Appendix B to Part 50--Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after September 27, 2007, every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design,
fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those
structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safetyrelated functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. Organization

The applicant [1] shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance
functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safetyrelated
functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. There persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the
many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed, shall have direct access to the levels of management necessary to perform this function.

II. Quality Assurance Program

The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. 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. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. 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. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

III. Design Control

Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: 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.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

IV. Procurement Document Control

Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

V. Instructions, Procedures, and Drawings

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

VI. Document Control

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.

VII. Control of Purchased Material, Equipment, and Services

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear powerplant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

VIII. Identification and Control of Materials, Parts, and Components

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.

IX. Control of Special Processes

Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

X. Inspection

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.

XI. Test Control

A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

XII. Control of Measuring and Test Equipment

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

XIII. Handling, Storage and Shipping

Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.

XIV. Inspection, Test, and Operating Status

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.

XV. Nonconforming Materials, Parts, or Components

Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

XVI. Corrective Action

Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

XVII. Quality Assurance Records

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

XVIII. Audits

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

[35 FR 10499, June 27, 1970, as amended at 36 FR 18301, Sept. 11, 1971; 40 FR 3210D, Jan. 20, 1975; 72 FR 49505, Aug. 28, 2007]

[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant or a fuel reprocessing plant or has received an early site permit, design approval, design certification, or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses, and manufacturing licenses.

OPERABILITY DETERMINATIONS & FUNCTIONALITY ASSESSMENTS FOR RESOLUTION OF DEGRADED OR NONCONFORMING CONDITIONS ADVERSE TO QUALITY OR SAFETY

Code Cases that describe methods, criteria, or requirements different from the Code referenced in 10 CFR 50.55a cannot be used without prior NRC review and approval unless they are endorsed in Regulatory Guide 1.147, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1." Code Case N–513, which describes an acceptable alternative to the methods described in the Code for the acceptance of a flaw in a Class 3 moderate-energy piping system, is endorsed in RG 1.147. A flaw that is evaluated in accordance with, and meets the acceptance criteria of, Code Case N–513 is acceptable to both ASME and to the NRC. If the flaw does not satisfy the requirements of Code Case N–513, the system containing the flaw is inoperable.

NRC has accepted Code Case N–513 for application in the licensees inservice inspection programs, with the following conditions:

a. Specific safety factors in paragraph 4.0 of Code Case N–513 must be satisfied, and

b. Code Case N–513 may not be applied to:
   (1) components other than pipe and tubing,
   (2) leakage through a gasket,
   (3) threaded connections employing nonstructural seal welds for leakage prevention (through-seal weld leakage is not a structural flaw, but thread integrity must be maintained), and
   (4) degraded socket welds.

If a flaw exceeds the thresholds of the ASME Code, Generic Letter 90-05, Code Case N–513, or any other applicable NRC-approved Code Case, the system containing the flaw is inoperable until the NRC approves an alternative analysis, evaluation, or calculation to justify the system's return to service with the flaw and the subsequent operability of the system. The inoperable system is subject to the applicable TS LCO before receiving the NRC approval for the alternative analysis, evaluation, or calculation.

C.12 Operational Leakage From Code Class 1, 2, and 3 Components

Leakage from the reactor coolant system, as specified in TSs, is limited to specified values in the TSs depending on whether the leakage is from identified, unidentified, or specified sources such as the steam generator tubes or reactor coolant system pressure isolation valves. If the leakage exceeds TS limits, the LCO must be declared not met and the applicable conditions must be entered. For identified reactor coolant system leakage within the limits of the TS, the licensee should determine operability for the degraded component and include in the determination the effects of the leakage on other components and materials.

Existing regulations and TSs require that the structural integrity of ASME Code Class 1, 2, and 3 components be maintained in accordance with the ASME Code. In the case of specific types of degradation, other regulatory requirements must also be met. If a leak is discovered in a Class 1, 2, or 3 component in the conduct of an inservice inspection, maintenance activity, or facility operation, corrective measures

may require repair or replacement activities in accordance with IWA-4000 of Section XI. In addition, the leaking component should be evaluated for flaws according to IWB-3000, which addresses the analytical evaluation and acceptability criteria for flaws.

The TSs do not permit any reactor coolant pressure boundary (RCPB) leakage. The operational leakage LCO must be declared not met when pressure boundary leakage is occurring. Upon discovery of leakage from a Class 1, 2, or 3 pressure boundary component (pipe wall, valve body, pump casing, etc.), the licensee must declare the component inoperable. Evidence of leakage from the pressure boundary indicates the presence of a through-wall flaw. It may be possible to use visual methods to determine the exterior dimension(s) and orientation of a through-wall flaw in a leaking component. When the outside surface breaking dimension of a through-wall flaw is small, the length and extent of the flaw inside the component wall may be quite long and potentially outside the limits established by the Code. For these reasons the component is declared inoperable while methods such as ultrasonic examination are performed to characterize the actual geometry of the through-wall flaw. However, after declaring inoperability for leakage from Class 3 moderate-energy piping, the licensee may evaluate the structural integrity of the piping by fully characterizing the extent of the flaw using volumetric methods and evaluating the flaw using the criteria of paragraph C.3.a of Enclosure 1 to GL 90-05. If the flaw meets the criteria, the piping can subsequently be deemed operable but degraded until relief from the applicable Code requirement or requirements is obtained from the NRC. Alternatively, the licensee can evaluate the structural integrity of leaking Class 3 moderate-energy piping using the criteria of Code Case N–513, which is approved with limitations imposed by the NRC staff and incorporated by reference in 10 CFR 50.55(a)(b)(2)(xiii). The limitations imposed by the NRC staff are as follows:

a. Specific safety factors in paragraph 4.0 of Code Case N–513 must be satisfied, and

b. Code Case N–513 may not be applied to:
   (1) components other than pipe and tubing,
   (2) Leakage through a gasket,
   (3) threaded connections employing nonstructural seal welds for leakage prevention (through seal weld leakage is not a structural flaw, but thread integrity must be maintained), and
   (4) degraded socket welds.

Following the declaration of inoperability, the licensee may also decide to evaluate the structural integrity of leaking Class 2 or 3 moderate-energy piping using the criteria of Code Case N–513–1. The same limitations imposed by the NRC staff on Code Case N–513 apply to Code Case N–513–1. Code Case N–513–1 has been reviewed and found acceptable by the NRC. However, Code Case N–513–1 has not yet been incorporated into RG 1.147 or the Code of Federal Regulations for generic use. Therefore, until Code Case N–513–1 is approved for generic use in either RG 1.147 or 10 CFR 50.55a, the licensee must request relief and obtain NRC approval to use Code Case N–513–1.

If the piping meets the criteria of ASME Code Case N–513, continued temporary service of the degraded piping components is permitted. If the licensee decides to control the leakage by mechanical clamping means, the requirements of Code Case 523-2, •Mechanical Clamping Devices for Class 2 and 3 Piping Section XI, Division 1," may be followed, as referenced in 10 CFR 50.55a(b)(2)(xiii). This Code Case is to maintain the structural integrity of Class 2 and 3 piping which is 6 inches (nominal pipe size) and smaller and shall not be used on piping larger than 2 inches (nominal pipe size) when the nominal operating temperature or pressure exceeds 200°F or 275 psig. These and other applicable Code Cases which have been determined to be acceptable for licensee use without a request or authorization from the NRC are listed in RG 1.147. These Code Cases do not apply to Class 1 pressure boundary components.

The NRC has no specific guidance or generically approved alternatives for temporary repair of flaws (through-wall or non-through-wall) in Class 1, 2, or 3 high-energy system components, or for Class 2 or 3 moderate-energy system pressure boundary components other than piping. Therefore, all such flaws in these components must be repaired in accordance with Code requirements, or relief from Code requirements must be requested of and approval obtained from the NRC.

C.13 Structural Requirements

Structures may be required to be operable by the TSs, or they may be related support functions for SSCs in the TSs. Examples of structural degradation are concrete cracking and spalling, excessive deflection or deformation, water leakage, rebar corrosion, missing or bent anchor bolts, and degradation of door and penetration sealing. If a structure is degraded, the licensee should assess the structure's capability of performing its specified function. As long as the identified degradation does not result in exceeding acceptance limits specified in applicable design codes and standards referenced in the design basis documents, the affected structure is either operable or functional.

NRC inspectors, with possible headquarters support, should review licensees' evaluations of structural degradations to determine their technical adequacy and conformance to licensing and regulatory requirements.

END