NCA-4473(b) invokes a NCA-4250 Quality System Program with modifications per NCA-4400		
	NCA-4251 - RESPONSIBILITY AND ORGANIZATION		
1	NCA-4251.1 - General		
1A	The Polyethylene Material Organization establishes Q.S. Program for control of quality and traceability of polyethylene material/source material. The Program is planned, documented, implemented, and maintained	NCA-4251.1 NCA-4473	
1B	The Program includes technical aspects and planning for accomplishment of activities affecting quality. The Program provides for special controls, processes, test equipment, tools, and skills to attain and verify quality.	NCA-4251.1	
2	NCA-4251.2 - Scope and Applicability		
2A	Quality Manual defines specific activities included in the scope of work proposed to perform: 1) Operations performed during melting, processes, services, design, supply, manufacture, dimensions and certification requirements as: a) Polyethylene Source Material Manufacturer b) Natural Compound Manufacturer c) Pigment Concentrate Compound Manufacturer d) Polyethylene Compound Manufacturer e) Polyethylene Material Manufacturer f) Polyethylene Material Supplier g) Polyethylene Service Supplier 2) Testing or examination required by the material specification and certification of the results. 3) Receipt, identification, verification, handling, storage, and shipment of polyethylene material or polyethylene source material. 4) Qualification of Polyethylene Service Suppliers 5) (Not Applicable) 6) Utilization of unqualified polyethylene source material is prohibited.	NCA-4251.2(a)(1) Appendix DD NCA-4471.1 NCA-4471.2 NCA-4471.3 NCA-4471.4 NCA-4471.5 NCA-4471.6 NCA-4471.7 NCA-4251.2(a)(2) NCA-4251.2(a)(3) NCA-4251.2(a)(4) NCA-4473(b)(7) NCA-4473(b)(1)	
2B	The Program includes measures to comply with requirements of NCA-4200 and NCA-4470 to the extent necessary, to assure compliance with the (polyethylene material and polyethylene source material) requirements of Section III.	NCA-4200 NCA-4470	
3	NCA-4251.3 - Organization		
3A	The organization structure provides the persons and organization performing Quality Systems functions the required authority and organizational freedom.	NCA-4251.3(a)	
3B	Persons and organizations responsible for defining and measuring the overall effectiveness of the Program shall: 1) be designated. 2) be sufficiently independent from the pressures of production. 3) have direct access to management where appropriate action can be initiated. 4) report regularly on the effectiveness of the Program.	NCA-4251.3(b)	

Checklist for Quality System Program Requirements

Company Name: _____

Quality Manual Revision #: _____ Date: _____

Item No.	Quality Element	Code Reference	Quality System Manual Reference
3C	Organization structure, functions, authority, and lines of communication shall be documented. Persons and organizations responsible for the Q.S. Program and verification of quality shall have sufficient authority, access, and organization freedom to: 1) identify quality problems. 2) initiate, recommend, or provide solutions, 3) verify implementation of solutions, 4) assure further processing, delivery, or use is controlled until proper disposition has occurred.	NCA-4251.3(c)	
3D	Individuals and groups assigned responsibility of checking, auditing or otherwise verifying production and quality control activities shall be independent of the individual or group performing the specific activity. Such persons shall not report directly to the supervisor with immediate responsibility for the work being verified.	NCA-4251.3(d)	
3E	Management shall regularly review the status and adequacy of the Program.	NCA-4251.3(e)	
NCA-4252 - PERSONNEL			
4	NCA-4252.1 - Indoctrination, Training and Qualification of Personnel		
4A	Measures are established to assure all personnel performing or managing activities affecting quality are indoctrinated and trained. Indoctrination and training measures shall include: 1) Personnel to be indoctrinated and trained shall be identified (documented). 2) Extent of indoctrination and training shall be commensurate with the nature of the activity as well as the education, experience, and proficiency of the person. 3) Personnel shall be indoctrinated in the general criteria, applicable codes, standards, company procedures, Quality System Program requirements, job responsibilities, and authority related to the function. 4) Training shall provide initial proficiency, maintain proficiency, and adapt to changes.	NCA-4252.1(a)	
4B	NDE personnel shall be qualified in accordance with Appendix XXVI-5420.	Appendix XXVI-5420	
4C	Persons who lead audits shall be qualified based on education, experience, training, audit participation, and examination as defined in the Quality System Program.	NCA-4252.1(c)	
5	NCA-4252.2 - Personnel Records		
5A	Records of indoctrination & training shall be maintained.	NCA-4252.2(a)	
5B	NDE personnel qualification records shall be documented and maintained.	NCA-4252.2(b)	
5C	Lead audit personnel qualification records including education, experience, audit training, examination and audit participation are documented and maintained.	NCA-4252.2(c)	
NCA-4253 - PROGRAM DOCUMENTATION			
6	NCA-4253.1 - Quality System Manual		

Checklist for Quality System Program Requirements

Company Name: _____

Quality Manual Revision #: _____ Date: _____

Item No.	Quality Element	Code Reference	Quality System Manual Reference
6A	The Quality System Program shall be described in a Quality System Manual which shall be the major basis for demonstration of compliance with Division 1.	NCA-4253.1(a)	
6B	The Program documented in the Manual shall be implemented by written procedures which are maintained either separately or in the Manual.	NCA-4253.1(b)	
6C	Technical procedures and processes, such as nondestructive examination, are not part of the Manual, however, the controls of such shall be covered by the Manual.	NCA-4253.1(c)	
6D	The controls for making the approved revisions of the Manual (electronic or hard copy) available to organization personnel, are described.	NCA-4253.1(d)	
7	NCA-4253.2 - Procedures, Instructions, and Drawings		
7A	Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances.	NCA-4253.2(a)	
7B	These documents shall include acceptance criteria.	NCA-4253.2(b)	
8	NCA-4253.3 - Document Control		
8A	The preparation, issue, and change of documents that specify quality requirements, such as Quality System Manuals, purchase specifications, instructions, procedures, and drawings, shall be controlled to assure the correct documents are being used at the location where the activity is performed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.	NCA-4253.3	
9	NCA-4253.4 - Quality Assurance Records		
9A	Records that furnish evidence of quality shall be specified and maintained. Records shall be legible, identifiable and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.	NCA-4253.4	
10	NCA-4253.5 Records of Examinations and Tests		
10A	Characteristics required to be reported by the material specification and this Section shall be verified and the results recorded. Records shall be traceable to the document and revision to which an inspection, examination, or test was performed.	NCA-4253.5	
	NCA-4255 - CONTROL OF PURCHASED POLYETHYLENE MATERIALS, POLYETHYLENE SOURCE MATERIALS, AND SERVICES		
11	NCA-4255.1 – General		
11A	Measures established to assure purchased polyethylene material, polyethylene source material and subcontracted services conform to the requirements of Division 1.	NCA-4255.1(a)	
11B	Repair is prohibited	NCA-4473(b)(1) NCA-4473(b)(3)	(Not Applicable)
11C	Measures are designed to prevent the use of incorrect or defective polyethylene material or polyethylene source material which have not received the required examinations or tests.	NCA-4255.1(c)	
12	NCA-4255.2 - Sources of Polyethylene Material, Polyethylene Source Material and Services		

Checklist for Quality System Program Requirements

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Item No.	Quality Element	Code Reference	Quality System Manual Reference
12A&B	Polyethylene material, polyethylene source material and services shall be furnished by qualified Polyethylene Material Organization through evaluation by ASME or by a Certificate Holder .	NCA-4255.2 NCA-4472.1 NCA-4472.2	
12C	Polyethylene Service Supplier shall be surveyed & qualified by the Polyethylene Source Material Manufacturer or Polyethylene Material Manufacturer using the service.	NCA-4472.3	
13	NCA-4255.3 - Approval and Control of Suppliers of Source Material and Services		
13A&B	Prohibited.	NCA-4473(b)(1)	(Not Applicable)
13C&D	Accreditation by International Laboratory Accreditation Cooperation Mutual Recognition Arrangement with the additional requirements of NCA-4255.3 (c) for calibration and NCA-4255.3 (d) for testing.	NCA-4473(b)(1) NCA-4255.3(c)&(d) NCA-4472.3 NCA-4472.4	
13E	The Polyethylene Material Organization is responsible for assuring all materials and activities conform to applicable requirements of NCA-4250 and NCA-4470.	NCA-4250 NCA-4470	
14	NCA-4255.4 - Procurement Document Control		
14A	Procurement documents include requirements to assure compliance with the requirements of Division 1.	NCA-4255.4(a)	
14B	Procurement documents require polyethylene material, polyethylene source material or subcontracted services be furnished to the requirements of NCA-4470.	NCA-4255.4(b)	
14C	Procurement documents require qualified polyethylene service suppliers through evaluations by a party other than the Society to reference the accepted quality system or controls established by the Polyethylene Material Organization (excluding Polyethylene Material Supplier) or Certificate Holder on documentation that accompanies the polyethylene source material or services furnished.	NCA-4255.4(c)	
14D	Procurement documents "that specify quality requirements or activities" shall be reviewed for adequacy and approved for release by authorized personnel.	NCA-4255.4(d)	
15	NCA-4255.5 - Utilization of Unqualified Source Material		
15A	Prohibited	NCA-4473(b)(1)	
	NCA-4256 - IDENTIFICATION MARKING AND CONTROL OF POLYETHYLENE MATERIAL AND POLYETHYLENE SOURCE MATERIAL		
16	NCA-4256.1 - General		
16A	Control is established to assure that correct and accepted polyethylene material or polyethylene source material is used. Identification shall be maintained on these materials or on documents traceable to these materials, or in a manner which assures that the identification is established and maintained.	NCA-4256.1(a)	
16B	Measures established for controlling and identifying polyethylene material or polyethylene source material throughout the manufacturing process, during tests, examinations, and during receipt, storage, handling, and shipment.	NCA-4256.1(b)	
16C	Identification marking shall be transferred when polyethylene material or polyethylene source material is divided.	NCA-4256.1(c)	

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Company Name: _____

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Item No.	Quality Element	Code Reference	Quality System Manual Reference
17	NCA-4256.2 - Marking		
17A	Polyethylene materials and polyethylene source materials shall be identified by any method acceptable to the purchaser which will not result in harmful contamination or sharp discontinuities and will identify these materials in accordance with the material specification.	NCA-4256.2 NCA-4473(b)(8) NCA-4473(b)(9)	
18	NCA-4256.3 - Identification of Polyethylene Material		
18A	The identification of polyethylene material is to be permanently marked in accordance with NCA-4473(b)(8) and additional marking required by Section III, Division 1 to facilitate traceability to reports of the results of all tests and examinations.	NCA-4256.3(a) NCA-4473(b)(8)	
18B	(Not Applicable).	NCA-4473(b)(1)	
18C	A marking symbol or code may be used, provided such code or symbol is defined & described in the Polyethylene Material Manufacturer's Quality System Manual and the Certified Polyethylene Test Report.	NCA-4256.3(c) NCA-4473(b)(8)(e)	
18D	Material specification shall be met except where exempted or superseded by Division 1. When requirements or provisions of Division 1 conflict with the requirements of the material specification, the material specification and classification number shall be followed with an asterisk (*) to indicate that the material specification has been modified as shown on the certified polyethylene test report.	NCA-4256.3(d)	
18E	Prohibited	NCA-4473(b)(1)	
18F	(Not Applicable).	NCA-4473(b)(10)	
19	NCA-4256.4 - Welding and Brazing Materials Identification		
19A	(Not Applicable).	NCA-4473(b)(1)	
	NCA-4257 - PROCESS CONTROL		
20	NCA-4257.1 - General		
20A	Processes affecting polyethylene materials, polyethylene source materials, or services are controlled. Special processes that control or verify quality, such as fusion or nondestructive examination, are performed by qualified personnel using qualified procedures.	NCA-4257.1	
21	NCA-4257.2 - Manufacturing Process Control		
21A	Operations shall be performed using process sheets, shop procedures, checklists, travelers, or equivalent procedures. Measures established to ensure control of processes in accordance with the material specification and rules of Division 1.	NCA-4257.2	
22	NCA-4257.3 - Welding		
22A	(Not Applicable).	NCA-4473(b)(1)	
23	NCA-4257.4 - Handling, Storage, Shipping and Preservation		

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Company Name: _____

Quality Manual Revision #: _____ Date: _____

Item No.	Quality Element	Code Reference	Quality System Manual Reference
23A	Instructions shall be established for handling, storage, shipping, and preservation of polyethylene material or polyethylene source material to prevent damage or deterioration.	NCA-4257.4	
	NCA-4258 - CONTROL OF EXAMINATIONS, TESTS, AND NONCONFORMING POLYETHYLENE MATERIAL & POLYETHYLENE SOURCE MATERIAL		
24	NCA-4258.1 - Inspection, Examination and Test Control		
24A	Inspections, examinations, and tests shall assure conformance with the material specification and Division 1.	NCA-4258.1(a)	
24B	Inspections or examinations shall be planned. Characteristics to be inspected or examined, and methods to be employed, shall be specified. Results shall be documented.	NCA-4258.1(b)	
24C	Tests shall be planned. Characteristics to be tested and methods to be employed shall be specified. Results shall be documented and their conformance with acceptance criteria shall be evaluated.	NCA-4258.1(c)	
25	NCA-4258.2 - Control of Measuring and Test Equipment		
25A	Procedures shall be in effect to assure tools, gages, instruments, and other measuring and testing devices used to verify compliance with the Material Specification and Section III are calibrated and adjusted at specific periods or use intervals. Periodic checks may be performed to determine that calibration is maintained.	NCA-4258.2(a)	
25B	Calibration shall be against certified equipment having known valid relationships and documented traceability to nationally recognized standards, where such standards exist. If no nationally recognized standard exists, document basis for calibration.	NCA-4258.2(b)	
25C	Control measures shall include equipment identification and calibration status by equipment marking or on records traceable to the equipment.	NCA-4258.2(c)	
26	NCA-4258.3 - Discrepancies in Measuring or Testing Equipment		
26A	When discrepancies in equipment are found at calibration, corrective action shall be taken, and polyethylene material and polyethylene source material measured or tested since the previous calibration shall be reviewed to determine that requirements have been met.	NCA-4258.3(a)	
26B	When periodic checks are performed, polyethylene material or polyethylene source material discrepancies need only be resolved to the previous check, provided: 1) The methods used and frequency of periodic checking are described in calibration procedures; and 2) The calibration discrepancy was found by periodic check.	NCA-4258.3(b)	
27	NCA-4258.4 - Inspection and Test Status		
27A	Measures established so that status and results of required inspections, examinations, or tests can be determined at any time. Status is maintained by indicators such as physical location and tags, marking, shop travellers, stamps, inspection records, or other suitable means. The authority for application and removal of indicators shall be specified.	NCA-4258.4	
28	NCA-4258.5 - Control of Nonconforming Polyethylene Material and Polyethylene Source Material		
28A	Control shall be established to prevent the use of polyethylene material or polyethylene source material that does not conform to requirements.	NCA-4258.5(a)	
28B	Polyethylene material or polyethylene source material with nonconformances shall be identified, segregated, and reviewed for acceptance or rejection by documented procedures. The responsibility and authority for the disposition of nonconformances shall be defined.	NCA-4258.5(b)	

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Company Name: _____

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Item No.	Quality Element	Code Reference	Quality System Manual Reference
28C	Repair is prohibited	NCA-4473(b)(3)	
28D	Control of further processing of nonconforming polyethylene material or polyethylene source material, pending a decision on its disposition, shall be established and maintained. These controls shall extend to notification of affected organizations, as appropriate.	NCA-4258.5(d)	
NCA-4259 - AUDITS AND CORRECTIVE ACTION			
29	NCA-4259.1 Audits		
29A	Internal audits shall be performed in accordance with the requirements of (b) through (f) below:	NCA-4259.1(a)	
29B	Audits shall be performed to written procedures or checklists by personnel not having direct responsibility in the areas being audited.	NCA-4259.1(b)	
29C	Audit results shall be documented by auditing personnel for review by management having responsibility in the area being audited.	NCA-4259.1(c)	
29D	Procedures shall include documentation of corrective action taken to deficiencies. Follow-up action shall be taken and documented; including reaudit, if necessary.	NCA-4259.1(d)	
29E&F	In addition to audits of Polyethylene Service Suppliers, a comprehensive system of planned and periodic internal audits shall be carried out to assure compliance with all aspects of the Quality System Program and to determine the effectiveness of the Program. All elements of the Quality System Program shall be audited at least annually. (NCA-4473(b)(5)).	NCA-4259.1(e)&(f) NCA-4473(b)(5)	
30	NCA-4259.2 - Corrective Action		
30A	Conditions adverse to quality such as failures, malfunctions, deviations, defective material and equipment, nonconformances, and quality system deficiencies, are identified and reported to management. Measures assure cause of conditions adverse to established quality levels is determined and corrected.	NCA-4259.2(a)	
30B	The identification of significant or recurring conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to management.	NCA-4259.2(b)	
30C	These requirements shall extend to the performance of Polyethylene Service Suppliers corrective action measures.	NCA-4259.2(c)	
NCA-4474 – CERTIFICATION REQUIREMENTS			
31	Certificates of Analysis. The Polyethylene Source Material Manufacturer shall supply a Certificate of Analysis. (NCA-4471.1(d))		
31A	Certificate of Analysis shall include polyethylene source material identification as required by NCA-4473(b)(9), actual test and examination results, and any other required certifications.	NCA-4474.1(a)	
31B	A certification shall be included that affirms that contents of the Certificate of Analysis are correct and accurate and that all test results and examinations performed by the organization and its subcontractors are in compliance with the material specification and the specific material requirements of Division 1.	NCA-4474.1(b)	
31C	Required Certificates of Analysis shall be transmitted at the time of shipment.	NCA-4474.1(c)	

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Company Name: _____

Quality Manual Revision #: _____ Date: _____

Item No.	Quality Element	Code Reference	Quality System Manual Reference
32	NCA-4474.2 Certified Polyethylene Test Reports. The Polyethylene Material Manufacturer and Polyethylene Material Supplier shall provide a Certified Polyethylene Test Report for polyethylene material		
32A	The Certified Polyethylene Test Reports shall include polyethylene material identification as required by NCA-4473(b)(8), actual test and examination results, and any other required certifications.	NCA-4474.2(a)	
32B	A certification shall be included that affirms that contents of the report are correct and accurate and that all test results and operations performed by the organization and its subcontractors are in compliance with the material specification and the specific material requirements of Section III, Division 1.	NCA-4474.2(b)	
32C	The Polyethylene Material Manufacturer shall also certify that the polyethylene material conforms to the applicable dimensional requirements.	NCA-4474.2(c)	
32D	The Polyethylene Material Manufacturer and Polyethylene Material Supplier shall transmit all required Certified Polyethylene Test Reports, including Certificates of Analysis from the Polyethylene Source Material Manufacturer, at the time of shipment.	NCA-4474.2(d)	
33	NCA-4474.3 Additional Certification Requirements		
33A	The Certified Polyethylene Test Report shall include the actual results of all required physical and mechanical property tests. A certification that the polyethylene source material used was made from virgin polyethylene, not scrap or regrind polyethylene material, shall also be included.	NCA-4474.3(a)	
33B	When required tests or nondestructive examinations are subcontracted, the approved Polyethylene Service Supplier's certification for the operations performed shall be furnished as an identified attachment to the Certified Polyethylene Certified Test Report.	NCA-4474.3(b)	
33C	When operations other than tests or nondestructive examinations that require maintenance of traceability are subcontracted, these operations and the approved Polyethylene Service Supplier performing them shall be listed on the Certified Polyethylene Test Report, or the approved Polyethylene Service Supplier Suppliers.	NCA-4474.3(c)	
33D	Reporting of actual dimensions and visual examination results is required.	NCA-4474.3(d)	
33E	Polyethylene material identification shall be described in the Certified Polyethylene Test Report.	NCA-4474.3(e)	
34	NCA-4474.4 - Quality System Program Statement		
34A	When the Polyethylene Material Organization holds a Quality System Certificate, the organization's Certificate number and expiration date shall be shown on the Certified Material Test Report or Certificate of Compliance, or on a Certificate of Analysis and Certified Polyethylene Test Report.	NCA-4474.4(a)	
34B	When the organization has been qualified by a party other than the Society, the identification, revision and date of the applicable written Quality System Manual shall be shown on the Certificate of Analysis and Certified Polyethylene Test Report.	NCA-4474.4(b)	
34C	The inclusion of the Quality System Certificate number and expiration date or reference to identification, revision and date of the applicable Quality System Manual shall be considered as the organization's certification that all activities have been performed to the requirements of Division 1.	NCA-4474.4(c)	