

May 5, 2004

Mr. Vince Langman  
ACR Licensing Manager  
Atomic Energy of Canada Limited (AECL) Technology, Inc.  
481 North Frederick Avenue, Suite 405  
Gaithersburg, Maryland 20877

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION - ACR-700 PRE-APPLICATION  
QUALITY ASSURANCE REVIEW

Dear Mr. Langman:

Atomic Energy of Canada Limited (AECL) submitted a formal request for a pre-application review of the Advanced CANDU Reactor (ACR-700) design dated June 19, 2002.

The Nuclear Regulatory Commission (NRC) staff is reviewing technical information provided by AECL as part of the ongoing pre-application review activities for the ACR-700 design. The NRC staff has determined that additional information is necessary to continue the review. The requests for additional information (RAIs) are included in the enclosure. The topics covered in these RAIs include the quality assurance controls applied to design and testing activities associated with the ACR-700 reactor. An advanced copy of the RAIs were sent to you via electronic mail on April 13, 2004. On May 3, 2004, AECL participated in a teleconference with the staff to discuss the content of the RAIs and agreed to provide the documents containing the ACR-700 information requested in the RAIs by May 31, 2004.

If you have any questions or comments concerning this matter, you may contact the undersigned at (301) 415-4125 or [jsk@nrc.gov](mailto:jsk@nrc.gov).

Sincerely,

*/RA/*

James Kim, Project Manager  
New Reactors Section  
New, Research and Test Reactors Program  
Division of Regulatory Improvement Programs  
Office of Nuclear Reactor Regulation

Project No. 722

Enclosure: As stated

cc: See next page

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ADAMS ACCESSION NUMBER: ML041260008

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DATE	5/5/04	5/5/04	5/5/04

**OFFICIAL RECORD COPY**

Distribution for Request For Additional Information #9 dated May 5, 2004

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Requests for Additional Information (RAIs) - Letter 9  
ACR-700 Pre-Application Review

Based on review of the Advanced CANDU Reactor (ACR) quality assurance framework, the staff requests Atomic Energy of Canada, Limited (AECL) to provide additional information regarding the nuclear quality assurance (NQA) controls applied to design and testing activities associated with the ACR-700 project. Part 1 of the RAI addresses the NQA-1/N286 comparison. Part 2 of the RAI addresses other quality issues.

**Part 1 - Comparison of American Society of Mechanical Engineers (ASME) NQA-1-1994 Requirements Versus CSA N286 Series of Standards**

The staff completed a preliminary comparison of the Canadian CSA N286 series of standards to the 1994 edition of the U.S. ASME NQA-1 quality assurance standard. The AECL comparison is documented in AECL Assessment Document 108US-01919-ASD-001, dated February 2003. The NRC staff has reviewed this document and generally concurs with the differences identified by AECL. However, the staff finds the corresponding assessments to be incomplete in that no justification is provided for differences deemed to be “not significant” or final dispositions for differences that are identified for further consideration.

In addition to the differences identified by AECL, the staff has identified differences for which the following information is requested. AECL’s response should address design, procurement, and testing activities and items.

237. Conducting Activities Under Controlled Conditions

NQA-1 Basic Requirement 2 requires that the program provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions and assurance that prerequisites for the given activity have been satisfied. N286 does not have a similar requirement.

Please address this NQA-1 requirement.

238. Nondestructive Examination Auditor Qualifications

NQA-1 Supplementary Requirement 2S-2 provides amplified requirements for the qualification of personnel who perform radiographic, magnetic particle, ultrasonic, liquid penetrant, electromagnetic, etc., also referred to as nondestructive testing. N286 does not have similar requirements.

Please address these requirements.

239. Lead Auditor Qualifications

NQA-1 Supplementary Requirement 2S-2 provides amplified requirements for the qualification of lead auditors. Amplified requirements include communication, training, audit participation, examination, maintenance of qualification, requalification, and record of certification. N286 does not have similar requirements.

Please address these NQA-1 requirements.

240. Audits Conducted by a Third-Party

NQA-1 Basic Requirement 2 requires that management regularly assesses the adequacy and effective implementation of the quality assurance program. N286 states that formal reviews of the effectiveness of the overall program shall be conducted by, or on behalf of the owner, at least annually.

Please address this NQA-1 requirement. Does the term “on behalf of the owner” permit third-party auditing, which is not allowed under an NQA-1 program?

241. Documentation of Regulatory Requirements in Working Documents

NQA-1 Supplementary Requirement 3S-1 requires that applicable design inputs such as design bases and regulatory requirements be identified and documented. N286 does not have similar requirements.

Please address this NQA-1 requirement.

242. Design Controls

NQA-1 Supplementary Requirement 3S-1 describes critical reviews that provide assurance that the final design is correct and satisfactory. Design reviews address the following: (1) Were the design inputs correctly selected?; (2) Are assumptions necessary to perform the design activity adequately described and reasonable, and are the assumptions identified for subsequent reverification when the detailed design activities are completed?; (3) Was an appropriate design method used?; (4) Were the design inputs correctly incorporated into the design?; (5) Is the design output reasonable compared to the design inputs, and; (6) Are the necessary design input and verification requirements for the interfacing organization specified in the design document or in supporting procedures or instructions? N286.2 guidance is not as rigorous in defining design reviews.

Please address this NQA-1 requirement.

243. Control of Design Documents Related to External Organizations

NQA-1 Supplementary Requirement 3S-1 requires identification and control of design interfaces and requires coordination of the design efforts among the participating organizations. N286.2 does not specifically address design interfaces.

Please address this NQA-1 requirement. Discuss the N286.2 requirement for communicating with external organizations.

244. Qualification Testing

NQA-1 Supplementary Requirement 3S-1 requires that testing demonstrates adequacy of performance under conditions that simulate the most adverse conditions. N286.2 does not address testing under adverse conditions.

Please address this NQA-1 requirement.

245. Design Approval

NQA-1 Supplementary Requirement 3S-1 requires that changes be approved by the same affected groups or organization which reviewed and approved the original design documents. N286.2 does not address this requirement.

Please address this NQA-1 requirement.

246. Documents in Use at Prescribed Activity

NQA-1 Supplementary Requirement 6S-1 requires documents to be reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. N286.0 does not address this requirement.

Please address this NQA-1 requirement.

247. Document Review and Approval

NQA-1 Supplementary Requirement requires document changes to be reviewed and approved by the same organizations that performed the original review and approval unless other organization are specifically designated. N286.0 does not address this requirement.

Please address this NQA-1 requirement.

248. Commercial-Grade Items

NQA-1 Supplementary Requirement 7S-1, provides for an acceptable alternative when the design utilizes commercial grade items, except for the requirements of Supplement 4S-1 and the following: (1) The commercial-grade item is identified in an approved design output document. An alternate commercial-grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial-grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application; (2) Source evaluation and selection, where determined necessary by the Purchaser base on complexity and importance to safety, shall be in accordance with paragraph 3.1 of this Supplementary Requirement; (3) Commercial-grade item shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number); (4) After receipt of a commercial-grade item, the Purchaser shall determine that: (a) damage was not sustained during shipment; (b) the item received was the item ordered; (c) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements, and; d) documentation, as applicable to the item, was received and is acceptable. N286 does not provide similar requirements.

Please describe the quality assurance controls that ensure ACR-700 design and testing activities will properly control commercial-grade items procured for ACR-700 activities.

249. Contractor Performance Monitoring

NQA-1 Supplementary Requirement 7S-1 requires that the extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. N286.1 does not address this requirement.

Please address this NQA-1 requirement.

250. Inspection Activities

NQA-1 Supplementary Requirement 10S-1 requires that inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. If inspection of processed items is impossible or is not advantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. N286 does not address this requirement.

Please address this NQA-1 requirement.

251. Protective Environments

NQA-1 Supplementary Requirement 13S-1 requires that when required for particular items, special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified. N286 does not address this requirement.

Please address this NQA-1 requirement.

252. Notification of Nonconformances

NQA-1 Basic Requirement 15 requires that controls shall provide for notification of nonconformances to affected organizations. N286 does not address this requirement.

Please address this NQA-1 requirement.

253. Trained Auditors

NQA-1 Supplementary Requirement 2S-3 requires trained auditors. N286 does not address this requirement.

Please address this Appendix B requirement.

254. NQA-1-1994, Part II

Part II of NQA-1-1994 provides quality assurance requirements for the planning and execution of identified tasks during the fabrication, construction, modification repair, maintenance, and testing of SSCs for nuclear facilities. Part II is an integral part of the quality assurance framework of NQA-1 and is applicable to work oriented activities, such as fabrication,

construction, modification, repair, maintenance, and testing activities. Section 2., "Applicability," of Part II of NQA-1 defines these activities to include the performing function of attaining quality objectives and verifying that activities affecting quality have been correctly performed. These activities include planning, subsurface investigations, fabrications, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying.

Please describe the quality assurance controls which are applicable to the ACR design that will ensure, to the extent applicable the activities being performed, the application of Part II, or portions thereof, and the provisions of Part II that shall be specified in written contracts, policies, procedures, or instructions related to design and testing activities of the ACR-700 project.

## **Part 2 - Quality Related Issues**

### **255. Safety Classification (Safety Related)**

The term "safety related" as defined by 10 CFR Part 50, paragraph 50.2, refers to those structures, systems and components (SSCs) that are relied upon to remain functional during and following design basis events to assure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or to prevent or mitigate the consequences of accident which could result in potential offsite exposure comparable to defined regulatory guideline exposures.

Please cite the Canadian regulation(s) that define "safety-related" for the ACR-700. Provide specific reference to applicable Canadian regulatory guidance and consensus standards that amplify this classification.

Please provide a matrix of all items and activities classified as safety-related. The information should include the quality standards (e.g., N286) that apply.

### **256. Safety Classification (Important-to-Safety)**

Appendix A to 10 CFR Part 50 provides for quality assurance criteria for SSCs important to safety. General Design Criteria 1 states that "Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed."

Examples of systems important to safety include (1) fire protection (§50.46), (2) environmental qualification (§50.49), (3) anticipated transients without scram, (4) station blackout (§50.63), (5) pressurized thermal shock (§50.61).

Please cite the Canadian regulation(s) that pertain to "important-to-safety" for the ACR-700. Provide specific reference to applicable regulatory guidance and consensus standards that amplify this classification.

Please provide a matrix of all items and activities classified as "important-to-safety." The information should include the quality standards (e.g., N286) that apply.

257. Independent System Operation (ISO) Quality Programs

The staff has not approved use of ISO quality programs for design, procurement, or testing of “safety related” or “important to safety” SSCs. The staff’s assessment of the approaches for adopting international quality standards for safety-related components is documented in SECY-03-0117, dated July 23, 2003.

Please identify the use of ISO quality programs for ACR design, procurement, and testing. Address the specific issues raised in SECY-03-0117.

258. Legacy Issues

AECL has stated that about 85 percent of the ACR-700 design is based on the testing and design completed previous to the inception of ACR-700 design. It is understood that some of the testing on which the ACR-700 design relies may not have been conducted under a quality program equivalent to N286 or NQA-1.

Please provide a matrix of testing which will support the ACR-700 design. This matrix should provide a brief description of the test, the area of ACR-700 design its supports, the date when the test was performed, and the quality assurance program imposed.

259. Procurement

Procurement regulations apply to both hardware and services. Part 21 requires that suppliers report defects and noncompliances that have the potential for creating a substantial safety hazard. The licensing of an ACR-700-type plant in the United States will require that the applicant impose Part 21 on the nuclear steam system (NSS) supplier. For design, Part 21 is particularly applicable to the procurement of engineering and testing.

Please discuss how AECL plans to address Part 21 in its application for certifying the ACR-700, particularly for procurement of engineering and testing in support of the ACR

260. Control of Sub-contractors

At the meeting on March 18, 2004, AECL discussed how “participants”, partners and subcontractors had contributed to the ACR-700 design. AECL identified Babcock and Wilcox Canada and Hitachi as examples of participants.

Please identify all participants, partners and subcontractors who contributed to the ACR design, the scope of services provided, the information exchanged, and the quality controls for documenting, verifying, and validating this information.

ACR-700

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