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QUALITY CONTROL BULLETIN

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ISSUED BY: RELIABILITY & QUALITY ASSURANCE DIVISION
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Subject:

AEC Interpretation of the 18 Criteria
of Quality Assurance of 10CFR50, Appendix B

During a meeting in Manchester, New Hampshire on 3/16/73, AEC/DORO discussed with Mr. K.W. Sieving, Project Manager of Seabrook their expectations for the Quality Assurance Program for Seabrook. They also provided UE&C with a copy which they categorized as the "ultimate" in compliance with Appendix B to CFR50. It contains the 18 Criteria of Quality Assurance ~~...~~

A copy of this "strong" interpretation of 10CFR50, Appendix B is presented in the interests of acquainting our readers with the AEC's current thinking on Quality Assurance for nuclear power plants.

John Kroehler, Jr.

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ULTIMATE INTERPRETATION BY AEC OF THE
CRITERIA OF APPENDIX B 10 CFR 50.
OBTAINED IN MANCHESTER, N.H. 3/6/73

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I. ORGANIZATION

A. Requirement

"The applicant shall be responsible for the establishment and execution of the quality assurance program..."

Comment

Our position is that the applicant has an obligation to assure that a QA program is instituted (Set-up), and to assure that the quality assurance program is implemented.

B. Requirement

"... The applicant may delegate to other organizations the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefor..."

Comment

Our position is that the applicant may assign the obligation for instituting or setting up the QA program or any part thereof, but this assignation does not relieve the licensee from being accountable or answerable for the QA program content or implementation.

C. Requirement

"... The authority and duties of persons and organizations performing quality assurance functions shall be clearly established and delineated in writing..."

Comment

Our position is that persons and/or the body of persons assigned to perform quality assurance functions shall have the power or right to give commands, enforce obedience and perform any actions necessary to the accomplishment of their mandate. These authorities and duties shall be clearly established and delineated in writing.

*Requirements
A, B
and C
are little
explanatory
however
Requirements
and C
are particularly
significant.*

D. Requirement

"... Such persons and organizations shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions..."

Comment

Our position is that persons and bodies of persons performing quality assurance functions shall have the power or right to give commands, and enforce obedience. These persons performing quality assurance functions shall be liberated from the authority/control of the persons or organization where this person or organization is assigned to perform such quality functions. These quality functions include identification of quality problems, to advise or counsel, or to furnish clarification or answers and to confirm or substantiate the placing in effect of the advice or counsel.

This appears to apply the management aspects as compared to the next paragraph which addresses "Management Measures."

E. Requirement

"... In general, assurance of quality requires management measures which provide that the individual or group assigned the responsibility for checking, auditing, inspecting, or otherwise verifying that an activity has been correctly performed is independent of the individual or group directly responsible for performing the specific activity."

Comment

This appears to be self explanatory in that the persons controlling or directing must take action to assure that the individual or group obligated to check, audit, inspect or otherwise verify that an activity has been correctly performed, is free from the influence or control of the individual or group directly responsible for performing the specific activity.

II. QUALITY ASSURANCE PROGRAM

A. Requirement

"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."

Comment

Our position is that portions of the QA program should precede the preparation of the PSAR in order to assure inclusion in the PSAR of regulatory requirements and organizational structures consistent with these requirements.

B. Requirement

"... 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..."

Comment

This is an instance of conflict with ANSI N 45.2 which omits policies. Our position is that the program shall be documented, in writing, by governing principles, plans, or courses of action (policies); a particular course of action or way of doing a particular task (procedures); or direction or orders (instructions), and shall be carried out throughout plant life in accordance with these policies, procedures or instructions.

C. Requirement

"... 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..."

Comment

Our position is that all equipment, within the primary pressure boundary or the accident mitigating or preventing systems, are those structures, systems, and components which must be identified and covered by the QA program. The term, "designated functions" can also be defined as "specified required activities."

D. Requirement

"... 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..."

Comment

This frequently is construed to mean that Appendix B, in its entirety, does not apply to those equipments which require little control under the code. Our position is that all of Appendix F is applicable, to assure that all controls required by the applicable codes, regardless of the extent or severity, have been rigorously applied.

E. Requirement

"... Activities affecting quality shall be accomplished under suitably controlled conditions..."

Comment

This can exist as a policy statement.

F. Requirement

"... 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..."

Comment

This has generic application which may be covered by a policy statement; however, our position is that each "Implementing/operating/maintenance procedure" must reflect the conditions stated above in specific terms, for example; Concrete work requires forms to be tight, clean, and within specified temperature limits, prior to placing the concrete; Pipe Welding, requires procedures and personnel to be qualified, and process parameters controlled; and Operations such as core physics testing, or maintenance activities in an operating facility requires calibrated instrumentation of qualified personnel.

G. Requirement

"... 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 inspections and test..."

Comment

This area has generic application which may be covered by a policy statement; however, this item is in the same category as in II F above. Our position is that each implementing/operating/maintenance procedure must reflect the need for special controls, processes, test equipment and skills as applicable to the particular quality task to be performed.

H. Requirement

"... 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..."

Comment

Our position is that, throughout all phases of construction and operations, the program must furnish the means of supporting instruction in the quality principles/doctrines for personnel performing activities affecting quality as necessary to assure that appropriate competency and skill is achieved and maintained. The program must address and reference the indoctrination and training of experienced employees in order to that proficiency is maintained. The frequency of indoctrination/training must also be stated.

I. Requirement

"... The applicant shall regularly review the status and adequacy of the quality assurance program..."

Comment

Regularly as used here is interpreted to mean "at established intervals" or at a stated frequency. Our position is that the applicant shall, at a stated frequency, perform a re-examination of the state or condition and sufficiency of the quality assurance

program in accordance with procedures and/or checklists. In addition, the schedule of performance and the general constituency of the group performing the review must be included, applying the rule that these persons cannot inspect in the area where they are responsible for performing the activity being inspected, or under supervision of the person responsible for the activity being inspected.

J. Requirement

"... 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."

Comment

The comments pertaining to the applicants review are applicable here. As a minimum the licensee's program should include a policy statement and reference to the participating organizations program, which must meet the same requirements stated for the licensee.

III. DESIGN CONTROL

A. Requirement

"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..."

Comment

Our position is that a course of action shall be set-up to assure that applicable regulatory requirements, including those portions of 10 CFR 50, 20, 115, 70 etc., and the design basis, as defined in 10 CFR 50.2 and as specified in the license application, for those structures, systems, and components within the primary coolant pressure boundary or accident mitigating and preventing systems, are correctly translated into specifications, drawings, procedures and instructions. In addition, all structures, systems, and components subject to this appendix must be subjected to all parts of this Appendix and not selected parts. ~~Implementing procedures must be established to be certain to assure that this is accomplished.~~

B. Requirement

"... 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..."

Comment

Our position is that a course of action must be established which will assure that the proper quality standards are specified and included in design documents and that deviations are controlled. Implementing procedures must describe the mechanism for following this course of action, a means of verifying and documenting accomplishment, and a listing of quality standards to be applied to each structure, system, and component in the primary coolant pressure boundary and accident mitigating and preventing systems. Quality standards as used here means the principle characteristic elements of a particular structure, system, or component which will, if applied, produce a product that is consistent with the design objective.

C. Requirement

"... 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.

Comment

Our position is that a course of action must be established which will assure that each material, part, equipment, and process which is chosen is appropriate for the application. An independent re-examination of the chosen material, part, equipment, and process shall be performed to substantiate the appropriateness of the selection. The implementing procedure shall prescribe the mechanism for following this course of action, a means of verifying and documenting accomplishment for each structure, system, and component in the primary coolant pressure boundary and accident mitigating and preventing system, and assignment of responsibility for this function.

D. Requirement

"... Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations..."

Comment

Our position is that a course of action shall be established which will cause the identification of and the exercise of authority over the common design boundaries or areas of mutual responsibilities and to bring into proper order or relationship those designs produced by the several organizations participating in design activities. The implementing procedures must prescribe the division of authority between participating design organizations, where the final approval authority is vested, the mechanism for assuring that the course of action has been implemented, and the means of verifying and documenting its implementation for each structure, system, and component, in the primary coolant pressure boundary and the accident mitigating or preventing systems.

E. Requirement

"... 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..."

Comment

Our position is that a course of action which requires that implementing procedures prescribing the authorities of the several design organizations be established to assure that each design organization is aware of the extent of participation of the other design organization and beyond which point one organization cannot proceed prior to action by interfacing design organizations. Implementing procedures must provide a means of verifying and documenting participation of the several design organizations. Procedures must be correlated to assure a mutual understanding.

F. Requirement

"... 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..."

Comment

Our position is that a course of action shall be established, in those organizations delegated design responsibility, to assure that the design has been confirmed or tested for accuracy and conformance to the characteristic requirements of the system in which it is to be used and the applicable codes and standards. This shall be accomplished by a substitute or less complex calculational methods or by the performance of a suitable testing program. The implementing procedures shall prescribe the mechanism for following this course of action including the assumptions used in the design confirmation, the person or persons performing the verification of checking, and the means of verifying and documenting accomplishment for each structure, system, and component in the primary pressure boundary and accident preventing or mitigating system.

G. Requirement

"... 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..."

Comment

Our position is that a person within the same organization, with demonstrated qualifications in the particular discipline and area of concern within this discipline, must be on an organizational

level equal to or higher than the person who performed the initial design in order to perform the substitute or less complex calculations.

H. Requirement

"... 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 qualification testing of a prototype unit under the most adverse design conditions..."

Comment

Our position is that the test program to substantiate a specific design feature must be accomplished in accordance with a detailed procedure which contains, but is not limited to; parameters to be verified; identification of data to be recorded; approval, prior to commencement, of the test procedure; and approval of the results by appropriate and pre-determined design personnel.

I. Requirement

"... Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; and accessibility for in-service inspection, maintenance, and repair and delineation of acceptance criteria for inspections and tests..."

Comment

Our position is that the exercise of authority of those courses of action pertaining to design are not limited, but must include all of those characteristics of the particular design peculiar to a facility which must be considered over the entire design lifetime. The procedures must include qualitative and quantitative limits for those areas where empirical evaluation is required.

J. Requirement

"... Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and to be approved by the organization that performed the original design unless the applicant designates another responsible organization."

Comment

Our position is that any and all changes to the design shall undergo the same rigorous examination which is described for the original design, recognizing that the applicant may delegate his authority in this area. The implementing procedures shall establish those actions which must be taken, such as review and/or approval and those organizations delegated this authority, action required before work may proceed, the mechanism for accomplishing these actions and documentation verifying that the procedural requirements have been followed.

IV. PROCUREMENT DOCUMENT CONTROL

A. Requirement

"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..."

Comment

Our position is that a course of action shall be established, by the applicant, or by his contractors or subcontractors, to guarantee or assure that relevant regulatory requirements, which includes all of 10 CFR 50, design bases, and other requirements such as PSAR/FSAR commitments, are included or referenced in procurement documents of material, equipment, and services to assure that the material, equipment, and services will meet the requirements of these commitments. Implementing procedures shall provide information concerning each structure, system, and components in the primary pressure boundary and the accident preventing and mitigating systems. The procedures must also provide a mechanism for verifying and documenting that the prescribed course of action has been accomplished.

B. Requirement

"... 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."

Comment

Our position is that all producers of structures, systems, and components in the primary pressure boundary and accident preventing and mitigating systems are subject to the provisions of Appendix B, 10 CFR 50. The program is applicable in its entirety where the provisions are pertinent regardless of the degree or extent of restrictions invoked by the codes or standards. Those criterion which do not have an immediate or direct bearing on the product being produced may be excluded, such as Criterion III, with the exception of design changes, where the contractor is producing a structure, system or component to a design provided by the procurer.

V. INSTRUCTIONS, PROCEDURES AND DRAWINGS

A. Requirement

"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..."

Comment

Our position is that those specific actions which influence the quality of any structure, system, or component within the primary pressure boundary and accident preventing or mitigating systems, shall be defined and delineated in writing by instructions, procedures, or drawings. This includes each aspect of engineering, construction, operation, pre-operational test, startup, maintenance, procurement, and repair, for those structures, systems, and components.

B. Requirement

"... Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Comment

Our position is that the instructions, procedures and drawings applicable to those structures, systems and components within the primary pressure boundary and accident preventing and mitigating systems shall include qualitative or quantitative standards or limits, where applicable, in order that the adequacy of each aspect of engineering, construction, operation, preoperational test, startup, maintenance, procurement, and repair of these structures, systems, and components may be determined.

VI. DOCUMENT CONTROL

A. Requirement

"Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawing, including changes thereto, which prescribe all activities affecting quality..."

Comment

Our position is that a course of action shall be set-up to assure that documents, such as instructions, procedures, and drawings which apply to those structures, systems, and components within the primary pressure boundary and accident preventing and mitigating systems are current at all levels of those organizations responsible for engineering, construction, operations, pre-operational test, startup, maintenance, procurement and repair of these structures, systems and components. Implementing procedures shall describe the method of accomplishment, assignment of responsibility, and a means of verifying accomplishment.

B. Requirement

"... 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..."

Comment

The course of action for control of documents and changes to these documents shall include procedures for review of instructions, procedures, and drawings for engineering, construction, operations, pre-operational test, startup, maintenance, procurement and repair, for adequacy of the documents by a person procedurally authorized to sign and release these documents. Implementing procedures shall prescribe the method and assign responsibility for distribution and confirmation that documents are distributed to the location where the prescribed activity is performed.

C. Requirement

"... 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."

Comment

Our position is that changes to instructions, procedures, and drawings, applicable to those structures, and components in the primary pressure boundary and accident preventing and mitigating systems, to include engineering, construction, operations, pre-operational test, startup, maintenance, procurement and repair of these structures, systems, and components, shall receive the same review and approval as described for the original document. If responsibility for review and approval is assigned procedurally by the originator of the design to another organization, procedures shall provide for the same review and approval as would be required if the change were performed by the originating organization.

VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICE

A. Requirement

"Measures shall be established to assure that purchased material, equipment, service, whether purchased directly or through contractors and subcontractors, conform to the procurement documents..."

Comment

Our position is that a course of action shall be set-up to provide assurance that purchased material, equipment, and services for the structure shall be in the primary pressure boundary and accident preventing and mitigating systems, ~~conform to the procurement documents~~ regardless of the source effecting procurement. Implementing procedures shall dictate the method to be used in the determination of conformance to procurement documents, assignment of responsibility, the requirement for procurement document availability, type and content of certifying documentation from the vendor which is acceptable and the means of documenting and verifying conformance.

B. Requirement

"... 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..."

Comment

Our position is that several means of verification may be used to confirm that purchased material, equipment and service conforms to procurement documents. These methods may be used separately or in combination depending on the complexity of the material, equipment or service to be procured. Implementing procedures shall be explicit in the method or means to be used in source evaluation and selection, and shall include, as a minimum, assignment of responsibility, a quantitative or qualitative list of issues to be evaluated and a means of documenting and verifying conformance with the procedure. Inspection at the source by the licensee or his designated agent, shall be performed in accordance with procedures and shall provide quantitative or qualitative acceptance criteria for the area under evaluation. Procedures for inspection upon delivery to the licensee or his agent shall require that the documents be available;

the quality data required for acceptance be available; responsibility be assigned; and a means of documenting and verifying conformance with these procedures be provided.

C. Requirement

"... Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant site prior to installation or use of such material and equipment..."

Comment

Our position is that certifications supplied by the contractor are acceptable when all code requirements to which the material and equipment have been subjected are identified and a verification has been made and documented by the licensee representative that the data is true, correct, complete, and conforms to procurement requirements. By this definition, installation, may be effected on receipt of certification and documentation, as described above provided that procedures are prepared which define the responsibility for inspection, the information to be recorded, and documentation stating that all requirements as prescribed by the procurement specification and applicable codes have been met. Installation is defined as the "Fixing in position for use".

D. Requirement

"... This documentary evidence shall be retained at the nuclear power plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment..."

Comment

Our position on this item is included in the preceding item with the exception of record retention. Guidance is presently being developed to reconcile this requirement with the code requirements; however, in any event there must be the minimum documentation described above, that is, documentary evidence that the specific requirements of the codes, standards or specifications have been met, in lieu of the actual radiographs, hydrostatic test records, etc. The lack of documentation is considered as a deficiency equal in magnitude to a failure to conform with the procurement specification or code.

E. Requirement

"... 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."

Comment

Our position is that a periodic evaluation of the quality program of contractors and subcontractors providing material equipment and services for the primary coolant pressure boundary and the accident preventing and mitigating systems shall be performed, the extent and frequency to be based on the importance, complexity, and quantity of the product or services. A course of action shall be established stating the frequency of inspections, assigning responsibility, establishing check lists and procedures, recording and evaluation of findings, and method of increasing frequency where deficiencies are found.

VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

A. Requirement

"Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained 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, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components."

Comment

Our position is that a course of action shall be set up which will assure that materials, parts, and components for the primary coolant pressure boundary, and accident preventing and mitigating systems whether supplied by a contractor or subcontractor, shall be identified and regulated such that the item maintains its identity, either on the item or records traceable to the item throughout, erection, installation and use of the item. Implementing procedures shall describe the technique in each instance, assign responsibility and provide a means of verifying and documenting accomplishment throughout the several stages, in order to preclude use of incorrect or defective parts, materials or components.

IX. CONTROL OF SPECIAL PROCESSES

A. Requirement

"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 accordance with applicable codes, standards, specifications, criteria, and other special requirements."

Comment

Our position is that a course of action shall be set up which identifies special processes including but not limited to welding, heat treating, and nondestructive testing, which must be controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria and other special requirements. This course of action shall contain a requirement for procedures for each special process defining the requirements for control, the parameters to be considered, the acceptable methods of documentation, and the code, standard, specification or criteria which governs the qualification.

X. INSPECTION

A. Requirement

"A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity..."

Comment

Our position is that a plan for inspection of activities affecting quality for those structures, systems and components in the primary coolant pressure boundary and accident preventing and mitigating systems shall be set-up and accomplished by or for the organization performing the activity. This inspection plan shall include a requirement for the development and use of procedures or checklists based on the documented instructions, procedures, and drawings, as discussed in Criterion V used in the accomplishment of the activity and shall include a requirement for documentation of the qualitative or quantitative results of the specific parameters inspected.

B. Requirement

"Such inspection shall be performed by individuals other than those who performed the activity being inspected..."

Comment

Our position is that any qualified person may perform this inspection and may be from the same organization; however, the work may not be inspected by the person who performed the activity being inspected.

C. Requirement

"...Examinations, measurements, or tests of material or products 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 monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents."

Comment

Our position is that the plan shall identify those structures, systems and components requiring such examinations and tests. Procedures shall be developed for each structure, system, and component describing those work operations where examinations, measurements, or tests of material or products is to be performed, identifying the acceptable limits, assigning responsibility, and providing for documentation of the findings. Such procedures shall consider indirect monitoring by itself or in conjunction with examinations, measurements, or tests; however, the procedural requirements, qualitative or quantitative results, documentation, and assigning responsibility shall be included. Mandatory hold points shall be specified in procedures and specifications.

XI. TEST CONTROL

A. Requirement

"... A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational test, and operational test during nuclear power plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all pre-requisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions..."

Comment

Our position is that a plan must be established, to include all structures, systems and components in the primary pressure boundary and accident preventing and mitigating systems, both individually and collectively, to assure that these structures, systems and components will perform within the limits specified in the design documents. Several stages of testing are indicated. For example, prior to installation, all pre-requisite code requirements for mechanical components must be verified, and instrumentation bench tested for accuracy and span; implementing procedures must specify each area where verification prior to installation is required, the results of such tests, and specify the control to be used for each structure, system, and component so calibrated and verified subsequent to the installation of the structure, system or component. Procedures must include tests of portions of the total system, such as the engineered safeguards systems, and full operational tests of the entire system subsequent to the proof testing of the separate and individual systems. The procedures shall include environmental considerations, and define the test instrumentation requirements. The several procedures indicated above, must describe the test technique which is peculiar to each structure, system or component, assign responsibility, establish acceptance limits and provide a means of verifying and documenting results.

B. Requirement

"... Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Comment

Our position is that the documented test results shall be evaluated by the organization originating the design objectives and/or establishing the limits, as applicable. Such evaluation must be documented and shall establish the basis for acceptance, such as simplified calculational techniques where such techniques are acceptable.

XII. CONTROL OF MEASURING AND TEST EQUIPMENT

A. Requirement

"Measures shall be established to assure that tools, gages, instruments, other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Comment

Our position is that a course of action shall be taken to assure that tools, gages, instruments, and other measuring and testing devices, subject to maladjustment through use, wear or deterioration, which are used in inspecting and evaluating structures, systems, and components in the primary pressure boundary and accident preventing and mitigating systems, are controlled, calibrated and adjusted at a stated frequency in order to maintain accuracy within specified limits. Implementing procedures shall assign responsibility; designate a means of maintaining an inventory; define the frequency for calibrating or adjusting each tool, gage, instrument, and device or generic grouping of these devices; prescribe the method for identifying the latest inspection date on the device or record traceable to the device, and define the system for assuring that each device is calibrated and adjusted on or before the date required, based on the defined frequency. In the area of operations, the procedure must consider those devices used by the facility to perform calibration of devices such as relays, nuclear and process instrumentation, as well as, those tools, gages, and instruments normally available in a power plant. Other instruments, such as, but not limited to, crane limit and movement devices, control and shim rod drop time measuring devices, and other measuring and testing devices, which are peculiar to, or have safety significance, in a nuclear power plant.

XIII. HANDLING, STORAGE AND SHIPPING

A. Requirement

"Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided."

Comment

~~Our position is that a course of action shall be established on the control of handling, storage, shipping, cleaning and preservation of material and equipment in accordance with the manufacturer's instructions or recommendations, design requirements, and applicable codes and standards for equipment and material designated for use in the primary pressure boundary and accident preventing and mitigating systems. Supplementing procedures shall be developed for each generic classification of material with unique characteristics and requirements.~~

Handling procedures shall include assignment of responsibility, the handling method or technique for each material and equipment or generic classification from receipt to storage and storage to installation, the storage locations, and a means of documenting and verifying that the handling was performed in accordance with the prescribed method or technique.

Storage procedures for each material and equipment or generic classification shall define the storage technique, any special precautions or requirements, the manufacturer's instructions/recommendations, or applicable codes and standards for the equipment or material during storage and after installation, but prior to use. In addition, the frequency at which verification is to be performed to determine that the specified storage techniques are being maintained, assignment of responsibility, and documented verification of performance of these activities.

Cleaning procedures shall define the state or level of cleanliness which must be maintained, for equipment and material during storage and installation, and subsequent to installation, the technique and controls used to establish and maintain the cleanliness level, assignment of responsibility and a means of documenting and verifying that the specified cleanliness level was established and maintained.

Shipping procedures shall include the manufacturer's recommendations and any special precautions or techniques, assignment of responsibility, and documentation and verification that the shipper is aware of shipping requirements.

XIV. INSPECTION, TEST AND OPERATING STATUS

A. Requirement

"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 inspection and tests performed upon individual items of the nuclear power plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by-passing of such inspection and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant, such as by tagging valves and switches, to prevent inadvertent operation."

Comment

Our position is that a course of action shall be established to assure that individual items of those structures, systems and components in the primary pressure boundary and associated preventing and mitigating systems are identified as to the status of required inspection and tests as prescribed by procedures instructions or drawings in order to preclude the failure to perform the test or inspection and/or inadvertent operation. The technique for identification of equipment status shall be such that the status may be determined on or immediately adjacent to the item of equipment. Implementing procedures shall describe the method for identification of equipment inspection and test status, the method of indicating operating status, such as the use of markings, such as stamps, tags, labels, routing cards, the assignment of responsibility, the method of maintaining an inventory of equipment test/inspection and operating status, and documentation of accomplishment throughout the test/inspection and pre-operational phases.

XV. NONCONFORMING MATERIALS, PARTS OR COMPONENTS

A. Requirement

"Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent 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."

Comment

Our position is that a course of action shall be established to prevent inadvertent use of materials, parts, and components, in the primary pressure boundary and accident preventing and mitigating systems, which do not conform to the requirements of the applicable codes, standards, license commitments, and/or procurement specifications. Lack of documentation for materials, parts and components required by the codes, standards, license commitments, procurement specifications, and the licensee documentation requirements is considered a nonconformance of equal magnitude to a physical defect or failure to meet operational requirements. Installation is defined as the "fixing in position for use." The course of action shall include a requirement for procedures. These implementing procedures shall assign responsibility, and prescribe the documents which must be available to the person or persons performing receipt inspection of materials, parts, and components in order to assure conformance to all requirements. In addition, the means to document qualitatively or quantitatively the acceptance, rejection, or other disposition; the mechanism for notification of the affected organization and documentation of same; the mechanism for segregation or other means of identifying materials, parts and components, which do not conform to the specified requirements; the mechanism to be used in determining and documenting the basis of action in the disposition of materials, parts, and components such as review and acceptance, rejection, repair or rework. Repair or rework shall be accomplished in accordance with approved instructions, procedures or drawings described in Criterion V, after design review, where necessary, discussed under Criterion III.

XVI. CORRECTIVE ACTION

A. Requirement

"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."

Comment

Our position is that a course of action shall be established and implementing procedures developed, to assure that conditions adverse to the quality of those structures, systems and components in the primary pressure boundary and accident preventing and mitigating systems are promptly identified and corrected. Significant conditions adverse to quality which differ from those conditions adverse to quality during the course of routine inspections normally identified and are significant by virtue of the magnitude of the adverse condition or the adverse effect on the structures, systems, and components. Significant conditions adverse to quality shall be subjected to a course of action which assures that the cause of the condition is determined and preventive measures taken to preclude the recurrence of similar adverse conditions.

Implementing procedures shall provide: a mechanism for documenting failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances; a mechanism for assuring that each item so identified and documented is corrected; a mechanism for assuring that corrective action is identified and correlated with the original documentation of the condition; the basis to be used in establishing that a condition is significant; the mechanism for assuring that the significant condition, to include cause and corrective action is reported to the appropriate level of management; and assignment of responsibility to include the level of management responsible for the review of significant deficiency documentation.

XVII. QUALITY ASSURANCE RECORDS

A. Requirement

"Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and results of reviews, inspections, test audits, monitoring of work performance, and material analyses. The records shall also include closely-related data such as qualification of personnel, procedures, and equipment..."

Comment

Our position is that those records necessary to provide proof of accomplishment of quality affecting activities required by applicable codes, standards, regulatory requirements, licensing commitments, and the quality assurance and quality control procedures, instructions, and drawings, developed to conform with Appendix B must be maintained, on those structures, systems, and components in the primary pressure boundary and accident preventing and mitigating systems. Implementing procedures shall identify those operating logs, reviews, inspections, tests, audits, monitoring of work performance, materials analyses, and other pertinent records which are to be retained. In addition, the retention period for the several types of records, the temporary and permanent storage location, and assignment of responsibility shall be specified in the procedures.

B. Requirement

"...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..."

Comment

Our position is that each procedure, instruction or drawing issued for use in verification that the quality requirements are met; or to satisfy the requirements of this Appendix, the applicable codes and standards, other regulatory requirements and licensing commitments have been met,

shall require, as a minimum, the identity of the inspector or data recorder, the qualitative and/or quantitative criteria against which an evaluation of acceptability may be made, the type of observation, and the action taken in connection with any deficiencies detected.

C. Requirement

"... Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning records retention, such as duration, location, and assigned responsibility."

Comment

Our position is that the implementing procedures shall provide a means of identifying all records/documents described above, in such a manner that the contents and the structure, system or component to which they relate, is identifiable, and approximate date(s) covered by the records/documents, the organization originating the document/records, and location, interim and final, of these records.

XVIII. AUDITS

A. Requirement

"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..."

Comment

Our position is that a detailed method shall be formulated for the regular and orderly examination of the quality assurance program to confirm or substantiate that all aspects of the quality assurance program have been implemented in accordance with the procedures, instructions or drawings. This course of action shall also establish a means of determining the effectiveness of the program through evaluation of these program examinations by appropriate levels of management.

B. Requirement

"...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. Follow-up action, including re-audit of deficient areas, shall be taken where indicated."

Comment

Our position is that the course of action shall include provisions for implementing procedures/check lists for use in the preplanned program examination. These procedures shall: assign responsibility for the audit program; establish the frequency for the audits; provide the mechanism and establish a requirement for the development, review and approval of the procedures/check lists; provide minimum qualifications for persons participating and for their independence from the area being audited; and prescribe the format for documenting the results. In addition, the procedures shall prescribe the mechanism for submission of audit results to appropriate management personnel and the Criterion for follow-up action in deficient areas.