AECL
TECHNOLOGIES INC.

May 31, 2004

Our File: 108US-01321-021-001
Your File: Project No. 722

U.S. Nuclear Regulatory Commission,
Document Control Desk,
Washington, D.C. 20555

Attention: Ms. B. Sosa
Project Manager, ACR

References:

1. Letter J. Kim to V.J. Langman, "Requests for Additional Information – ACR-700 Pre-Application Quality Assurance Review", May 05, 2004.

Re: **Response to NRC's Requests for Additional Information (RAIs) on Quality Assurance**

In response to NRC's request (Reference 1) and in support of the NRC's pre-application review of the ACR-700, Attachment 1 provides AECL's responses to NRC staff requests for additional information on the ACR-700 Quality Assurance Program.

If you have any questions on this letter and/or the enclosed material please contact the undersigned at (905) 823-9060 extension 6543.

Yours sincerely,

Vince Lang

Vince J. Langman
ACR Licensing Manager

/Attachment:

1. Response to NRC's Requests for Additional Information (RAIs) on Quality Assurance

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Attachment 1
(Letter V.J. Langman to B. Sosa, "Response to NRC's Requests for Additional Information (RAIs) on Quality Assurance", May 31, 2004)

Response to NRC's Requests for Additional Information (RAIs) on Quality Assurance

AECL's responses to NRC's requests for additional information on Quality Assurance are provided in italic fonts following each of the NRC's questions as follows:

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.

AECL Response:
It should be noted that although the ACR-700 / AECL Design QA Program is based on N286.2, it goes beyond N286.2 in several areas. Complete coverage is provided in the ACR-700 / AECL QA Manuals and the documents and the procedures referenced therein. The ACR-700 scope of work consists of design and testing work. At this stage, procurement activities are limited only to those items which are being tested.

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.

AECL Response:
N286.0 also has similar wording (Clause 11: "the right items, processes, procedures shall be used"), and N286.2 says (Clause 3.9: "Only specified processes and practices shall be used...").

As stated in the ACR-700 QA Manual, ACR-700 activities for safety related systems and components (which encompass activities affecting quality) are performed using qualified items, processes and procedures. Prerequisites (or input requirements) for the given activity are identified and addressed during the performance of that activity. (Example: Refer to Clause 4.7 of the ACR-700 QA Manual where the use of Work Plans and Work Activity Plans is described. These provide further indications that the work is performed under controlled conditions).

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.

AECL Response:
Such requirements are covered through the CSA Z299 Series of manufacturing standards or equivalent which are invoked when manufacturing/testing is required. ACR-700 procurement documents such as EQRs and Technical Specifications refer to such standards.

For pressure boundary components, these requirements are covered under N285.0 and CSA B51. For NDE personnel qualification Canadian Government Specification Board (CGSB) Standards are followed which meet or exceed American Society of Nondestrustive Testing (ASNT) requirements, as required by NQA-1 Supplementary Requirement 2S-2.

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.

AECL Response:
The requirements and the process for qualification and training of auditors and lead auditors are defined in AECL procedure 00-904.5 "Qualification of QA Audit Personnel" (referenced in the ACR-700 QA Manual).

Additional requirements on auditor and lead auditor qualification and records of qualification have been assessed and an NQA-1 specific procedure will be developed and used, and included in the ACR-700 QA Program.

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?

AECL Response:
As specified in the ACR-700 QA Manual, ACR-700 management regularly (annually) assesses the adequacy and effective implementation of the quality assurance program.

For Suppliers' qualification, some recognized third party audits / certifications are performed. This practice conforms to all national and international norms and standards, including NQA-1.

In addition, AECL also performs quality surveillance or audits on Suppliers' programs.

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.

AECL Response:
The ACR-700 QA Program requires that all applicable design inputs such as design bases and regulatory requirements are identified and documented. Such requirements are identified in the Design Requirements documents. The ACR-700 QA Program refers to the AECL Company-Wide Design QA Manual. Section 5.2.1 of the Company-Wide Design QA Manual specifies requirements for addressing and documenting applicable design inputs.

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.

AECL Response:
The ACR-700 QA Program uses the AECL Corporate procedure 00-531.2 on design reviews. Procedure 00-531.2 requires a design review to address all the stated NQA-1 Supplementary Requirements 3S-1.

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.

AECL Response:
The ACR-700 QA Manual (Section 3.4) deals with interfaces with external and internal organizations. Section 3.4 of the ACR-700 QA Manual is being strengthened to define controls which would require identification and control of design interfaces as well as coordination of the design efforts among the participating organizations. These design interfaces are governed by the division of responsibility documents agreed by the parties. Furthermore, the project schedule defines the coordination of design efforts among parties.

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.

AECL Response:
The ACR-700 QA Program meets this requirement. Further clarification will be provided to the NRC and included in the ACR-700 QA Manual.

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.

AECL Response:
The ACR-700 QA Program meets this requirement. Changes are reviewed and approved by the same affected groups or organizations which reviewed and approved the original design documents. Where, in some cases, the organization which reviewed and approved the original design is not in existence anymore, then the organization / person who reviews and approves the changes has the information and knowledge of the requirements and intent of the original design, process and practices. The ACR-700 QA Manual will provide this clarification.

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.

AECL Response:
The ACR-700 QA Program meets this requirement. The ACR-700 QA Manual (Section 4.3), supplemented by the AECL Company-wide Design QA Manual (Sections 3.14, 5.4 and 5.8), describes the requirements for document control. Detailed requirements are specified in procedures 00-414.3 and 108-414.3.1.

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.

AECL Response:
See response to RAI 245, above.

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.

AECL Response:
Normally, for new plants, commercial grade items for safety related systems are not used.

For replacement items, AECL has developed a process for evaluating alternate commercial grade items. The process will be applied to the ACR-700 Program when and if needed.

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.

AECL Response:
The ACR-700 QA Program follows the AECL Company-Wide Procurement QA Manual, which meets the stated Supplementary Requirement of NQA-1.

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 disadvantageous, 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.

AECL Response:
This requirement is covered in the manufacturing standards CSA Z299 (under "Special Processes" and "Inspection and Test Plans"), or equivalent standards. AECL procedure 00-912.1 (followed by the ACR-700 Project) covers this 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.

AECL Response:
Such requirements are covered in the manufacturing standards CSA Z299 (under handling and storage) or equivalent standards.

These requirements are also covered under AECL's manufacturing specifications which become part of the purchase orders.

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.

AECL Response:
ACR-700 will develop and use an NQA-1 specific procedure. This procedure will be referenced in the ACR-700 QA Manual (see also response to RAI 259 below).

253 Trained Auditors

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

Please address this Appendix B requirement.

AECL Response:
AECL uses trained auditors. For further details see response to RAI 239 above.

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 to 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.

AECL Response:
Although not explicitly required by the N286 Standards, AECL procurement documents include technical specifications for fabrication and construction. AECL procedure on EQR and related procedures 00-852.1, 00-852.2 and 00-852.2.1 specify these requirements.

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.

AECL Response:
For the ACR-700 US design, AECL will apply the term "safety related" as defined by 10CFR50 and will organize the list of systems into classes which will clearly identify the safety related systems and the systems important-to-safety according to the US definitions. These classes will be indicated in a table in Section 3.2 of the ACR-700 Design Control Document.

For background information and in response to paragraph two of RAI 255, the traditional CANDU definition of "safety related" applies to all systems that perform a safety function, including all backup systems, rather than just those that prevent or mitigate an accident. The definition is included in the N286.0 standard, which is accepted by the Canadian regulator prior to issue. The CANDU definition is a combination of the 10CFR50 definition of "safety related" and the U.S. definition of systems important-to-safety.

Also for background information, a table of the systems that are safety related (per the traditional CANDU definition) is included in the CANDU Safety Guide for Safety Related Systems (108-03650-SDG-001, Revision 3, March 2004), which was submitted to the NRC under cover letter dated March 26, 2004. Safety related activities are not listed, but are addressed in the work procedures as part of the Quality Assurance Programs for each stage of the work.

In Canada, all safety related systems follow the N286 quality assurance requirements (which are consensus standards) and in addition follow any quality assurance requirements arising from applicable technical standards, such as ASME.

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.

AECL Response:
As noted in the response to RAI 255, the Canadian definition of "safety related" systems includes those that are designated as systems "important-to-safety" under the US definition, so there are no separate Canadian regulations or standards for these systems. This includes fire protection systems, the second shutdown system (that addresses ATWS), and any additional power supplies needed to maintain the plant in a safe state.

For the ACR-700 US design, AECL intends to meet the requirements outlined in the Standard Review Plan 3.2.2, Draft Rev. 2 – April 1996 for items and activities "important-to-safety". As mentioned in the response to RAI 255, AECL will organize the list of systems into classes which will clearly identify the safety related systems and the systems important-to-safety according to the US definitions. These classes will be indicated in a table in the ACR-700 Design Control Document.

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.

AECL Response:
The ACR-700 design (including qualification testing and the related procurement activities) meets the N286 Standards requirements.

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.

AECL Response:
The CANDU validation matrices are structured on a discipline basis (e.g., fuel and fuel channel, physics, system thermal hydraulics, containment). These matrices provide a detailed summary of all of the data that provides the technology bases for the CANDU reactor design. As such the majority of this data is generally applicable to the ACR-700, and much of it is specifically applicable. AECL is in the process of updating these validation matrices to include recent tests that provide additional support for the ACR-700 design. AECL will also be identifying which legacy data cited in the matrices are integral to the ACR-700 technology base. In addition, the QA programs and/or procedures in use at the time these identified legacy data were produced will also be summarized. This information will be available for NRC review at the time of the ACR-700 design certification application.

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.

AECL Response:
Part 21 requirements will be imposed as part of the ACR-700 QA program for reactors to be installed in the US. ACR-700 will develop a procedure, which will meet the requirements of Part 21. This procedure will be then imposed on all the suppliers. The ACR-700 QA Manual will be modified to include this requirement.

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.

AECL Response:
A list of participants, partners and subcontractors who contribute to ACR-700 design, and the scope of the services provided and the information exchanged will be provided to the NRC at a later date (August 2004).

The ACR-700 QA program follows the AECL Company-Wide Procurement QA Manual for procurement of safety related items and services. Corporate procedures in the 800 and 900 series have been developed which describe quality controls including documenting, verifying and validating information.