VI. Fuel and Radioactivity Control

Criterion 69—Control of releases of radioactive materials to the environment. The nuclear power unit design shall include means to control suitably the release of radioactive materials in gaseous and liquid effluents and to handle radioactive solid wastes produced during normal reactor operation, including anticipated operational occurrences. Sufficient holdup capacity shall be provided for retention of gaseous and liquid effluents containing radioactive materials, particularly where unfavorable site environmental conditions can be expected to impose unusual operational limitations upon the release of such effluents to the environment.

Criterion 61—Fuel storage and handling and radioactivity control. The fuel storage and handling, radioactive waste, and other systems which may contain radioactivity shall be designed to assure adequate safety under normal and postulated accident conditions. These systems shall be designed (1) with a capability to permit appropriate periodic inspection and testing of components important to safety, (2) with suitable shielding for radiation protection, (3) with appropriate containment, confinement, and filtering systems, (4) with a residual heat removal capability having reliability and testability that reflects the importance to safety of decay heat and other residual heat removal, and (5) to prevent significant reduction in fuel storage coolant inventory under accident conditions.

Criterion 62—Prevention of criticality in fuel storage and handling. Criticality in the fuel storage and handling system shall be prevented by physical systems or processes, preferably by use of geometrically safe configurations.

Criterion 63—Monitoring fuel and waste storage. Appropriate systems shall be provided in fuel storage and radioactive waste systems and associated handling areas (1) to detect conditions that may result in loss of residual heat removal capability and excessive radiation levels and (2) to initiate appropriate safety actions.

Criterion 64—Monitoring radioactivity releases. Means shall be provided for monitoring the reactor containment atmosphere, spaces containing components for recirculation of loss-of-coolant accident fluids, effluent discharge paths, and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

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 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 safety-related 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. These 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 and composing to be satisfied, 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 cleanliness; 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 power plant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant 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 iden-
tification and control of materials, parts, and
components, including partially fab-
cicated assemblies. These measures shall as-
sure that identification of the item is main-
tained 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,
errection, installation, and use of the item.
These identification and control measures
shall be designed to prevent the use of incor-
crect or defective material, parts, and compo-
nents.

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 ac-
cordance with applicable codes, standards,
specifications, criteria, and other special re-
quirements.

X. INSPECTION
A program for inspection of activities af-
fecting quality shall be established and exe-
cuted 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 indi-
viduals other than those who performed the
activity being inspected. Examinations,
measurements, or tests of material or prod-
ucts 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 moni-
toring shall be provided when control is in-
adequate without both. If mandatory inspec-
tion hold points, which require witnessing or
inspecting by the applicant’s designated rep-
resentative and beyond which work shall not
proceed without the consent of its des-
ignated representative are required, the spe-
cific hold points shall be indicated in appro-
priate documents.

XI. TEST CONTROL
A test program shall be established to as-
sure that all testing required to demon-
strate that structures, systems, and compo-
nents will perform satisfactorily in service is iden-
tified and performed in accordance with
written test procedures which incorporate
the requirements and acceptance limits con-
tained 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 reprocess-
ing plant operation, of structures, systems,
and components. Test procedures shall in-
clude provisions for assuring that all pre-
requisites for the given test have been met,
that adequate test instrumentation is avail-
able and used, and that the test is performed
under suitable environmental conditions.
Test results shall be documented and evalu-
ated 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 activi-
ties affecting quality are properly con-
trolled, calibrated, and adjusted at specified
periods to maintain accuracy within nec-
essary 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 in-
structions to prevent damage or deteriora-
tion. When necessary for particular products,
special protective environments, such as
inert gas atmosphere, specific moisture con-
tent 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 nu-
clear power plant or fuel reprocessing plant.
These measures shall provide for the identi-
fication 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 oper-
ating status of structures, systems, and com-
ponents of the nuclear power plant or fuel re-
processing plant, such as by tagging valves
and switches, to prevent inadvertent oper-
ation.

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 pre-
vent 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 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.