June 16, 1994

Project No. 679

MEMORANDUM FOR: Gail W. Marcus, Director
Advanced Reactors Project Directorate
Associate Director of Advanced Reactor
and License Renewal

FROM: Dino Scaletti, Senior Project Manager
Advanced Reactors Project Directorate
Associate Director of Advanced Reactor
and License Renewal

SUBJECT: FORTHCOMING MEETING WITH AECL TECHNOLOGIES (AECLT)

DATE: & TIME: Tuesday, July 21, 1994
9 a.m. - 3:00 p.m.

LOCATION: AECL Technologies, Inc.
9210 Corporate Boulevard
Rockville, MD 20850

PURPOSE: To discuss the staff's initial comments related to the CANDU 3U Project Quality Assurance Manual, and to provide AECLT with insights concerning 10 CFR Part 52.

PARTICIPANTS*:

NRC	AECLT
G. Marcus	V. Snell
J. Wilson	R. Ferguson
R. Gramm	S. Grant
F. Allenspach	
E. Throm	
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Original signed by:

Dino Scaletti, Senior Project Manager
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and Special Project

*Meetings between the NRC technical staff and applicants or licensees are open for interested members of the public, petitioners, intervenors, or other parties to attend as observers pursuant to the "Open Meeting Statement of NRC Staff Policy", 43 Federal Register 208058, 6/28/78.

OFFICE	LA:PDAR:ADAR	PM:PDAR:ADAR	D:PDAR:ADAR
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DATE	6/15/94	6/15/94	6/16/94

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Meeting

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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Dino Scaletti

Dino Scaletti, Senior Project Manager
Advanced Reactors Project Directorate
Division of Advanced Reactor
and Special Project

Enclosure:
As stated

cc w/enclosure:
See next page

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CANDU
Project No. 679

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CANDU 3U QUALITY ASSURANCE AND 10 CFR PART 52
July 21, 1994

0900	Discussions related to staff comments on the CANDU 3U Project Quality Assurance Manual.
1200	Lunch
1300	10 CFR Part 52 Discussions
1500	ADJOURN

DISCUSSION TOPICS

General

- What QA program was in effect prior to the generation of Revision 1 in early 1994? What design control measures have existed to date for the CANDU project?

- If the predecessor to the May 1994 QA Manual was based on Canadian QA standards, then the equivalency of the Canadian standards to the US requirements of Appendix B will need to be established by AECLT.

- As a general comment, the level of detail contained in the QA manual is substantially less than has been invoked by the other Part 52 design certification applicants.

- The QA manual expends more text describing the organizational structure aspects than details of how applicable aspects of 18 criteria of Appendix B are to be implemented. While some sections of the QA manual combine more than one criteria from Appendix B, there is no amplifying information and it appears as though not all Appendix B language has been translated into the QA manual.

- Are any parts being purchased for use in test programs to support the design phase (Crit VII)? If so augment the QAM.

- Are any prototype equipment being fabricated that require controls over special processes (Crit IX)? If so, augment the QAM.

- Are any hardware activities being performed (prototype manufacturing, test rig assembly) that require inspection (Crit X)? If so augment the QAM.

- Are any design phase tests being performed that require test controls (Crit XI)? If so augment the QAM.

- Are any design phase test activities performed that require controls over measuring and test equipment (Crit XII)? If so augment the QAM.

- Are any procurement activities being performed that would necessitate the need for controls over storage and handling (Crit XII)? If so, augment the QAM.

- Are any procurement activities being performed that would necessitate the need for controls over nonconforming material and parts (Crit XV)? If so, augment the QAM.

Organization

- Page 6: The QAM should be augmented to confirm that persons performing QA functions are independent from cost and schedular considerations and that they have the requisite authority and organizational freedom.

Program

- Page 9: While Appendix B is stated to have formed the basis of the QA manual, it will ultimately have to be met by AECLT. AECLT needs to confirm that the QA manual implements all of the applicable Appendix B requirements.

- Page 9: The statement that the referenced Regulatory Guides and NQA standards formed the basis of the QAM needs to be restated as to whether AECLT commits to the RGs/NQA standards. Any exceptions need to be clearly identified in the QAM.

Design

- How has AECL Technologies, Inc. (the applicant) insured that design/procurement/and test activities performed to date by AECL of Canada (and their contractors) meet the requirements of Appendix B and the QAM?

- The staff will have to review CANDU 3 Standard Product Design Quality Assurance Manual that is referenced in the QAM.

- The staff will have to review the CANDU 3 Generic Design Verification Plan referenced in the QAM.

- The staff will have to review the CANDU 3 Standard Product design organization procedures related to control of design changes.

- Page 11: The QAM should be amplified to address the control of design interfaces between AECLT, AECL, the CANDU 3 Standard product design organization, and design contractors.

- Page 11: The QAM should be augmented to discuss how appropriate quality standards are specified in design documents.

- Page 12: The QAM should describe the independence of the staff performing design verification.

- The terminology "important-to-safety" needs to be defined. Is it the same as the definition of safety-related in 10 CFR?

- Augment the QAM with a description on how AECLT establishes the technical adequacy of design services such as through technical reviews of design output documents.

Procurement Control

- Page 13: Describe the provisions to ensure that contractor QA programs meet Appendix B requirements or provide an equivalent level of control.

Document Control

- Describe how Certified Design Material and the SSAR are treated under the document control provisions with respect to reviews and verification of material submitted to the NRC.

- Augment the QAM to include specific reference to the document control provisions that apply to design/engineering procedures and instructions.

Corrective Action

- Page 16: Augment the QAM to reflect that measures should be established for significant deficiencies, their cause, and corrective action taken be reported to appropriate levels of management, this may be in addition to the organization responsible for the deficient condition.

Records

-Page 17: Augment the QAM that records should be maintained for corrective action program documentation.

Audits and Assessments

- Page 18: The QAM should be augmented to reflect that the audit program should extend over all areas necessary and not just be limited to design. For example, testing and procurement of items used in the test program would be candidate areas for auditing.

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