



Department of Energy
National Nuclear Security Administration
Washington, DC 20585
January 14, 2004

The Honorable John T. Conway
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW.
Suite 700
Washington, D.C. 20004

Dear Mr. Chairman:

Action 3.3 of the Department's Quality Assurance Improvement Plan (QAIP) requires the National Nuclear Security Administration (NNSA) to validate and verify that quality assurance programs are effectively implemented for the design, procurement, fabrication, construction, and operation of safety systems. The completion date for this action is January 2004.

The NNSA approach to complete this action was recently developed in a workshop held at the Nevada Site Office on November 13-14, 2003. We appreciate the contribution of Ms. Neysa Slater-Chandler of your staff to the success of the workshop. As a result of the workshop, we have developed an approach and schedule that will result in a technically sound and comprehensive validation and verification of effective implementation of quality assurance programs. Our projected completion date is now July 2004.

We have directed our Site Offices to complete Action 3.3 in accordance with the approach and updated schedule. A copy of our direction to the Site Offices is enclosed for your information. This direction describes our approach to completing this action.

Should you or your staff have any questions regarding the above, please contact Mr. Rabi Singh of my staff at (301) 903-5864.

Sincerely,

A handwritten signature in black ink, appearing to read "Everet H. Beckner".

Everet H. Beckner
Deputy Administrator
for Defense Programs

Enclosure

cc w/enclosure:
M. Whitaker, DR-1
B. Cook, EH-1





Department of Energy
National Nuclear Security Administration
Washington, DC 20585
December 29, 2003

MEMORANDUM FOR MANAGER, LIVERMORE SITE OFFICE
MANAGER, LOS ALAMOS SITE OFFICE
MANAGER, NEVADA SITE OFFICE
MANAGER, SANDIA SITE OFFICE
MANAGER, KANSAS CITY SITE OFFICE
MANAGER, PANTEX SITE OFFICE
MANAGER, SAVANNAH RIVER SITE OFFICE
MANAGER, Y-12 SITE OFFICE

FROM:

Everet H. Beckner
Deputy Administrator
for Defense Programs

SUBJECT:

ACTION: Supplement Guidance on Quality Assurance
Improvement Plan Action 3.3

Consistent with the Department's Quality Assurance Improvement Plain (QAIP) for defense nuclear facilities, issued via memorandum to each of you on March 25, 2002, Action 3.3 requires that "NA will validate and verify that quality assurance programs are effectively implemented for the design, procurement, fabrication, construction, and operation of Safety Systems." The approach to be used to address this action was discussed at a workshop held at the Nevada Site Office on November 13-14, 2003. The final approach, developed in consultation with your staff, is included as Attachment 1 for your use. Additionally, a consistent reporting table was developed at the workshop, and is provided as Attachment 2.

The completion date for Action 3.3 is listed as January 2004. Given the approach developed, the schedule has been revised to ensure that we develop a technically defensible product. You are requested to meet the following updated schedule for completing Action 3.3: (1) select safety systems to be assessed and define your assessment schedule by January 9, 2004; (2) complete an initial assessment using the developed approach by January 31, 2004; (3) complete all assessments by May 30, 2004; (4) transmit your findings via a validation memorandum to my office using the reporting table by June 15, 2004. Given this schedule we intend to document our findings in a closeout letter to the Defense Nuclear Facilities Safety Board by July 2004. Note that once your initial assessment is completed in January 2004, we may convene a workshop in early February to review initial results and revise the assessment approach as needed.



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D. Crandall, NA-11
M. Thompson, NA-117
X. Ascanio, NA124
T. D'Agostino, NA-13
R. Singh, NA-124
J. Mangeno, NA-3.6
J. Kimball, NX
P. Chimah, NX
G. Betzen, KCSO
D. Zweifel, SRSO
J. Sanchez, NSO
K. Waltzer, PxSO
M. Glassman, YSO
L. Cordis, LSO
M. Hamilton, SSO

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

QAIP 3.3: NA Will Validate and Verify That Quality Assurance Programs are Effectively Implemented for the Design, Procurement, Fabrication, Construction, and Operation of Safety Systems

The overall approach for addressing this commitment will be for each of the site offices to select appropriate safety systems and by answering a set of questions, reach an overall conclusion regarding the effectiveness of Quality Assurance (QA) Program Implementation. This can be thought of as a mini vertical slice QA review focused on specific safety system(s) to provide objective evidence that QA Programs are validated and verified. For the purpose of this effort, work on safety systems that has been completed within the past two years can be used to answer the questions provided below. If no work on a safety system has been completed for a given topical area within the past two years, you may answer the questions from a program implementation (expectation) perspective.

For this effort validation refers to validating that an appropriate quality assurance program is in place, and verification refers to verifying implementation of that program via answers to a set of questions. For validation, evaluate implementing procedures for Design, Procurement, Fabrication, Construction, and Operation of safety systems to ensure they incorporate applicable requirements of approved Quality Assurance program description.

Answers to the questions may simply reference previous work if appropriate. One example could pertain to the work completed by most NNSA sites to address the implementation of DOE Order 420.1, Facility Safety. The DOE O420.1 exercise did examine mechanisms in place (both Federal and Contractor) related to aspects of QA Programs. Another example could be work completed to address DNFSB Recommendation 2000-2, Configuration Management Vital Safety Systems.

The verification questions are based on the quality assurance criteria found in 10 CFR Part 830.122. For each of the topical areas mentioned in QAIP 3.3, the ten QA criteria found in 10 CFR Part 830.122 were reviewed to select those most appropriate to that topical area. Positive answers to the questions should be based on objective evidence that an independent person could review to reach the same overall conclusion as the answer supplied. For example, while we do not desire to collect design review reports, we would like to ensure that such reports are available if you state that design reviews have been completed. The overall approach is to address each of the topical areas in the commitment separately. The bullets provided below each question are the type of objective evidence that should be available to demonstrate that the question is positively addressed.

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

Verification Questions:

Design of Safety Systems:

D1: Are safety systems being designed and/or modified using sound engineering principles and appropriate standards?

- Approved authorization basis that identifies safety functions and functional requirements.
- Design criteria linked to safety function and functional requirements.
- Design criteria explicitly checked against the set of appropriate standards.

D2: Is the adequacy of the design products for safety systems being validated and verified prior to approval and implementation?

- Contractor mechanism for completing design reviews explicitly used.
- Contractor design reviews completed by appropriate personnel.
- NNSA site office mechanism for participating or completing design reviews explicitly used.
- Participation in design reviews by NNSA project personnel with appropriate support from subject matter experts.
- Independent peer reviews completed as necessary.
- Specific training for design reviewers.

D3: Are applicable requirements and design bases incorporated into design work and design changes?

- Design reports demonstrate that requirements and design bases met.
- Design calculations and analyses demonstrate that requirements and design bases met.

D4: Are design interfaces identified and controlled during design?

- Integrated Safety Management during design defined and documented.
- Documented Safety Analysis requirements planned and scheduled, including appropriate design inputs and outputs.
- Design interfaces identified, evaluated, and incorporated.

D5: Are design control processes and mechanisms reviewed and approved before safety system design proceeds?

- Design control procedures and mechanisms explicitly identified and documented.
- Design control procedures and mechanisms reviewed and approved.
- Surveillance of design control work completed, to ensure that procedures and mechanisms are being properly executed.

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

D6: Are adequate records of design products for safety systems defined and maintained?

- Design configuration management plan that defines those records that are developed and maintained.
- Evaluation of design records.
- Design calculations and analyses documented and retrievable.

Procurement of Safety Systems:

P1: Are applicable requirements and design bases established and incorporated into procurement activities?

- Use of standard specifications/industry standards for procurements.
- Identification of critical hold points prior to commencing procurement.
- Definition of critical elements, attributes, and receipt inspection requirements using a defined process for all purchases.
- End-users develop specifications, identify critical attributes, and participate in receipt inspections.
- Provide clear requirements to subcontractors, vendors, & those doing the work.
- Maintain effective configuration management by incorporation of changes to As-Built drawings.
- Use of multi-discipline subject expert (SME) reviewers to review design changes prior to design change authorization.
- Engineering specifies the required certifications.

P2: Are prospective suppliers evaluated and selected on the basis of specified criteria?

- Send qualified personnel on vendor audits and surveillances.
- Define and control purchase processes at the front end to gain the desired results.
- Pre-qualify vendors/suppliers, including sub vendor/suppliers.

P3: Have you established and implemented processes to ensure that approved suppliers continue to provide acceptable items and services?

- Surveys, visits, inspections of vendor/suppliers.
- Site/facility qualified personnel review and approve vendor changes for in-progress procurements. Cognizant personnel allow no vendor changes of approved designs without customer authorization.
- Site insists on notification/approval of substitutions or changes. Use of “or equivalent” parts/services are approved by site technical staff.
- Site use of QA and suspect/counterfeit parts clauses in procurement contracts.
- Site Lessons Learned system includes procurement activities.
- Vendor inspections look at the product and QA documentation.
- Inclusion of on-site verification requirements as part of the procurement contract.

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

- A formal process is established that ensures the thorough understanding of procurement specifications and technical requirements and communicates effectively with suppliers

P4: Are specified items, services, and processes inspected and tested using established acceptance and performance criteria?

- Receipt inspections performed by end-users, technically qualified design organization personnel, or qualified receipt inspectors.
- Clear identification of the critical item elements and attributes to be verified during the receipt inspection.
- Technically qualified personnel or end-users develop specifications, identify critical attributes, and participate in receipt inspections.
- Use of graded receipt inspections.
- Definition of critical elements, attributes, and receipt inspection requirements for purchases.
- Non-conforming items identified and dispositioned.
- Integrated system pre-testing of critical systems prior to shipping from the vendor

P5: Is equipment used for inspections and tests calibrated and maintained?

Fabrication of Safety Systems:

F1: Does the fabricator perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements?

- Fabrication work is performed using approved instructions, procedures, or other appropriate means.
- Items/materials utilized in the fabrication process are identified and controlled to ensure their proper use.
- Items/materials utilized in the fabrication process are maintained to prevent their damage, loss, or deterioration.
- Equipment used during the fabrication process is calibrated and maintained.

F2: Was status, identification, and control of fabricated items and suppliers controlled?

- An appropriate self-life program exists and is implemented.
- A non-conforming reporting process exists and is implemented.
- Non-conforming parts and supplies are controlled, tagged, and segregated when practical to prevent inadvertent use.
- Disposition of questionable items is appropriately determined.

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

F3: Does a formal process exist that ensures the thorough understanding of the fabrication design requirements prior to initiating fabrication?

- Preparation, issue, and change of documents that specify quality requirements such as procedures are established, controlled and utilized to control production quality.
- Status, identification and control of fabricated items (part numbering, storage, separation of bad parts). Processes are utilized to control materials in-process and finished items.
- A formal process is established for acceptance of fabricated items.

F4: Are special processes (e.g., welding, nondestructive examinations, heat treating) performed in fabricating the safety systems, and if so, are the process, personnel, and process materials qualified?

- The processes and process parameters are specified in approved procedures.
- Process operators are qualified and certified as capable of performing the specified process.
- Process materials (e.g., weld filler metal, NDE chemicals and equipment) are controlled to be within specified parameters.
- Special process documents and records are controlled and maintained on file.

Construction of Safety Systems:

C1: Do you have a work control process for construction of safety systems?

- Procedures and/or mechanisms are established and utilized to ensure a thorough understanding of requirements prior to initiating construction activities.
- Procedures and/or mechanisms are established and utilized to ensure that work planning is integrated at the facility/process level and fully analyzes hazards and develops appropriate controls.
- Safety systems are constructed in a manner that ensures high confidence that the system will function as designed and meet operational specifications.

C2: Is testing acceptance criteria consistent with safety system performance requirements?

- A formal process for testing and acceptance of safety system performance has been established.
- Safety system are maintained and periodically operated in a manner that ensures that the system will meet acceptance specifications.
- Technically qualified personnel have authority to assess appropriate information and facilities in order to verify acceptance and perform inspections/tests.

ATTACHMENT 1 – NNSA Approach for Addressing QAIP Action 3.3

C3: Are construction work activities and tasks verified in the field?

- Procedure and or mechanisms are established and utilized by construction personnel who define oversight and inspection activities to ensure products meet specified requirements.
- Inspection test data and information, including witness verification and hold points, are evaluated for conformance with applicable plans, specifications, and identified acceptance criteria.
- Pertinent operating manual, equipment parts listing have been received and are being controlled and maintained.
- Formal process for turnover from construction to operations established and utilized.

Operation of Safety Systems:

O1: Are personnel trained to operate safety systems?

- Operations personnel adequately trained to perform their assigned duties and responsibilities relative to operation of safety systems.
- Operations, maintenance, and engineering personnel, including subcontractors, trained to perform their assigned duties and responsibilities relative to maintenance of safety systems.

O2: Do safety system personnel receive continuing training?

- Operations, maintenance, and engineering personnel receive necessary refresher training and additional training necessary to maintain proficiency in safety system operations.

O3: Are safety systems operated in accordance with approved procedures?

- Safety system operations activities (including system/equipment status monitoring, operation, inspections, etc.) conducted using approved procedures.
- Safety system maintenance conducted using approved policies and procedures for preventive, predictive, and corrective maintenance activities.
- Procedures independently reviewed and verified/validated for technical content, consistency with safety basis, accuracy, sequence of steps/actions etc. by qualified individuals who were not significantly involved in their development.

O4: Are appropriate records prepared, maintained, and evaluated regarding the operation and maintenance of safety systems?

- Logs and records completed and maintained concerning safety system operation; findings from operator rounds, tours, and inspections, etc. of the system; shift turnover sheets; equipment alignment checklists; system alarms; equipment deficiency reports; and documentation of abnormal operating conditions, problems, concerns.

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- Results of system maintenance, tests, inspections, calibrations, etc., maintenance logs, are evaluated to identify trends, reliability issues, and potential problems.

O5: Are safety systems operated consistent with controls and standards?

- System equipment operated and maintained consistent with system design requirements, safety basis assumptions, applicable standards, and manufacturers recommendations.
- Safety system testing performed that verifies that the system performs acceptably (i.e., that test acceptance criteria consistent with system performance requirements and applicable standards are met).
- All work on the safety system (including system changes and modifications, upgrades, and maintenance) subject to a configuration management work control and change control process that ensures that consistency is maintained between the system requirements, the installed system, and associated documents.
- System equipment/components appropriately identified and labeled consistent with the system design and safety bases and facility documentation.

O6: Are safety systems being properly maintained and calibrated, including appropriate process monitoring and data collection?

- Maintenance activities formally planned, scheduled, reviewed, approved, and coordinated with affected organizations.
- Status of safety system maintenance activities is known.
- System components that are susceptible to degradation over time (e.g., seals, gaskets, o-rings, etc.) identified and scheduled for monitoring and replacement consistent with applicable standards and manufacturer recommendations.
- Equipment used to operate safety systems, monitor safety system performance, collect safety system data, and verify that test acceptance criteria are met calibrated and maintained.

ATTACHMENT 2 – Common NNSA QAIP Action 3.3 Reporting Table

QAIP 3.3: Verification and Validation of Quality Assurance Programs for Safety System Design, Procurement, Fabrication, Construction, and Operation				
Review Questions and Objective Evidence Guidance	Yes/No	Validate by Standards/Requirements and Process/Procedures	Verify by Objective Evidence	Institutionalized Yes/No
<p style="text-align: center;">Design</p> <p>System Reviewed: _____</p> <p>D1: Are safety systems being designed and/or modified using sound engineering principles and appropriate standards?</p> <p>D2: Is the adequacy of the design products for safety systems being validated and verified prior to approval and implementation?</p> <p>D3: Are applicable requirements and design bases incorporated into design work and design changes?</p> <p>D4: Are design interfaces identified and controlled during design?</p> <p>D5: Are design control processes and mechanisms reviewed and approved before safety system design proceeds?</p> <p>D6: Are adequate records of design products for safety systems defined and maintained?</p>	<p>Yes, where review questions can be answered positively and objective evidence exists; No, otherwise.</p>	<p>Identify the applicable standards, requirements, and associated process/ procedures applied that result in effective implementation and production of the objective evidence.</p>	<p>This column identifies the objective evidence where it exists (e.g., records, reports, work packages, e-mails, meeting minutes, and other documents).</p>	<p>This column indicates if the process/ procedures are applicable to all site safety systems).</p>

Procurement

System Reviewed: _____

P1: Are applicable requirements and design bases established and incorporated into procurement activities?

P2: Are prospective suppliers evaluated and selected on the basis of specified criteria?

P3: Have you established and implemented processes to ensure that approved suppliers continue to provide acceptable items and services?

P4: Are specified items, services, and processes inspected and tested using established acceptance and performance criteria?

P5: Is equipment used for inspections and tests calibrated and maintained?

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ATTACHMENT 2 – Common NNSA QAIP Action 3.3 Reporting Table

<p style="text-align: center;">Fabrication</p> <p>System Reviewed: _____</p> <p>F1: Does the fabricator perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements?</p> <p>F2: Was status, identification, and control of fabricated items and suppliers controlled?</p> <p>F3: Does a formal process exist that ensures the thorough understanding of the fabrication design requirements prior to initiating fabrication?</p> <p>F4: Are special processes (e.g., welding, nondestructive examinations, heat treating) performed in fabricating the safety systems, and if so, are the process, personnel, and process materials qualified?</p>				
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Construction				
<p>System Reviewed: _____</p> <p>C1: Do you have a work control process for construction of safety systems?</p> <p>C2: Is testing acceptance criteria consistent with safety system performance requirements?</p> <p>C3: Are construction work activities and tasks verified in the field?</p>				

ATTACHMENT 2 – Common NNSA QAIP Action 3.3 Reporting Table

<p style="text-align: center;">Operation</p>				
<p>System Reviewed: _____</p> <p>O1: Are personnel trained to operate safety systems?</p> <p>O2: Do safety system personnel receive continuing training?</p> <p>O3: Are safety systems operated in accordance with approved procedures?</p> <p>O4: Are appropriate records prepared, maintained, and evaluated regarding the operation and maintenance of safety systems?</p> <p>O5: Are safety systems operated consistent with controls and standards?</p> <p>O6: Are safety systems being properly maintained and calibrated, including appropriate process monitoring and data collection?</p>				