Task I.F: Quality Assurance (Rev. 5)

The objective of this task was to improve the quality assurance program (QA) for design, construction, and operations to provide greater assurance that plant design, construction, and operational activities were conducted in a manner commensurate with their importance to safety.

ITEM I.F.1: EXPAND QA LIST

DESCRIPTION

Historical Background

The Three Mile Island (TMI) Action Plan [1] identified that several systems important to the safety of Three Mile Island Unit 2 (TMI-2) were not designed, fabricated, and maintained at a level equivalent to their safety importance; i.e., they were not on the QA list for the plant. This condition existed at other plants and resulted primarily from the lack of clarity in U.S. Nuclear Regulatory Commission (NRC) guidance on graded protection. Evaluation of this issue included the consideration of Issue 5 (see Section 3).

Safety Significance

One of the difficulties in establishing a QA list based on safety importance was the absence of relative risk assignments to equipment. At the time this issue was initially evaluated, QA requirements were applied principally to structures, systems, and components that prevented or mitigated the consequences of postulated accidents that could cause undue risk to the health and safety of the public (Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants").

Possible Solution

The TMI Action Plan stated that the NRC would develop guidance for licensees to expand their QA lists to cover equipment important to safety (ITS) and rank the equipment in order of its importance to safety. Experience in the use of the revised Office of Nuclear Reactor Regulation review procedure for developing QA lists for individual operating license applicants was to be factored into the generic guidance to be developed and when determining backfit requirements.[2] At the time this issue was identified, there was a task underway to define the applicability of Appendix B to 10 CFR Part 50 to equipment that met the requirements of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50.

PRIORITY DETERMINATION

The principal benefit to be derived from an expanded QA list was the knowledge that adequate guidance provided to each licensee to establish QA programs and requirements that were commensurate with the safety importance of structures, systems, and components, as determined from completed risk assessments. This guidance would not only result in the inclusion or addition to each licensee’s QA list of other ITS systems that were previously excluded but would also aid in clarifying the QA level of effort deemed necessary.

The risk reduction was probably proportionate to the difference between what would normally be the level of effort expended and the level defined. At the time this issue was initially evaluated, there was no measure of risk variation as a function of the variance in QA level of effort. However, it appeared

[1] NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.
[2] NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.

reasonable to assume that a significant reduction in public risk could be achieved at those plants where the QA levels were held to the previous minimum acceptable level. Important questions to which there were no answers were (1) the number of plants that would be designed, built, and maintained below the new quality acceptance level and (2) how far below the new level the QA programs of these plants would actually operate.

Cost Estimate

Industry Cost: It was estimated that (1) the plant user cost applied to 40 plants in the design phase or under construction, (2) an average of 0.5 man-year/plant was required to develop an expanded QA list, (3) an additional 0.25 man-year/plant over 4 years was required to ensure compliance with the added QA requirements, and (4) an additional 0.1 man-year/plant would be expended to ensure compliance with the expanded QA list during the 40-year operating life of each affected plant. These estimates totaled 220 man- years and, at a rate of $100,000/man-year, the total industry cost was estimated to be $22 million (M).

NRC Cost: The NRC cost was estimated in the TMI Action Plan[3] to be 2.5 man-years or $0.25M.

Total Cost: The total industry and NRC cost associated with the solution was $(22 + 0.25)M or $22.25M.

CONCLUSION

Although a value/impact score was not calculated, the staff believed that the assurance of safer operation justified a high priority ranking for the issue.

The original intent of this issue was to identify those systems, structures, and components beyond those labeled "safety-related," prioritize their importance to safety, and prepare a generic QA list. This was reflected in 10 CFR 50.34(f)(3)(ii), which states, "Ensure that the quality assurance (QA) list required by Criterion II, app. B, 10 CFR part 50 includes all structures, systems, and components important to safety. (I.F.1)." However, the staff's "Interim Reliability Evaluation Program [IREP] Procedures Guide," issued March 1983,[4] failed to identify either the need for a QA list for ITS structures, systems, and components or the basis for a generic list even if one should be needed. The first four IREP studies performed at nuclear plants were reported in NUREG/ CR-2787, "Interim Reliability Evaluation Program: Analysis of the Arkansas Nuclear One—Unit Once Nuclear Power Plant," issued June 1982;[5] NUREG/CR-2802, "Interim Reliability Evaluation Program: Analysis of the Browns Ferry Unit 1 Nuclear Plant," issued August 1982;[6] NUREG/CR-3085, "Interim Reliability Evaluation Program: Analysis of the Millstone Point Unit 1 Nuclear Power Plant," issued April and July 1983;[7] and NUREG/CR-3511, "Interim Reliability Evaluation Program: Analysis of the Calvert Cliffs Unit 1 Nuclear Power Plant," issued May and October 1984.[8] The staff's resolution of the IREP issue is discussed in Item II.C.1.

In January 1984, the NRC issued Generic Letter 84-01, "NRC Use of the Terms, 'Important to Safety' and 'Safety Related,'"[9] to clarify agency use of the terms "important to safety" and "safety related." This letter

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[3] NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.
[4] NUREG/CR-2728, "Interim Reliability Evaluation Program Procedures Guide," U.S. Nuclear Regulatory Commission, March 1983.
[5] NUREG/CR-2787, "Interim Reliability Evaluation Program: Analysis of the Arkansas Nuclear One—Unit One Nuclear Power Plant," U.S. Nuclear Regulatory Commission, June 1982.
[6] NUREG/CR-2802, "Interim Reliability Evaluation Program: Analysis of the Browns Ferry Unit 1 Nuclear Plant," U.S. Nuclear Regulatory Commission, August 1982, (Appendix A) August 1982, (Appendix B) August 1982, (Appendix C) August 1982.
[7] NUREG/CR-3085, "Interim Reliability Evaluation Program: Analysis of the Millstone Point Unit 1 Nuclear Power Plant," U.S. Nuclear Regulatory Commission, (Vol. 1) April 1983, (Vol. 2) August 1983, (Vol. 3) July 1983, (Vol. 4) July 1983.
[8] NUREG/CR-3511, "Interim Reliability Evaluation Program: Analysis of the Calvert Cliffs Unit 1 Nuclear Power Plant," U.S. Nuclear Regulatory Commission, (Vol. 1) May 1984, (Vol. 2) October 1984.
[9] Letter to All Holders of Operating Licenses, Applicants for Operating Licenses and Holders of Construction Permits for Power Reactors from U.S. Nuclear Regulatory Commission," NRC Use of the

summarized the NRC's intention to pursue QA requirements for ITS equipment on a case-by-case basis; further clarification was provided in the Commission's Memorandum and Order CLI-84-9[10] in June 1984. The first proposed rule on ITS was presented in SECY-85-119, "Issuance of Proposed Rule on the Important-to-Safety Issue," dated April 5, 1985,[11] and was later disapproved by the Commission, which concluded that a specific listing of ITS equipment was not required to be maintained.[12] Thus, the issue of expansion of the QA list to cover ITS equipment was considered to be closed and was not addressed in the second staff submittal on the ITS rule in SECY-86-164, "Proposed Rule on the Important-to-Safety Issue," dated May 29, 1986.[13] Therefore, this issue was RESOLVED with no new requirements.[14]

ITEM I.F.2: DEVELOP MORE DETAILED QA CRITERIA

DESCRIPTION

Historical Background

The overall objective of this TMI Action Plan[15] item was the improvement of the QA program for design, construction, and operations to provide greater assurance that plant design, construction, and operational activities were conducted in a manner commensurate with their importance to safety. Several systems important to the safety of TMI-2 were not designed, fabricated, and maintained at a level equivalent to their safety importance. This condition existed at other plants and resulted primarily from the lack of clarity in NRC guidance. This situation and other problems relating to the QA organization, authority, reporting, and inspection were identified by the various TMI accident investigations and inquiries.[16]

Safety Significance

The intent of this item was to provide more explicit and detailed criteria concerning the elements that, in general, were found in well-conducted QA programs. Providing these more detailed criteria was expected to result in the establishment of QA programs of the caliber desired. The NRC believed that such programs would result in the detection of deficiencies in design, construction, and operation.

Possible Solutions

The proposed more detailed QA criteria for design, construction, and operations included the following:[17]

Terms, `Important to Safety' and `Safety Related' (Generic Letter 84-01)," January 5, 1984. [ML031150515]

10 Memorandum and Order CLI-84-9, U.S. Nuclear Regulatory Commission, June 6, 1984. [8406070146]

11 SECY-85-119, "Issuance of Proposed Rule on the Important-to-Safety Issue," U.S. Nuclear Regulatory Commission, April 5, 1985. [8505030656]

12 Memorandum for W. Dircks from S. Chilk, "Staff Requirements—SECY-85-119—`Issuance of Proposed Rule on the Important-to-Safety Issue,'" December 31, 1985. [8601160559]

13 SECY-86-164, "Proposed Rule on the Important-to- Safety Issue," U.S. Nuclear Regulatory Commission, May 29, 1986. [8607010004]

14 Memorandum for V. Stello from E. Beckjord, "Resolution of Generic Issue I.F.1, `Expand QA List,'" January 12, 1989. [9704150147]

15 NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.

16 NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.

17 NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," U.S. Nuclear Regulatory Commission, May 1980, (Rev. 1) August 1980.

(1)	Assure the independence of the organization performing the checking functions from the organization responsible for performing the tasks. For the construction phase, consider options for increasing the independence of the QA function. Include an option to require that licensees perform the entire quality assurance/quality control (QA/QC) function at construction sites. Consider using the third- party concept for accomplishing the NRC review and audit and making the QA/QC personnel agents of the NRC. Consider using the Institute of Nuclear Power Operations to enhance QA/QC independence.
(2)	Include the QA personnel in the review and approval of plant operational maintenance and surveillance procedures and quality-related procedures associated with design, construction, and installation.
(3)	Include the QA personnel in all activities involved in design, construction, installation, preoperational and startup testing, and operation.
(4)	Establish criteria for determining QA requirements for specific classes of equipment such as instrumentation, mechanical equipment, and electrical equipment.
(5)	Establish qualification requirements for QA and QC personnel.
(6)	Increase the size of the licensees' QA staff.
(7)	Clarify that the QA program is a condition of the construction permit and operating license and that substantive changes to an approved program must be submitted to the NRC for review.
(8)	Compare NRC QA requirements with those of other agencies (i.e., National Aeronautic and Space Administration, Federal Aviation Administrations, U.S. Department of Defense) to improve NRC requirements.
(9)	Clarify organizational reporting levels for the QA organization.
(10)	Clarify requirements for maintenance of "as built" documentation.
(11)	Define the role of QA in design and analysis activities. Obtain views on prevention of design errors from licensees, architect-engineers, and vendors.

PRIORITY DETERMINATION

The NRC staff assumed that the above criteria would be adopted by the nuclear industry. The staff made a priority determination of the benefit of the above 11 items for improving QA. (The staff did not make a priority determination of the benefit of a QA program itself.)

To address this issue adequately, improvement in the QA program must be developed independent of the performing organization. Furthermore, the QA organization must have the confidence and the ear of higher management so that QA concerns can be heard and acted upon. The deficiency of the effort called for in this issue was that the effectiveness of the improvement program depended on the acceptance, attitudes, and emphasis given by plant management to the benefits to be derived from a QA program. Licensees that placed a high importance on QA efforts would probably be able to incorporate the intent of the QA enhancement program without making major changes to their organizational structure or in the way they performed their plant operations. However, for those licensees that continued to do business "as usual," the changes could be more cosmetic than real. They would probably seek ways to establish a QA organization that, on the surface, might appear reasonable but that, in reality, could be a "paper tiger." Enclosure 1 of SECY-82-352, "Assurance of Quality," dated August 20, 1982,[18] states the following: "In sum, the fundamental issues can best be characterized as a lack of total management commitment to

[18] SECY-82-352, "Assurance of Quality," U.S. Nuclear Regulatory Commission, August 20, 1982. [8209160068]

quality and the uncertainty in industry's and NRC's ability to detect and correct the resulting deficiencies."

CONCLUSION

Although the QA improvement program could result in the establishment of an improved QA organizational structure at many plants, the results depended heavily on management acceptance. Lack of program implementation and management acceptance, rather than inadequate criteria as suggested by this issue, were the primary causes of deficiencies in QA. Increasing the detail of the QA criteria had little potential for improving the quality of design, construction, or operation and, therefore, reducing risk. Items I.F.2(2), I.F.2(3), I.F.2(6), and I.F.2(9), which addressed the concern stated above, were included in the July 1981 revision to Chapter 17 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (the SRP).[19]

The NRC believed that the issue of QA in nuclear power plants should be a high priority. However, the issue and solutions to QA deficiency as described herein (except for completed issues I.F.2(2), I.F.2(3), I.F.2(6), and I.F.2(9)) failed to address the problem of management acceptance of QA programs. Therefore, the residual items were given a LOW priority.

The NRC staff conducted a review[20] of the seven LOW priority issues in 2010 to determine whether any new information would necessitate reassessment of original prioritization evaluations. The staff determined that the operating experience has not indicated a change in the safety significance of these issues. In addition, the staff verified that the current NRC regulatory requirements or guidance address these issues and identified the applicable regulatory framework as presented below. Because these items have been addressed by the existing regulations and the operating experience has not raised the significance of these issues, the NRC staff DROPPED these issues from further pursuit. The following section provides a discussion to demonstrate the application of the NRC regulatory framework for QA to each issue and to support their disposition.

ITEM I.F.2(1): ASSURE THE INDEPENDENCE OF THE ORGANIZATION PERFORMING THE CHECKING FUNCTION

This item was evaluated in Item I.F.2 above and was determined to be a LOW-priority issue in the main report of NUREG-0933, published in November 1983. In 1998, consideration of new information[21] on the lack of independence in the checking function submitted by Region IV in April 1997 did not change this conclusion.[22]

The staff conducted a review[23] of this issue in 2010 to determine whether any new information would necessitate reassessment of original prioritization evaluations. According to 10 CFR 50.34(f)(3)(iii), "each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982," in addition to "each applicant for a design certification, design approval, combined license, or manufacturing license under part 52" of 10 CFR, needs to "establish a quality assurance (QA) program based on consideration of: (A) Ensuring independence of the organization performing checking functions from the organization responsible for performing the functions." In addition, Section 17.5 of the SRP[24] states that "the QA program requires independence

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[19] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.
[20] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]
[21] SECY-89-081, "Final Report on Chernobyl Implications," U.S. Nuclear Regulatory Commission, March 7, 1989. [8903200205]
[22] Memorandum for T. Gwynn from T. Martin, "Periodic Review of Low-Priority Generic Safety Issues," July 13, 1998. [9909290134]
[23] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]
[24] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.)

between the organization performing checking functions from the organization responsible for performing the functions. (This provision applies to DC applicant, ESP, and construction QA programs. This provision is not applicable to design reviews/verifications.)"

The NRC staff concluded that this item has been adequately addressed by the NRC's regulations and DROPPED this item from further pursuit.[25]

ITEM I.F.2(2): INCLUDE QA PERSONNEL IN REVIEW AND APPROVAL OF PLANT PROCEDURES

This item was evaluated in Item I.F.2 above and was determined to be RESOLVED when new requirements were established with changes made in July 1981 to Chapter 17 of the SRP.[26]

ITEM I.F.2(3): INCLUDE QA PERSONNEL IN ALL DESIGN, CONSTRUCTION, INSTALLATION, TESTING, AND OPERATION ACTIVITIES

This item was evaluated in Item I.F.2 above and was determined to be RESOLVED when new requirements were established with changes made in July 1981 to Chapter 17 of the SRP.[27]

ITEM I.F.2(4): ESTABLISH CRITERIA FOR DETERMINING QA REQUIREMENTS FOR SPECIFIC CLASSES OF EQUIPMENT

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states that "The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety." In addition, applicants or license holders commit to the following standards, which identify requirements for specific classes of equipment:

(1) Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," American Society of Mechanical Engineers (ASME) NQA-1-1994

(2) Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants," ASME NQA-1-1994

(3) Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," ASME NQA-1-1994

(4) Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants," ASME NQA-1-1994

Based on the review of NRC regulations related to this issue, the staff concluded that Item I.F.2(4) has been adequately addressed by the existing regulations. Therefore, the staff changed the status of Item I.F.2(4) and DROPPED this item from further pursuit.[28]

July 1981.

[25] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

[26] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

[27] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

[28] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

ITEM I.F.2(5): ESTABLISH QUALIFICATION REQUIREMENTS FOR QA AND QC PERSONNEL

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

Criterion II of Appendix B to10 CFR Part 50 establishes requirements for the training of personnel: "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained." In addition, Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants,"[29] Revision 3, provides guidance that is acceptable to the NRC staff on qualifications and training for nuclear power plant personnel. This regulatory guide endorses American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants,"[30] with certain clarifications, additions, and exceptions.

Moreover, 10 CFR 50.34(f)(3)(iii) states that "each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982," in addition to "each applicant for a design certification, design approval, combined license, or manufacturing license under part 52" of 10 CFR needs to "establish a quality assurance (QA) program based on consideration of…(E) establishing qualification requirements for QA and QC personnel." Finally, Section 17.5 of the SRP11 describes the SRP acceptance criteria for "Training and Qualification Criteria—Quality Assurance."

Based on the review of the NRC regulations related to this issue presented above, the staff concluded that Item I.F.2(5) has been adequately addressed by the existing regulations. Therefore, the staff changed the status of Item I.F.2(5) and DROPPED this item from further pursuit.[31]

ITEM I.F.2(6): INCREASE THE SIZE OF LICENSEES' QA STAFF

This item was evaluated in Item I.F.2 above and was determined to be RESOLVED when new requirements were established with changes made in July 1981 to Chapter 17 of the SRP.[32]

ITEM I.F.2(7): CLARIFY THAT THE QA PROGRAM IS A CONDITION OF THE CONSTRUCTION PERMIT AND OPERATING LICENSE

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

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[29] Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, March 1971, (Rev. 1) September 1975 [8801130111], (Rev. 1-R) May 1977 [7907100073], (Rev. 2) April 1987. [8907180147]

[30] ANSI/ANS 3.1, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," American National Standards Institute, 1981.

[31] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

[32] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

The regulation at 10 CFR 50.54(a)(1) clearly states that implementation of the QA program is a condition in every nuclear power reactor operating license issued under 10 CFR Part 50: "Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel." In addition, 10 CFR 50.54(a)(1) is also a condition in every combined license issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Finally, 10 CFR 52.17(a)(1)(xi), 10 CFR 52.47(a)(19), and 10 CFR 52.79(a)(25) outline the QA program requirements for applicants for early site permits (ESPs), standard design certifications (DCs) and combined licenses, respectively. SRP[33] Section 17.5 outlines a standardized QA program for DC, ESP, construction permit, operating license, and combined license applicants and holders.

Moreover, this issue specifies that "substantive changes to an approved program must be submitted to NRC for review." This part of the issue is also addressed by 10 CFR 50.54(a)(4), which states that "Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation." The regulation at 10 CFR 50.54(a)(4)(i)–(iv) outlines the process to make these changes.

Based on the review of the NRC regulations related to this issue presented above, the staff concluded that Item I.F.2(7) has been adequately addressed by the existing regulations. Therefore, the staff changed the status of Item I.F.2(7) and DROPPED this item from further pursuit.[34]

ITEM I.F.2(8): COMPARE NRC QA REQUIREMENTS WITH THOSE OF OTHER AGENCIES

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

On July 9, 2003, the results of the staff's effort to review international quality assurance standards against the existing Appendix B to 10 CFR Part 50 framework were reported by issuance of SECY-03-0117, Approaches for Adopting More Widely Accepted International Quality Standards."[35] In addition, approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework were assessed. SECY-03-0117[36] also reviewed existing NRC quality assurance requirements and efforts to improve their effectiveness and efficiency. The staff concluded in SECY-03-0117[37] that considerable actions had already been taken or were in progress to reduce unnecessary regulatory burden on licensees resulting from compliance with Appendix B to 10 CFR Part 50 requirements. In addition, the proposed 10 CFR 50.69 risk-informed rulemaking would provide a more efficient and effective regulatory process while continuing to maintain safety. The staff evaluation of the differences between Appendix B to 10 CFR Part 50 and ISO 9001 is summarized in the attachment to SECY-03-0117.[38]

The staff concluded that the analysis presented in SECY-03-0117[39] addressed Item I.F.2(8) adequately

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33 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

34 Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

35 SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," July 9, 2003. [ML031490421]

36 SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," July 9, 2003. [ML031490421]

37 SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," July 9, 2003. [ML031490421]

38 SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," July 9, 2003. [ML031490421]

39 SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," July

and DROPPED this item from further pursuit.[40]

ITEM I.F.2(9): CLARIFY ORGANIZATIONAL REPORTING LEVELS FOR THE QA ORGANIZATION

This item was evaluated in Item I.F.2 above and was determined to be RESOLVED when new requirements were established with changes made in July 1981 to Chapter 17 of the SRP.[41]

ITEM I.F.2(10): CLARIFY REQUIREMENTS FOR MAINTENANCE OF "AS-BUILT" DOCUMENTATION

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

Criterion VI, "Document Control," and Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50 establish requirements for issuing, identifying, and retrieving QA records. In addition, NRC-accepted practices for the collection, storage, and maintenance of QA records for nuclear power plants, independent storage of spent nuclear fuel and high-level radioactive waste facilities, special nuclear materials, packaging and transportation of radioactive materials, and gaseous diffusion plants are described in ANSI/ASME NQA-1.[42]

Criterion VI of Appendix B to 10 CFR Part 50 describes the requirements to control changes in documents: "Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization."

Moreover, 10 CFR 50.34(f)(3)(iii) states that "each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982," in addition to "each applicant for a design certification, design approval, combined license, or manufacturing license under part 52" of 10 CFR, needs to "establish a quality assurance (QA) program based on consideration of…(G) establishing procedures for maintenance of 'as-built' documentation." Finally, Section 17.5 of the SRP[43] states that "A program is required to be established to control the development, review, approval, issue, use, and revision of documents." This section includes as-built drawings as one of the examples of controlled documents: "Examples of controlled documents include design drawings, as-built drawings, engineering calculations."

Based on the review of the NRC regulations related to this issue presented above, the staff concluded that Item I.F.2(10) has been adequately addressed by the existing regulations. Therefore, the staff changed the status of Item I.F.2(10) and DROPPED this item from further pursuit.[44]

9, 2003. [ML031490421]

[40] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

[41] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

[42] American Society of Mechanical Engineers, "Quality Assurance Program Requirements for Nuclear Facility Applications," ANSI/ASME Standard NQA -1, Washington, DC.

[43] NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," U.S. Nuclear Regulatory Commission, (1st Ed.) November 1975, (2nd Ed.) March 1980, (3rd Ed.) July 1981.

[44] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]

ITEM I.F.2(11): DEFINE ROLE OF QA IN DESIGN AND ANALYSIS ACTIVITIES

This item was evaluated in Item I.F.2 above and was determined to be a LOW priority issue in the main report of NUREG-0933, published in November 1983.

Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 describes the requirements of the program for the design of items. As explained in this criterion, measures should be established to assure that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions. In addition, these measures should include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. The design control measures provide for verifying or checking the adequacy of design and are applied to items such as the reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.

Moreover, 10 CFR 50.34(f)(3)(iii) states that "each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982," in addition to "each applicant for a design certification, design approval, combined license, or manufacturing license under part 52" of 10 CFR, needs to "establish a quality assurance (QA) program based on consideration of…(H) providing a QA role in design and analysis activities." Finally, Section 17.5 of the SRP11 states that "The QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. (This applies to DC applicants, ESP, and construction QA programs.)"

Based on the review of the NRC regulations related to this issue presented above, the staff concluded that Item I.F.2(11) has been adequately addressed by the existing regulations. Therefore, the staff changed the status of Item I.F.2(11) and DROPPED this item from further pursuit.[45]

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[45] Memorandum for B.W. Sheron from B.G. Beasley, "LOW Priority Generic Issues," March 17, 2011. [ML092520025]