UNCONTROLLED

CANDU 3U

PROJECT

QUALITY ASSURANCE MANUAL

Revision 1

May 1994

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CONTROL MANUAL NUMBER_____

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FOREWORD

This Quality Assurance Manual describes the quality assurance program currently in use for AECL Technologies Inc., management of the design and licensing of the CANDU 3U Pressurized Heavy Water Reactor. This Quality Assurance Manual specifies overall quality assurance controls established by the Applicant, AECL Technologies Inc., and is applicable to all design activities carried out by the CANDU 3 Standard Product Design organization in its role as the principal design agency.

This manual is subject to preparation, revision and control as a controlled document. Controlled copies and revisions, thereto, are issued to a standard distribution. Each registered holder is responsible for updating this Manual in accordance with the latest revision as issued and for removing the corresponding obsolete or superseded pages. Each controlled copy of this Manual is registered and loaned to a position within the organization, not to an individual and, as such, shall be either returned to AECL Technologies Inc., upon departure of the recipient or transferred to his or her successor.

1.0 POLICY

1.1 INTRODUCTION

This section describes AECL Technologies Inc., policy for establishing and maintaining an overall quality assurance program for the design and licensing of the CANDU 3U design. The program includes management controls sufficient to achieve and demonstrate compliance with industry, regulatory, and quality assurance requirements applicable to the design and licensing of the CANDU 3U design.

1.2 POLICY

The Applicant, AECL Technologies Inc. along with each organizational entity responsible for the design and licensing of the CANDU 3U design, shall prepare, maintain, and implement a quality assurance program covering items and activities considered important-to-safety. Structures, systems, and components (SSCs), characterized as important-to-safety, are identified in Section 3.2 of the CANDU 3U Safety Analysis Report.

Activities affecting achievement and/or assurance of quality shall be accomplished in accordance with written and approved instructions, procedures, and drawings.

A fundamental principal of the CANDU 3U quality assurance program is that the achievement of quality is the responsibility of the individual performer. Each performer shall be suitably qualified (through education, training, and work experience) to accomplish his or her activities in a technically competent manner. Performing organizations are responsible for assuring that the work they produce is verified commensurate with its importance-to-safety. Sufficient resources and management supervision shall be provided to ensure timely and effective quality achievement through all phases of the CANDU 3U design process.

Organizations and persons performing quality assurance functions shall have authority and organizational freedom to identify problems; to initiate, recommend, or provide solutions; and to verify timely and effective resolution.

Assurance of quality achievement will be accomplished through periodic audit and surveillance by individuals suitably qualified to assess the work being performed and who, in addition, are independent of those directly responsible for work production.

2.0 ORGANIZATION

2.1 ORGANIZATIONAL RESPONSIBILITIES

2.1.1 Atomic Energy of Canada Limited (AECL) was established as a Crown Corporation by the Canadian Government in 1952, with a mandate to develop and exploit the peaceful uses of atomic energy.

2.1.2 AECL Technologies Inc., is a company duly incorporated under the laws of the State of Delaware, having its principal offices in Rockville, Maryland. AECL Technologies Inc., is a wholly-owned subsidiary of Atomic Energy of Canada Limited.

2.1.3 AECL Technologies Inc., is ultimately responsible for design and licensing of the CANDU 3U design in accordance with US utility or regulatory requirements and for establishing and implementing the CANDU 3U quality assurance program. AECL Technologies Inc. is responsible for identifying, initiating, and authorizing design changes to the CANDU 3 Standard Product Design to meet US requirements.

2.1.4 AECL CANDU is an operating division of AECL and is responsible for design of the CANDU class of nuclear power reactors.

2.1.5 The CANDU 3 Standard Product Design organization, under AECL CANDU Projects, the principal design agency, is responsible for design of the CANDU 3 Standard Product Design and for design of modifications, if any, identified (and authorized) by the AECL Technologies Inc., to accommodate US utility or regulatory requirements.

2.2 MANAGEMENT RESPONSIBILITIES

AECL Technologies Inc.

2.2.1 The President, AECL Technologies Inc., is responsible for design and licensing of CANDU 3U, including modifications to the CANDU 3 Standard Product Design, if any, to accommodate US utility and/or regulatory requirements. The President, AECL Technologies Inc., is also responsible for the quality assurance program for the CANDU 3U design and licensing effort and for assessing the status, adequacy, and effectiveness of the total program.

2.2.2 The Director, Safety and Licensing, is responsible for management of the license application process and for submittal of the Application for Standard Design Certification. He is also the primary interface with the US Nuclear

Regulatory Commission.

2.2.3 The Quality Assurance Manager, AECL Technologies Inc., is responsible for independently verifying status, adequacy and effectiveness of the CANDU 3U quality assurance program. This includes QA programs established by the CANDU 3 Standard Product Design organization, as well as other contractors responsible for CANDU 3U design. The Quality Assurance Manager is responsible to the President, AECL Technologies Inc., for verification of timely and effective quality program implementation. He also reports to the Manager, Quality Assurance, AECL-CANDU, for guidance with respect to QA policy.

2.2.4 The Executive Consultant, US CANDU Initiative, provides management advice and consul with respect to licensing, marketing, partnering, and utility requirements.

CANDU 3 Standard Product Design Organization

2.2.5 The General Manager, CANDU 3 Standard Product Design organization, is responsible for the design of the CANDU 3U design; that is, the CANDU 3 Pressurized Heavy Water Reactor Standard Product Design plus modifications to the Standard Product Design, if any, authorized by AECL Technologies Inc. He is also responsible for establishing and implementing the CANDU 3 Standard Product Design Quality Assurance program applicable to CANDU 3U structures, systems, and components designated important-to-safety.

2.2.6 The Manager, Technical Operations A, is responsible for design of the CANDU 3U control, instrumentation, and electrical systems; reactor systems; and fuel handling systems, in accordance with management controls defined in the CANDU 3 Standard Product Design Quality Assurance Manual.

2.2.7 The Manager,Technical Operations B, is responsible for design of CANDU 3U process engineering systems; civil engineering structures and components; information technology systems; and safety/licensing analysis, in accordance with the management controls defined in the CANDU 3 Standard Product Design Quality Assurance Manual.

2.2.8 The Manager,Quality Assurance, is responsible for independently verifying status, implementation, and effectiveness of the CANDU 3 Standard Product Design QA program. He also reports to the Manager, Quality Assurance, AECL CANDU, for guidance with respect to QA policy.

2.3 INTEGRATED CANDU 3U ORGANIZATION

The integrated CANDU 3U organization is depicted in Figure 2-1, below:

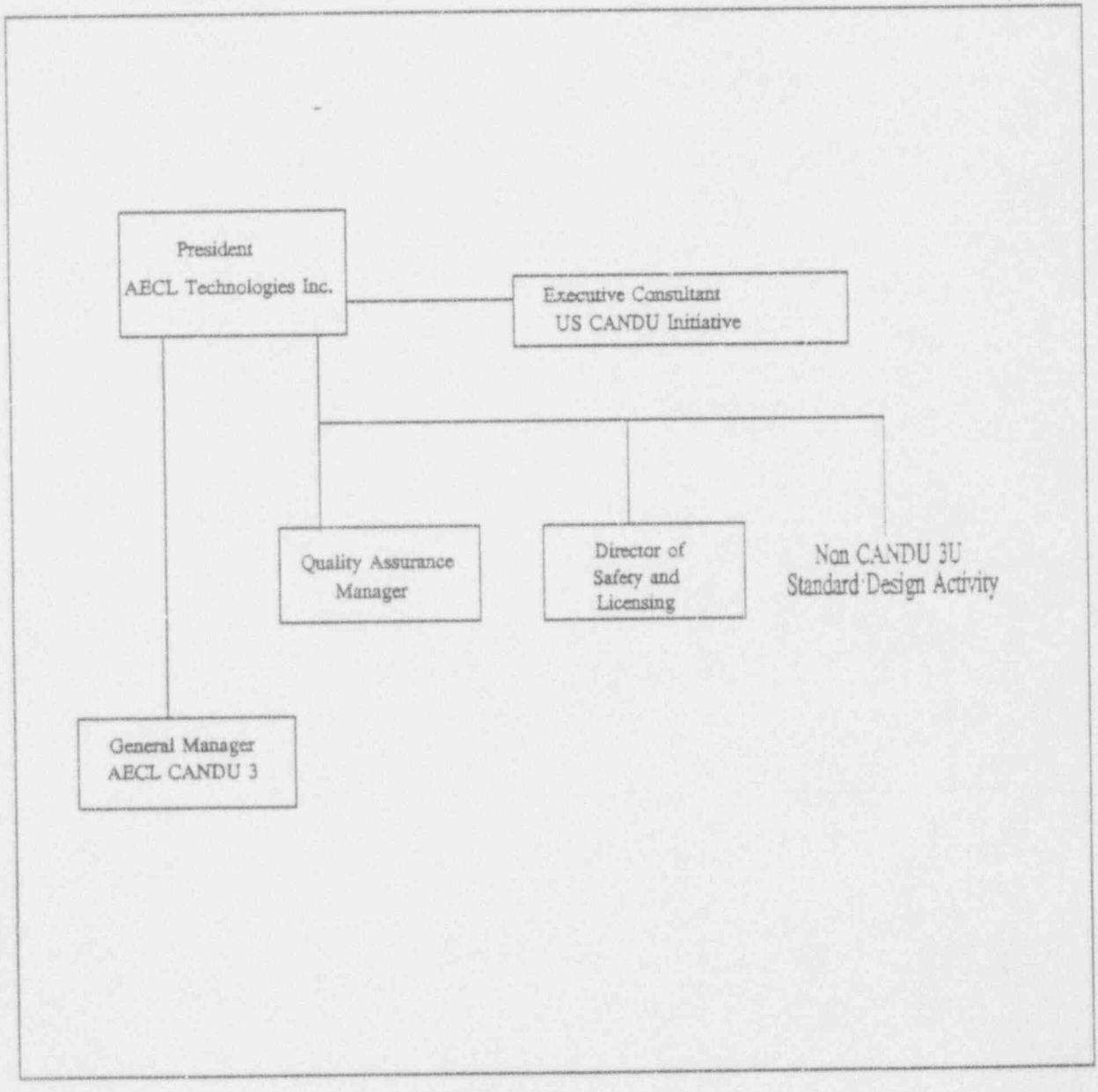

Figure 2-1

2.4 TYPICAL CANDU 3 STANDARD PRODUCT DESIGN ORGANIZATION

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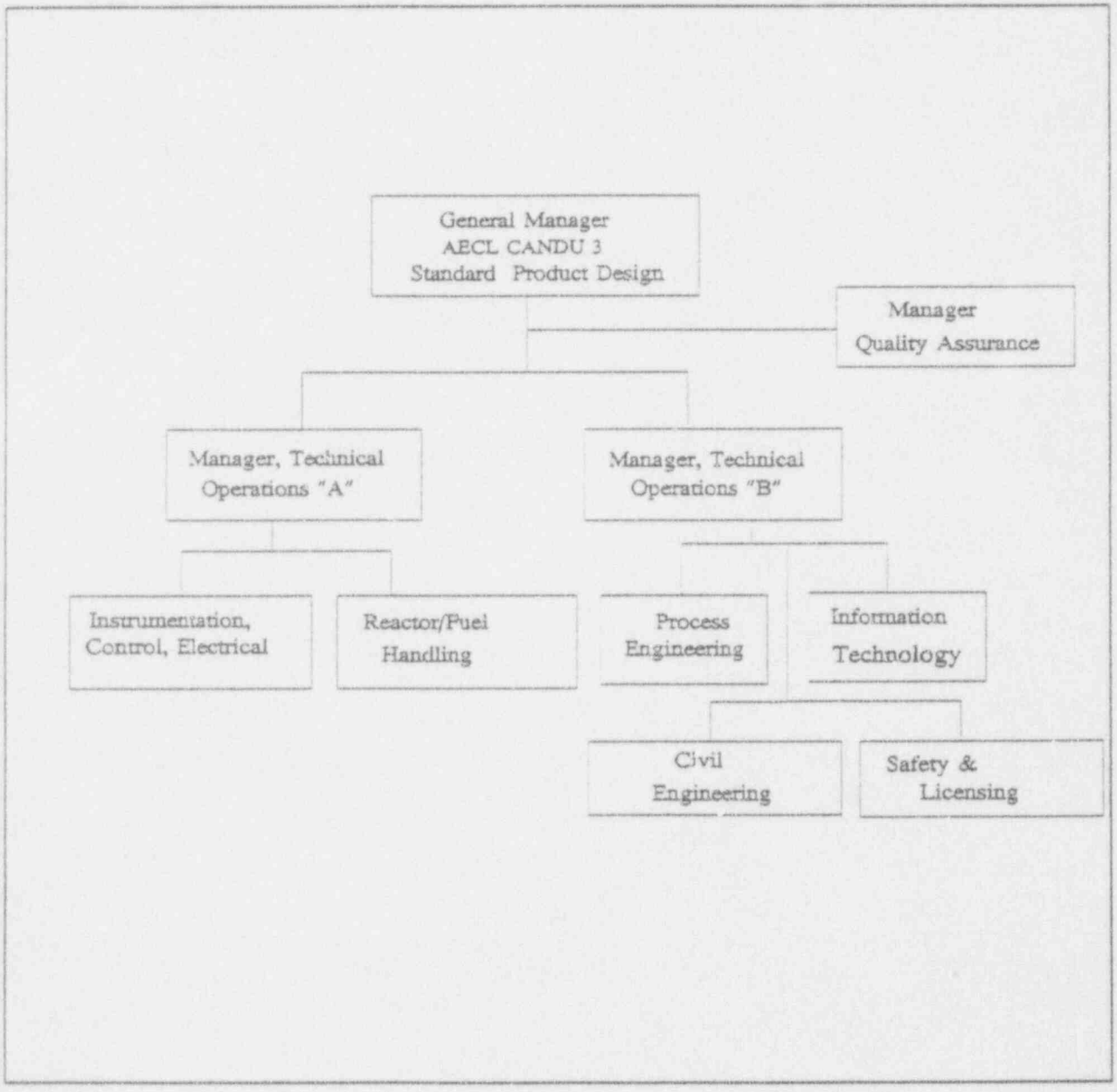

Figure 2-2

3.0 CANDU 3U PROJECT QUALITY ASSURANCE PROGRAM

3.1 SCOPE

This manual establishes quality assurance program requirements applicable to the design and licensing of the CANDU 3U Pressurized Heavy Water Reactor. The quality assurance requirements described herein are applicable to those structures, systems, and components designated important-to-safety.

3.2 PROGRAM BASIS

The following NRC Regulatory Guides, Codes, and ASME Standards form the principal bases for the CANDU 3U quality assurance program:

a. 10CFR50 Appendix B Quality Assurance Criteria for Nuclear Facilities

b. NRC Regulatory Guide 1.28, Quality Assurance Program Requirements (Design and Construction) - August 1985

c. NRC Regulatory Guide 1.70, Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - November 1978

d. ANSI/ASME NQA-1-1989, Quality Assurance Requirements for Nuclear Facilities, including Addenda 1a, 1b and 1c.

e. ANSI/ASME NQA-2-1989, including Addenda 2a-1990 and 2b-1991, Quality Assurance Requirements for Nuclear Facility Applications

3.3 QUALIFICATION AND TRAINING

The CANDU 3U quality assurance program described herein requires that all personnel performing functions within the scope of the QA program be suitably qualified by virtue of education, work experience, and training, sufficient to perform their assigned work functions in a competent manner.

The program provides for indoctrination and training of individuals carrying out performance, verification, and audit functions, sufficient to ensure required levels of proficiency are achieved and maintained.

3.4 INSTRUCTIONS AND PROCEDURES

Implementation of the CANDU 3U quality assurance program is on the basis of approved instructions and procedures. AECL Technologies Inc. instructions and procedures are contained in a controlled Operating Instruction Manual (OIM) and are further supplemented by Administrative Control Procedures (ACPs) uniquely applicable to the CANDU 3U project. Instructions and procedures developed by the principal design agency are referenced in an Appendix to the CANDU 3 Standard Product Design Quality Assurance Manual.

3.5 PROGRAM REVIEW

Management of AECL Technologies Inc. (the Applicant) shall regularly review and assess the status, adequacy, and effectiveness of the total CANDU 3U quality assurance program.

Management of other organizations participating in the CANDU 3U design effort, including the CANDU 3 Standard Product Design organization, shall regularly review the status, adequacy, and effectiveness of that portion of the CANDU 3U quality assurance program for which they have been assigned responsibility.

4.0 DESIGN CONTROL

4.1 DESIGN RESPONSIBILITY

The CANDU 3 Standard Product Design organization has been designated principal design agency, responsible for the following activities:

- Design of the CANDU 3 Pressurized Heavy Water Reactor Standard Product Design.

- Design of modifications to the CANDU 3 Pressurized Heavy Water Reactor Standard Product Design authorized by the Applicant, AECL Technologies Inc. (and accepted by the CANDU 3 Standard Product Design organization), necessary to satisfy US utility and/or regulatory requirements.

4.2 DESIGN BASIS

A program for the conduct and control of CANDU 3U design activities designated important-to-safety has been established by the CANDU 3 Standard Product Design organization and is defined in the CANDU 3 Standard Product Design Quality Assurance Manual and in CANDU 3 Standard Product Design organization procedures and instructions. The program provides for systematic control of design inputs/outputs, processes, computer software, interfaces, changes, records, and verification activities. Collectively, these activities provide assurance that design inputs have been correctly translated into drawings, specifications, procedures, and instructions and, further, that the final design complies with applicable design bases, including regulatory criteria. Other organizations responsible for CANDU 3U design, or portions thereof, will control their design activities on the basis of written procedures and instructions.

4.3. DESIGN VERIFICATION

A program for the systematic verification of the CANDU 3U design, applicable to structures, systems, and components designated important-to-safety, has been established by the CANDU 3 Standard Product Design organization. This program is described in the CANDU 3 Generic Design Verification Plan and provides for a level of verification commensurate with the designs importance-to-safety of structures, systems, and components, the complexity of the design, the degree of standardization, the state of the art, and similarity to previously proven designs. Verification/validation of computer software used in the design process is included in the program.

The CANDU 3U design verification program provides for independent verification and checking of design by means of design reviews, alternate calculations, and/or qualification testing. The program also provides for verification of design prior to release of design output (i.e., analyses, drawings, specifications, procedures, and instructions). In instances where design verification cannot be completed prior to release of design output, suitable measures are provided to identify, track, and control the release and use of unverified design output.

4.4 CHANGE/CONFIGURATION CONTROL

A program for the control of design changes has been established and is described in CANDU 3 Standard Product Design organization procedures. The program provides for the documentation and control of changes to the CANDU 3U design commensurate with measures applied to the original design. Changes in design require review and approval by the original design organization or by a suitably qualified alternate.

5.0 PROCUREMENT CONTROL

5.1 SCOPE

This section describes the scope, responsibilities and process controls applicable to the procurement of services in support of the design and licensing of the CANDU 3U Pressurized Heavy Water Reactor. Services are defined as technical or professional services performed by a contractor or consultant such as design, engineering analysis, testing, and computer code development, verification, or validation. Procurement of materials, equipment, fabrication, installation, and testing in support of construction of the CANDU 3U reactor system is excluded from the requirements specified in this manual.

5.2 RESPONSIBILITIES

The Applicant, AECL Technologies Inc., and the principal design agency, the CANDU 3 Standard Product Design organization, are individually responsible for the procurement and control of services designated important-to-safety. Procurement of services important-to-safety required in support of CANDU 3U design and licensing is accomplished on the basis of written and approved procedures prepared by the responsible procurement organization.

5.3 PROCUREMENT PROCESS

Procurement of services designated important-to-safety, whether accomplished through competitive bidding or on a sole source basis, will be initiated on the basis of a defined scope of work. The scope of work for services required will be prepared by the individual responsible for the specified work, reviewed by the designated quality representative, and approved by a management representative of the procuring organization. The scope of work for the services procured includes both technical and quality requirements, as applicable. Revisions or changes that affect either the technical or quality requirements of approved procurement documents are subject to the same or equivalent reviews as provided for the original document.

The basis for qualification of the selected services contractor or consultant is documented by the responsible individual within the initiating procurement organization and concurred with by that organization's designated quality representative. For important-to-safety activities of substantial scope, work performed by the services contractor or consultant is accomplished on the basis of an approved and controlled quality assurance program manual, a copy of which is reviewed, endorsed, and retained by the procuring organization. For important-to-safety activities of limited scope, including individual consulting agreements, the work may be accomplished within the controls specified by the procuring

organization's quality assurance program.

The Applicant, AECL Technologies Inc., and the lead design agency, CANDU 3 Standard Product Design Organization, are individually responsible for establishing measures for monitoring and controlling work performed under approved contracts or services agreements. Administration and supervision of work activities authorized under a contract or services agreement is provided by the responsible individual within the procuring organization. Work performed is monitored and controlled on the basis of progress reports and meetings, reviews of document submittals, periodic audits and surveillance, and other suitable controls.

6.0 DOCUMENT CONTROL

Measures have been established to control the preparation, review, issuance, distribution, and revision of documents used in the development of the CANDU 3U design. These measures are described in procedures and instructions prepared by the Applicant, AECL Technologies Inc.; by the principal design agency, the CANDU 3 Standard Product Design organization; and by other organizations participating in the CANDU 3U design effort. Examples of types of documents within the CANDU 3U document control system are as follows:

- Quality Assurance Manuals, Procedures, and Instructions
- Safety Analysis Reports
- Technical Descriptions
- System Design Descriptions
- Design Basis Criteria
- Design Calculations
- Design Drawings and Specifications
- Software Computer Codes
- Qualification Test Procedures

The document control system provides assurance that controlled documents, including changes, are reviewed for adequacy, further, that controlled documents are distributed to and used by persons performing quality-affecting activities; document distribution is timely; and superseded documents are controlled sufficient to preclude inadvertent use.

Substantive (i.e., non-editorial or clerical) changes to controlled documents are subject to the same or equivalent level of review and approval as provided for with the original baseline document. A master list of the current and approved version of design documents within the CANDU 3U document control system is prepared and maintained by the CANDU 3 Standard Product Design organization, and distributed to organizations responsible for performing and/or verifying CANDU 3U design.

A correspondence and commitment control system has been established by the Applicant, AECL Technologies Inc., for purposes of controlling designated correspondence with the NRC and the CANDU 3 Standard Product Design organization.

7.0 CORRECTIVE ACTION

A program has been established to assure conditions adverse to quality are promptly identified, evaluated, reported and corrected. For significant conditions adverse to quality, the program requires that the underlying cause of the condition be determined and that management actions be taken sufficient to preclude recurrence.

The Applicant, AECL Technologies Inc., is responsible for establishing and implementing corrective action procedures consistent with the scope of its responsibilities. The need for corrective action may result from evaluation of deficiencies identified in the course of audits, program reviews, trend analyses, design reviews, and QA monitoring activities. The need for corrective actions is appropriately documented and communicated to the management of the organization responsible for the deficient condition. In the event continuation of the activity would preclude identification, analysis, and correction, or otherwise increase the extent of the deficient condition, stop work action is taken. The President, AECL Technologies Inc., and the Quality Assurance Manager, AECL Technologies Inc., are each authorized to initiate stop work action.

The CANDU 3 Standard Product Design organization is responsible for establishing and implementing a corrective action program consistent with the scope of its design responsibilities. The program provides for identification, documentation, evaluation, and correction of conditions adverse to quality and is described both in the CANDU 3 Standard Product Design Quality Assurance Manual and in associated CANDU 3 Standard Product Design organization procedures and instructions. The CANDU 3 Standard Product Design program requires, for significant conditions adverse to quality, that the underlying cause of the condition be determined and appropriate management actions be taken to preclude recurrence. The QA Manager, CANDU 3 Standard Product Design Organization, is authorized to initiate stop work action in the event conditions adverse-to-quality are not corrected in a timely and effective manner.

8.0 QUALITY ASSURANCE RECORDS

A program has been established to assure records are generated and maintained during design of CANDU 3U sufficient to demonstrate acceptability of items and activities affecting quality. Records are generated and maintained of the final version of controlled design documents (calculations, analyses, drawings, system descriptions, specifications, qualification test results, etc.), as well as of work procedures and instructions, personnel qualification records, and the results of management reviews, audits/assessments, and design verifications. The program provides for administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of documents designated as QA records.

The Applicant, AECL Technologies Inc., the CANDU 3 Standard Product Design organization, and other organizations associated with the design and licensing of the CANDU 3U design, are individually responsible for establishing and implementing programs for the management and control of records of items and activities within their assigned scope of responsibility. Each organization's QA records program is procedurally described and includes criteria for use in determining types or categories of records to be generated; minimum retention requirements (lifetime or nonpermanent) for each category; identification, processing, and indexing requirements, and provisions for records storage, preservation, and safekeeping. Documents subject to control and safekeeping as QA records are individually specified in each organization's procedures and work instructions.

9.0 AUDITS AND ASSESSMENTS

A program of planned and comprehensive audits/assessments of the CANDU 3U design quality program has been established to (i) verify compliance with applicable aspects of the program and (ii) determine adequacy and effectiveness of program implementation. Audits/assessments are performed on the basis of written and approved plans, procedures, and/or checklists, and are carried out by personnel suitably qualified to assess the quality and acceptability of the work and who are independent of the work being examined. Audits/assessments are performed at early stages of the work and periodically, thereafter, consistent with the status and safety significance of ongoing work activity.

Audit/assessment results are documented and reported to the management of the organization directly responsible for the work. Follow-up actions are taken to assure responses received are timely and responsive to the concerns raised and, further, that corrective actions are taken sufficient to resolve identified concerns and prevent recurrence. Deficient areas are re-audited or checked, as appropriate, to verify the adequacy and effectiveness of resultant corrective actions.

The Applicant's audit and assessment program is described in AECL Technologies Inc. procedures. The program provides for timely audit and assessment of internal (AECL Technologies Inc.) work activities considered important-to-safety, as well as of (important-to-safety) activities performed by the principal design agency (CANDU 3 Standard Product Design), and by other organizations participating in the CANDU 3U design effort.

CANDU 3 Standard Product Design is responsible for performing timely internal audits and assessments of the design quality program established for the CANDU 3U design effort, including design activities performed by independent contractors, subcontractors, and consultants. The CANDU 3 Standard Product Design organization program for internal audits and assessments is described in the Overall Plan for CANDU 3 Internal Quality Audits.

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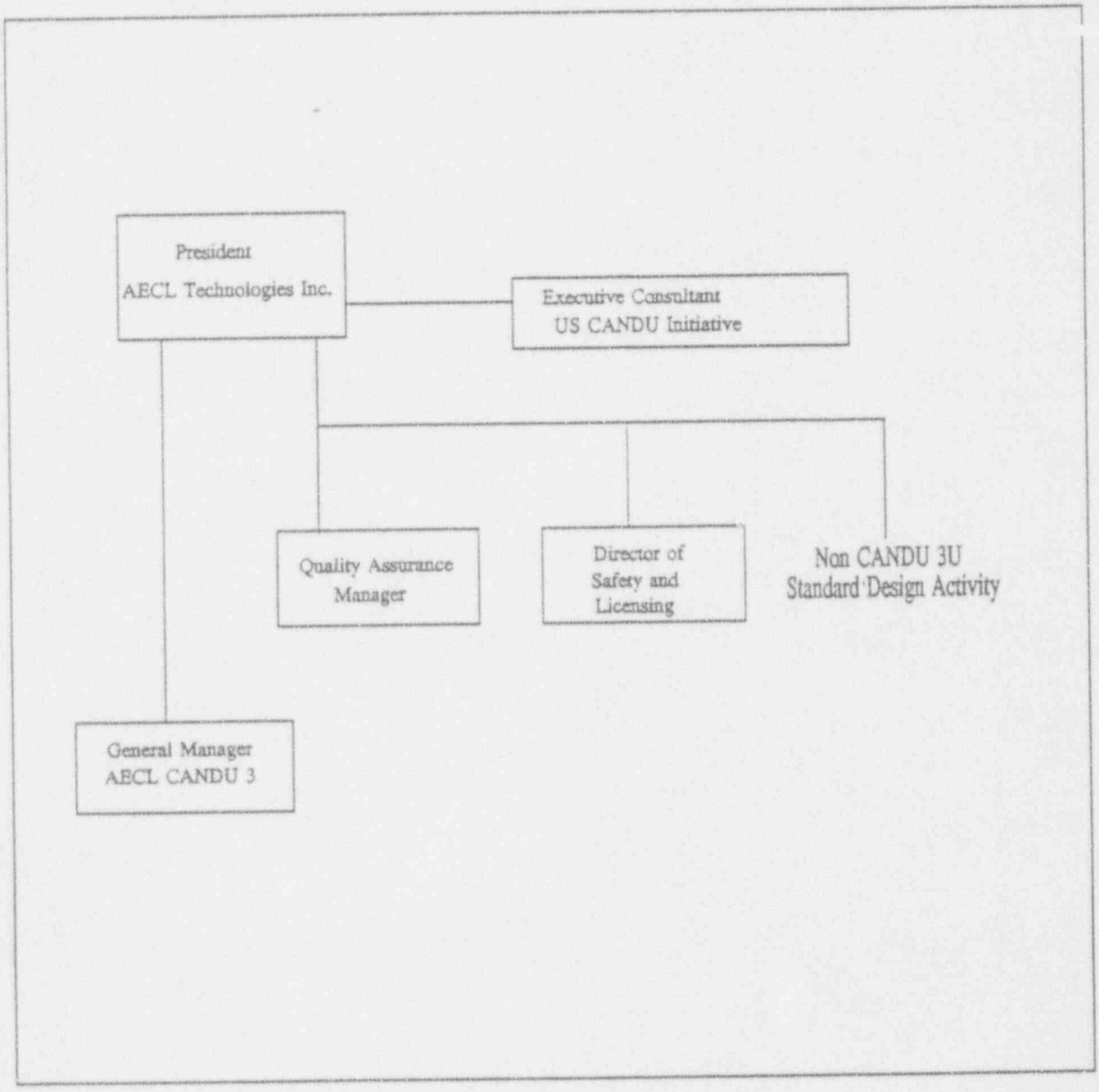

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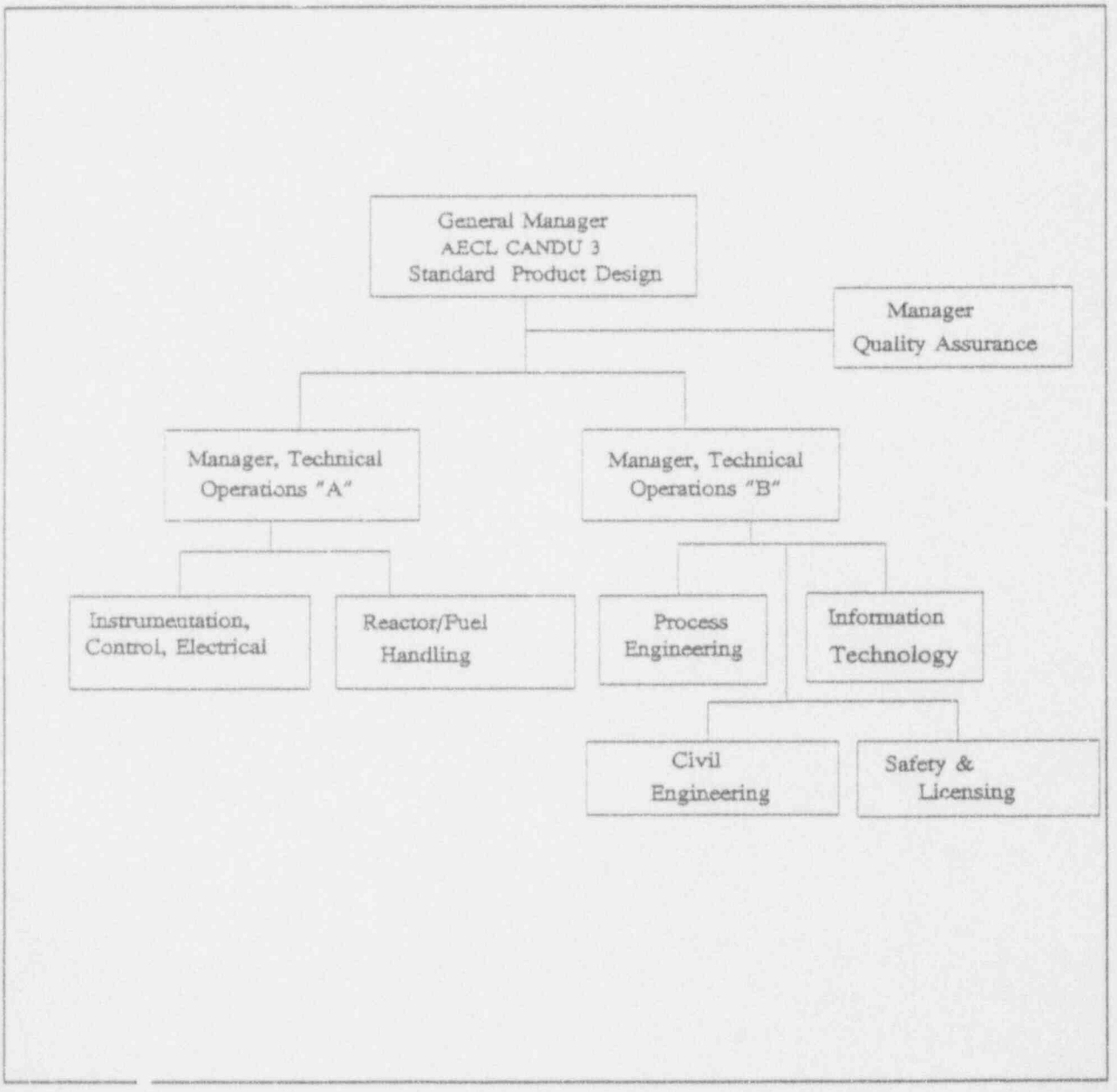

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- Design of modifications to the CANDU 3 Pressurized Heavy Water Reactor Standard Product Design authorized by the Applicant, AECL Technologies Inc. (and accepted by the CANDU 3 Standard Product Design organization), necessary to satisfy US utility and/or regulatory requirements.

4.2 DESIGN BASIS

A program for the conduct and control of CANDU 3U design activities designated important-to-safety has been established by the CANDU 3 Standard Product Design organization and is defined in the CANDU 3 Standard Product Design Quality Assurance Manual and in CANDU 3 Standard Product Design organization procedures and instructions. The program provides for systematic control of design inputs/outputs, processes, computer software, interfaces, changes, records, and verification activities. Collectively, these activities provide assurance that design inputs have been correctly translated into drawings, specifications, procedures, and instructions and, further, that the final design complies with applicable design bases, including regulatory criteria. Other organizations responsible for CANDU 3U design, or portions thereof, will control their design activities on the basis of written procedures and instructions.

4.3. DESIGN VERIFICATION

A program for the systematic verification of the CANDU 3U design, applicable to structures, systems, and components designated important-to-safety, has been established by the CANDU 3 Standard Product Design organization. This program is described in the CANDU 3 Generic Design Verification Plan and provides for a level of verification commensurate with the designs importance-to-safety of structures, systems, and components, the complexity of the design, the degree of standardization, the state of the art, and similarity to previously proven designs. Verification/validation of computer software used in the design process is included in the program.

The CANDU 3U design verification program provides for independent verification and checking of design by means of design reviews, alternate calculations, and/or qualification testing. The program also provides for verification of design prior to release of design output (i.e., analyses, drawings, specifications, procedures, and instructions). In instances where design verification cannot be completed prior to release of design output, suitable measures are provided to identify, track, and control the release and use of unverified design output.

4.4 CHANGE/CONFIGURATION CONTROL

A program for the control of design changes has been established and is described in CANDU 3 Standard Product Design organization procedures. The program provides for the documentation and control of changes to the CANDU 3U design commensurate with measures applied to the original design. Changes in design require review and approval by the original design organization or by a suitably qualified alternate.

5.0 PROCUREMENT CONTROL

5.1 SCOPE

This section describes the scope, responsibilities and process controls applicable to the procurement of services in support of the design and licensing of the CANDU 3U Pressurized Heavy Water Reactor. Services are defined as technical or professional services performed by a contractor or consultant such as design, engineering analysis, testing, and computer code development, verification, or validation. Procurement of materials, equipment, fabrication, installation, and testing in support of construction of the CANDU 3U reactor system is excluded from the requirements specified in this manual.

5.2 RESPONSIBILITIES

The Applicant, AECL Technologies Inc., and the principal design agency, the CANDU 3 Standard Product Design organization, are individually responsible for the procurement and control of services designated important-to-safety. Procurement of services important-to-safety required in support of CANDU 3U design and licensing is accomplished on the basis of written and approved procedures prepared by the responsible procurement organization.

5.3 PROCUREMENT PROCESS

Procurement of services designated important-to-safety, whether accomplished through competitive bidding or on a sole source basis, will be initiated on the basis of a defined scope of work. The scope of work for services required will be prepared by the individual responsible for the specified work, reviewed by the designated quality representative, and approved by a management representative of the procuring organization. The scope of work for the services procured includes both technical and quality requirements, as applicable. Revisions or changes that affect either the technical or quality requirements of approved procurement documents are subject to the same or equivalent reviews as provided for the original document.

The basis for qualification of the selected services contractor or consultant is documented by the responsible individual within the initiating procurement organization and concurred with by that organization's designated quality representative. For important-to-safety activities of substantial scope, work performed by the services contractor or consultant is accomplished on the basis of an approved and controlled quality assurance program manual, a copy of which is reviewed, endorsed, and retained by the procuring organization. For important-to-safety activities of limited scope, including individual consulting agreements, the work may be accomplished within the controls specified by the procuring

organization's quality assurance program.

The Applicant, AECL Technologies Inc., and the lead design agency, CANDU 3 Standard Product Design Organization, are individually responsible for establishing measures for monitoring and controlling work performed under approved contracts or services agreements. Administration and supervision of work activities authorized under a contract or services agreement is provided by the responsible individual within the procuring organization. Work performed is monitored and controlled on the basis of progress reports and meetings, reviews of document submittals, periodic audits and surveillance, and other suitable controls.

6.0 DOCUMENT CONTROL

Measures have been established to control the preparation, review, issuance, distribution, and revision of documents used in the development of the CANDU 3U design. These measures are described in procedures and instructions prepared by the Applicant, AECL Technologies Inc.; by the principal design agency, the CANDU 3 Standard Product Design organization; and by other organizations participating in the CANDU 3U design effort. Examples of types of documents within the CANDU 3U document control system are as follows:

- Quality Assurance Manuals, Procedures, and Instructions
- Safety Analysis Reports
- Technical Descriptions
- System Design Descriptions
- Design Basis Criteria
- Design Calculations
- Design Drawings and Specifications
- Software Computer Codes
- Qualification Test Procedures

The document control system provides assurance that controlled documents, including changes, are reviewed for adequacy, further, that controlled documents are distributed to and used by persons performing quality-affecting activities; document distribution is timely; and superseded documents are controlled sufficient to preclude inadvertent use.

Substantive (i.e., non-editorial or clerical) changes to controlled documents are subject to the same or equivalent level of review and approval as provided for with the original baseline document. A master list of the current and approved version of design documents within the CANDU 3U document control system is prepared and maintained by the CANDU 3 Standard Product Design organization, and distributed to organizations responsible for performing and/or verifying CANDU 3U design.

A correspondence and commitment control system has been established by the Applicant, AECL Technologies Inc., for purposes of controlling designated correspondence with the NRC and the CANDU 3 Standard Product Design organization.

7.0 CORRECTIVE ACTION

A program has been established to assure conditions adverse to quality are promptly identified, evaluated, reported and corrected. For significant conditions adverse to quality, the program requires that the underlying cause of the condition be determined and that management actions be taken sufficient to preclude recurrence.

The Applicant, AECL Technologies Inc., is responsible for establishing and implementing corrective action procedures consistent with the scope of its responsibilities. The need for corrective action may result from evaluation of deficiencies identified in the course of audits, program reviews, trend analyses, design reviews, and QA monitoring activities. The need for corrective actions is appropriately documented and communicated to the management of the organization responsible for the deficient condition. In the event continuation of the activity would preclude identification, analysis, and correction, or otherwise increase the extent of the deficient condition, stop work action is taken. The President, AECL Technologies Inc., and the Quality Assurance Manager, AECL Technologies Inc., are each authorized to initiate stop work action.

The CANDU 3 Standard Product Design organization is responsible for establishing and implementing a corrective action program consistent with the scope of its design responsibilities. The program provides for identification, documentation, evaluation, and correction of conditions adverse to quality and is described both in the CANDU 3 Standard Product Design Quality Assurance Manual and in associated CANDU 3 Standard Product Design organization procedures and instructions. The CANDU 3 Standard Product Design program requires, for significant conditions adverse to quality, that the underlying cause of the condition be determined and appropriate management actions be taken to preclude recurrence. The QA Manager, CANDU 3 Standard Product Design Organization, is authorized to initiate stop work action in the event conditions adverse-to-quality are not corrected in a timely and effective manner.

8.0 QUALITY ASSURANCE RECORDS

A program has been established to assure records are generated and maintained during design of CANDU 3U sufficient to demonstrate acceptability of items and activities affecting quality. Records are generated and maintained of the final version of controlled design documents (calculations, analyses, drawings, system descriptions, specifications, qualification test results, etc.), as well as of work procedures and instructions, personnel qualification records, and the results of management reviews, audits/assessments, and design verifications. The program provides for administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of documents designated as QA records.

The Applicant, AECL Technologies Inc., the CANDU 3 Standard Product Design organization, and other organizations associated with the design and licensing of the CANDU 3U design, are individually responsible for establishing and implementing programs for the management and control of records of items and activities within their assigned scope of responsibility. Each organization's QA records program is procedurally described and includes criteria for use in determining types or categories of records to be generated; minimum retention requirements (lifetime or nonpermanent) for each category; identification, processing, and indexing requirements, and provisions for records storage, preservation, and safekeeping. Documents subject to control and safekeeping as QA records are individually specified in each organization's procedures and work instructions.

9.0 AUDITS AND ASSESSMENTS

A program of planned and comprehensive audits/assessments of the CANDU 3U design quality program has been established to (i) verify compliance with applicable aspects of the program and (ii) determine adequacy and effectiveness of program implementation. Audits/assessments are performed on the basis of written and approved plans, procedures, and/or checklists, and are carried out by personnel suitably qualified to assess the quality and acceptability of the work and who are independent of the work being examined. Audits/assessments are performed at early stages of the work and periodically, thereafter, consistent with the status and safety significance of ongoing work activity.

Audit/assessment results are documented and reported to the management of the organization directly responsible for the work. Follow-up actions are taken to assure responses received are timely and responsive to the concerns raised and, further, that corrective actions are taken sufficient to resolve identified concerns and prevent recurrence. Deficient areas are re-audited or checked, as appropriate, to verify the adequacy and effectiveness of resultant corrective actions.

The Applicant's audit and assessment program is described in AECL Technologies Inc. procedures. The program provides for timely audit and assessment of internal (AECL Technologies Inc.) work activities considered important-to-safety, as well as of (important-to-safety) activities performed by the principal design agency (CANDU 3 Standard Product Design), and by other organizations participating in the CANDU 3U design effort.

CANDU 3 Standard Product Design is responsible for performing timely internal audits and assessments of the design quality program established for the CANDU 3U design effort, including design activities performed by independent contractors, subcontractors, and consultants. The CANDU 3 Standard Product Design organization program for internal audits and assessments is described in the Overall Plan for CANDU 3 Internal Quality Audits.