CATEGORY 1

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SUBJECT: "DPC TR for Duke-1 QA Program,Amend 21 Listing & Discussion of Amend 21 Contents."

DISTRIBUTION CODE: IE52D COPIES RECEIVED:LTR 1 ENCL 1 SIZE: 38+11
TITLE: 50.54A.3 & 50.55F.3 Change to QA Topical Report from Utility

NOTES:

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CATEGORY 1 DOCUMENT

17.3.3.2.7 Suppliers

Suppliers quality assurance programs are evaluated and monitored by the Nuclear General Office, Supplier Verification Section to assure that quality assurance requirements are met. Supplier Quality Assurance Programs require a system of periodic and planned supplier and subsupplier audits conducted by persons not directly involved in the activity being audited.

Duke assures that supplier quality assurance programs provide for surveillance, evaluation and approval of subsupplier supplying items and services. This assurance is accomplished by reviewing supplier audits of subsupplier as part of the pre-bid audit, by making supplier control of subsupplier work a criterion for supplier approval or disapproval, and by making supplier surveillance of subsupplier a requirement of the purchase requisition.

The Nuclear General Office, Supplier Verification Section maintains surveillance and performs audits on suppliers' quality assurance programs including the activities of their suppliers and subsuppliers, to assure that operations are in compliance with specified quality assurance requirements. In the case of an audit of a supplier, any deficiencies noted by the auditor are clearly outlined in writing and given to the suppliers quality assurance organization, which takes appropriate steps to resolve the deficiencies.

A reaudit is performed, if appropriate, to verify the implementation of the corrective action.

The Environmental Compliance Group is responsible for the overall coordination of the site Environmental Management Programs to assure compliance with applicable Federal, State, and Local requirements.

The Emergency Planning Group is responsible for the overall coordination of the Site Emergency Plan to assure compliance with applicable FEMA and NRC requirements.

17.3.3.2.5 Corporate Audit

Corporate audits are initiated and directed by the Senior Vice President, Nuclear Generation. This audit is performed annually on the Duke Power Quality Assurance Program.

The Senior Vice President, Nuclear Generation selects the audit team and appoints a team leader. The audit team consists of at least three qualified individuals, none of which is from the area audited.

The scope of the audit is determined by the Senior Vice President, Nuclear Generation and the audit team. Each audit includes a review of internal audits performed by the Nuclear General Office, Regulatory Audits Section is included. The audit is performed with preapproved checklists, instructions, or plans.

The audit team conducts a post-audit conference with the responsible management of the area audited to discuss the audit results, including deficiencies. The audit team prepares checklists and the audit report. The report is sent to the President and Chief Operating Officer and the Senior Vice President, Nuclear Generation.

The Senior Vice President, Nuclear Generation determines the need for corrective action and re-evaluation. Necessary corrective action and re-evaluation are performed as required.

All pertinent correspondence, checklists, and reports related to the audit are filed.

17.3.3.2.6 Self-Initiated Technical Audits

Self-Initiated Technical Audits are performed to assess the operational readiness and functionality of a safety system, component, or structure at a nuclear station. Input from appropriate Power Generation Group Departments is considered when establishing the annual audit plan. Consideration is given to problem systems and results of audits on other stations. The Manager, Nuclear Assessment and Issues is responsible for the development of the audit plan and has the responsibility for organizing and directing the audits and providing audit team leaders. Appropriate departments will supply audit team members who have the needed expertise and level of experience. Audit Reports will be distributed to the responsible management for review and appropriate action and the Nuclear Safety Review Board.

cognizance of the Nuclear Safety Review Board (NSRB) is reviewed by the NSRB staff. The lead auditor directs the audit team in developing checklists, instructions, plans and in the performance of the audit. The audit shall be conducted in accordance with checklists; the scope may be expanded upon by the audit team during the audit, if needed. One or more persons comprise an audit team, one of whom shall be qualified lead auditor.

Audits of selected aspects of operational phase activities are performed with a frequency commensurate with safety significance and in such a manner as to assure that an audit of all QA Condition 1 functions is completed within a period of two (2) years. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities.

The audit team concludes with a post-audit conference between the audit team and responsible management. The conference includes a brief discussion of audit results, including any deficiencies and recommendations. The audit results are documented in a report.

Within thirty (30) days of the post-audit conference, a report is issued to the responsible management with copies sent to the Vice President of the audited Site or department and other management as appropriate.

Within thirty days after receipt of the audit report, responsible management replies in writing to the Manager, Regulatory Audits Section, describing corrective action and an implementation schedule. The established electronic corrective action process may be used to convey this information. When necessary, after receipt of the management reply, a re-evaluation is made to verify implementation of corrective action. This re-evaluation is documented. The audit is closed with a letter to the responsible management. All pertinent correspondence, checklists, and reports related to the audit are filed.

Audit data are analyzed and the resulting reports on the effectiveness of the QA program, including any quality problems, are reported to management for review and assessment through periodic performance trend summaries. This data is also used to modify the audit schedule as necessary to assess potential weaknesses.

17.3.3.2.4 Safety Assurance

Safety Assurance, through the Safety Review Group, and Regulatory Compliance, monitors the day to day and overall performance of each nuclear station.

The Safety Review Group investigates significant occurrences and problems to determine the root cause(s) and to identify actions necessary to prevent recurrence. The Safety Review Group also performs in-plant reviews including checking documents, records, and work in progress to determine that quality assurance requirements are being properly implemented. Work in progress includes such activities as welding, maintenance, system testing, station operation, station modifications, refueling, and record management. These investigations and reviews are documented in reports and submitted to Management, NRC, and other authorities as appropriate. The Safety Review Group also coordinates the development of corrective actions for significant occurrences and problems.

The Regulatory Compliance Group is responsible for the preparation, issue, and maintenance of all site licensing documents; providing site personnel with interpretations on the licensing documents, the preparation and submittal of violation responses, and coordination of NRC inspection activities on site.

17.3.3 SELF ASSESSMENT

17.3.3.1 Methodology

The Self-Assessment process encompasses internal and corporate audits, independent review committee activities, in-plant reviews, and other independent assessments. This process is to confirm to management that activities affecting quality comply with the quality assurance program and that the quality assurance program has been implemented effectively. These functions are directed by the Manager, Nuclear Assessment & Issues Division and the Managers of Safety Assurance. The assessment activities are performed in accordance with instructions and procedures by organizations independent of the areas being assessed. Organizations performing self-assessment activities are technically and performance oriented, with the primary focus on the quality of the end product and a secondary focus on procedures and processes.

17.3.3.2 Assessment

17.3.3.2.1 Nuclear Safety Review Board

The Senior Vice President, Nuclear Generation, appoints a Nuclear Safety Review Board (NSRB) to serve as a nuclear safety review and audit backup to the normal operating organization. The Nuclear Safety Review Board reviews proposed changes to the stations' technical specifications and operating licenses, proposed tests and experiments, proposed station modifications, and proposed changes to procedures, when such involve an unreviewed safety question. Also, the Board reviews reportable occurrences, violations of a station's technical specifications, other events and trends of nuclear safety significance and makes recommendations to prevent recurrence. Functions, operations and responsibilities of the NSRB are detailed in Chapter 6 of the technical specifications for each station.

17.3.3.2.2 Plant Operations Review Committee

The Site Vice President appoints a Plant Operations Review Committee (PORC) to review selected nuclear safety related issues. The PORC is composed of specified senior members of the site management team most responsible for the safe and reliable operation of the station. The PORC also reviews the effectiveness of corrective actions taken for specified reportable events.

17.3.3.2.3 Internal Audits

Duke's Quality Assurance Program requires a comprehensive system of planned and periodic internal audits for all phases of station operations and supporting activities.

All organizational units conducting quality assurance activities are evaluated with a system of audits. These audits are performed to determine the effective implementation of all applicable criteria of 10CFR 50, Appendix B. Periodic audits of activities or records of processes (e.g., welding, maintenance, development of design, record management, or system testing), to verify compliance and effectiveness of the implementation of the Quality Assurance Program are performed. Internal audits are initiated under the direction of the Manager, Regulatory Audits. The Manager, Nuclear Assessment and Issues Division may initiate special audits or expand upon the scope of an existing audit. The scope of each audit is determined by the responsible Lead Auditor, under the direction of the Manager, Regulatory Audits Section. Additionally, the scope of audits performed under the

Technical Specifications and established national codes and standards. To the maximum extent practicable, records are stored such that they are protected from possible destruction by causes such as fire, flooding, theft, insects and rodents and from possible deterioration due to a combination of extreme variations in temperature and humidity conditions.

Record storage areas shall be evaluated by a qualified Fire Protection Engineer to assure the records are adequately protected from damage. The evaluation shall include the following considerations as a minimum:

a) Structural collapse.

b) Unprotected steel (suspended floor slab or roof).

c) Fire frequency of similar occupancies.

d) Quantities of combustible materials.

e) Ceiling height/Room configuration which would contribute to heat dissipation.

f) Fire detection.

g) Fixed fire suppression systems.

h) On-site fire fighting organizations including available equipment.

This evaluation shall be documented for each record storage area (includes satellite file locations).

c) Audit reports for audits conducted under the cognizance of the Nuclear Safety Review Board.

Records of activities within the purview of the Plant Operations Committees are maintained. These records document the meetings of the Plant Operations Review Committees. These records include:

a) Identification of the chairperson for each meeting.

b) A listing of the Plant Operations Review Committee members present at each meeting.

c) A listing of others present at each meeting.

d) A summary of the items/issue(s) discussed during each meeting.

e) The decisions/approvals reached by the Plant Operations Review Committee during each meeting.

Records of activities within the purview of the Nuclear General Office are maintained. These records include:

a) Supplier audit reports and surveillances.

b) Audit reports of Duke Power Company activities.

c) Audit and Supplier personnel qualification records.

Records of activities within the purview of the Electric System Support Department are maintained by the Electric System Support Department in a manner similar to that described above for station quality assurance records. These records include:

a) NDE inspection personnel certification records.

b) Calibration standard records and Measuring and Test Equipment (M & T E) calibration records.

c) Environmental compliance records.

Records of activities within the purview of the Information Technology Services Department are maintained by the Information Technology Services Department in a manner similar to that described above for station quality assurance records. These records include:

a) Software requirements.

b) Software test plans.

c) Software test results.

d) Program/Module specifications and source codes.

Records of activities within the purview of the Procurement, Services and Materials Department are maintained by the Procurement, Services and Materials Department in a manner similar to that described above for station quality assurance records. These records include:

a) Records of Materials and Equipment (MEDB) Catalog.

The retention times for the various quality assurance records are in accordance with applicable requirements, including those of the Code of Federal Regulations, a station's

h) Current calibrations for measuring and test devices.

i) Copies of approved purchasing documents for items requiring quality assurance certification.

j) Maintenance histories on QA Condition 1 instrumentation and electrical and mechanical equipment.

k) Records of special processes affecting QA Condition 1 structures, systems and components.

l) Copies of purchase specifications.

m) Operating records and logbooks.

n) Periodic testing records.

o) Records of inspections.

p) Copies of approved and of completed station procedures.

q) Copies of audit reports received from the Nuclear General Office, Regulatory Audits Section, and responses thereto.

r) Copies of reports concerning station activities sent to the Nuclear Regulatory Commission.

s) Copies of drawings and vendor documents.

t) Copies of reports of significant events.

u) Records of inservice inspections.

v) Records of quality control inspections.

w) Records such as vendor documentation packages and inspection reports, piping isometric drawings, welding records, etc. compiled during the design and construction of a nuclear station.

x) Records of in-plant reviews performed on station activities.

y) Records of the qualifications of quality control and other appropriate personnel.

Test inspection, and NDE records maintained by the station contain the following:

a) A description of the activity performed.

b) The date and results of the activity.

c) Information relating to discrepancies identified with regard to the activity.

d) An identification of the data recorder(s) or inspector(s) involved in the activity.

e) Evidence of the completion, and verification thereof, of the activity.

f) An identification of the acceptability of the results of the activity.

Records of activities within the purview of the Nuclear Safety Review Board are maintained. These records include:

a) Nuclear Safety Review Board meeting minutes.

b) Nuclear Safety Review Board Reports.

modification procedures are reviewed by cognizant station personnel to determine the need for inspections. Procedures developed and implemented for inspection identify the certifications, inspection methods, acceptance criteria, and provide means for documenting inspection results.

In the case of station activities of a non-recurring nature, e.g., preoperational tests, only an original copy of an approved procedure is available for use. Such copies are controlled and are replaced whenever the procedure is superseded by a new issue. For activities which are of a recurring nature, e.g., surveillance testing, current original copies of approved procedures are maintained in a controlled manner. Copies of these original copies are then utilized in the performance of work activities. When such "working copies" involve the documentation of compliance with acceptance criteria contained in the procedure, the "working copy" of the procedure utilized is compared with the applicable original copy to assure validity. Station procedures administratively control and provide means to document this comparison. Such completed procedures are retained - See Section 17.3.2.15, "Records." When recurring work activities do not involve documentation of compliance with acceptance criteria within the procedure, e.g., certain operating activities, issuance of the applicable "working copies" is controlled to assure that only current copies are available for use.

Drawings and supplier documents, as-built drawings and changes thereto, are normally received from Engineering for distribution and use. Distribution indices are established and utilized for such documents within each station in order to assure their proper distribution and use. A master file of drawings is maintained and a master index, updated regularly, is used to identify drawings, revisions, number of copies, and distribution. Design and procurement documents are maintained, controlled, and are updated, as necessary, by Engineering. As documents are received from Engineering all superseded copies shall be destroyed or clearly marked superseded.

A master copy of all controlled documents is maintained in the document control area of each station. Copies of controlled documents are distributed by station document control personnel utilizing a distribution index to assure proper distribution and use. Reviews are performed regularly and documented to assure proper functioning of the control system.

17.3.2.15 Records

Each nuclear station is required to maintain adequate identifiable and retrievable quality assurance records. Such records are managed in a controlled and systematic manner by means of a station Master File. Access to, and use of, this file is controlled. Records required to be retained include:

a) QA Condition 1 preoperational testing records.

b) Records of modifications to station QA Condition 1 structures, systems and components.

c) Radiation monitoring records.

d) Personnel radiation exposure records.

e) Records of radioactive releases and waste disposal.

f) Isotopic and physical inventory records of special nuclear materials.

g) Records of the qualifications, experience and training of appropriate station personnel.

With regard to specific operational activities associated with QA Condition 1 structures, systems and components, it is required that such activities be accomplished in accordance with procedures, instructions, drawings, checklists, etc. appropriate to the nature of the activities being performed. As necessary, such documents identify equipment necessary to perform an activity, specify conditions which must exist prior to and during performance of an activity, and include quantitative and/or qualitative acceptance criteria, compatible with any applicable design specifications, for determining that the activity addressed is satisfactorily accomplished. Also, the procedure will require independent verification by qualified personnel of the performance of specific procedural steps. Examples of documents established concerning quality related operational activities are:

a) Preoperational Test Procedures

b) Periodic Test Procedures

c) Operating Procedures

d) Emergency Procedures

e) Maintenance Procedures

f) Instrument Procedures

g) Radiation Protection Procedures

h) Alarm Responses

i) Chemistry Procedures

The frequency of procedure reviews shall be specified and may vary depending on the type and complexity of the activity involved, and may vary with time, not exceeding 6 years, as a given plant reaches operational maturity. Review of procedures can be accomplished in several ways, including (but not necessarily limited to) documented step-by-step use of the procedure (such as occurs when the procedure has a step-by-step checkoff associated with it), or detailed scrutiny of the procedure as part of a documented training program, drill, simulator exercise, or other such activity. A revision of a procedure can constitute a procedure review.

In addition to the above, files of drawings and supplier documents applicable to the station's structures, systems and components are maintained at each nuclear station and are utilized, as appropriate, in the performance of quality related activities.

Station procedures which address activities associated with QA Condition 1 structures, systems and components are subjected to a well-defined, established review and approval process. This process includes the requirement that each procedure be reviewed for adequacy by an individual/group other than the individual/group which prepared the procedure, but who may be from the same organization as the individual/group which prepared the procedure. As appropriate, such procedures are also reviewed by personnel from the Nuclear General Office, by other departments within the Company, by the Nuclear Safety Review Board or by vendor personnel. Each procedure as required by station Technical Specifications, and changes thereto, shall be reviewed and approved by an appropriate division manager, superintendent/manager, or one of their designated direct reports prior to implementation. For procedures which implement offsite environmental, technical, and laboratory activities, the above approval may be performed by the General Manager, Environmental Services or designee. Maintenance, instrumentation and

distribution indices from the Manager, Nuclear Assessment and Issues Division or designee.

The station Technical Specifications are considered Nuclear Regulatory Commission controlled documents and are distributed within Duke Power Company by cover letter from the Site Officer or designee. Proposed changes to the station Technical Specifications shall be prepared in accordance with the station Technical Specifications and appropriate administrative controls. Proposed changes to the station Technical Specifications shall be approved by the Station Manager, or for the Station Manager by a designated manager or company officer. Submittal cover letters for proposed changes to the station Technical Specifications shall be signed by an officer of Duke Power Company.

The Safety Analysis Reports are considered controlled documents and are distributed by cover letter from the Site Officer or his designee.

The Power Generation Group Nuclear Policy Manual and the manuals listed below specify the requirements for the development, review, approval, issue, control, and use of manuals and procedures to implement the requirements contained within the Topical Report.

The Nuclear Procurement Engineering Program Manual (NPEP) contains the policies and procedures that control nuclear procurement and supplier qualification. This manual imposes requirements on all departments involved with procurement, including Procurement, Services, and Materials (PSM). This manual is approved by the Senior Vice President, Nuclear Generation or designee.

The Nuclear Policy Manual provides the governing procedure for the Assessment Organization and the Plant Operations Review Committee. This manual is approved by the Site Vice Presidents.

A Nuclear System Directive provides governing procedures for the Nuclear Safety Review Board. This directive is approved by the Manager, Nuclear Assessment and Issues Division or designee.

The Information Management Quality Assurance Program Manual (IMQAP) provides governing procedures for the development and maintenance of software by Information Technology Services which supports QA Condition activities (activities associated with nuclear safety, radwaste, fire protection, and seismic structures, systems, and components) as identified in each station's Quality Standards Manual. This manual is approved by the Vice President, Information Technology Services or designee.

The Electric System Support Department functional area manuals contain the procedures governing the functions that this department performs such as NDE, calibration, and soils testing in support of the nuclear stations. These manuals are approved by the Vice President, Electric System Support or designee.

The Generation Organizational Effectiveness Services Department Manual contains the policies and procedures governing the functions that this department performs such as fitness for duty and fire protection. This manual is approved by the Director, Generation Human Resources or designee.

out upon written notification by a cognizant, responsible individual or other written documentation, of the satisfactory completion thereof. Closure of corrective action commitments which specifically involve other Department(s) require written notification by the other Department(s) of the satisfactory completion thereof.

Electronic processes are used to track, trend, and to facilitate in the resolution of site problems. Additionally, these electronic processes are used to measure and classify nuclear performance. Identified problems are considered for generic implications. Monthly reports are processed electronically and are also provided directly to senior management and the NSRB.

Discrepancies revealed during the performance of station operation, maintenance, inspection and testing activities must be resolved prior to verification of the completion of the activity being performed. In the event of the failure of QA Condition 1 structures, systems, and components, the cause of the failure is evaluated and appropriate corrective action taken. Items of the same type are evaluated to determine whether or not they can be expected to continue to function in an appropriate manner. This evaluation is documented in accordance with applicable procedures.

QA Condition 1 materials, parts and components which are determined to be nonconforming are identified, segregated or otherwise controlled in such a manner as to prevent installation and/or use. The determination of an item's nonconformance is documented and is retained on file by the Nuclear Generation Department and, as appropriate, by tags attached to the item. Nuclear Generation Department personnel are notified of any nonconformances identified in accordance with approved procedures.

The Nuclear Generation Department maintains a listing of the status of all nonconformance documents. These reports, when complete, identify the nonconforming material, part or component; applicable inspection requirements; and the resolution, and approval thereof, of the nonconformance. Provisions are established for identifying those personnel with the responsibility and authority for approving the resolution of nonconformances. Until a determination of conformance is made, a QA Condition 1 material, part or component cannot be issued or installed. Tags which are placed on items to identify nonconformances are removed upon resolution.

Information relating to nonconforming materials, parts and components is analyzed by Safety Assurance to determine if any discernible trends which might affect quality exist. When recurring nonconformances indicate possible supplier deficiencies, such information is considered in evaluation of supplier acceptability by the Nuclear General Office, Supplier Verification Section.

Significant trends will be/are reported to appropriate levels of management.

17.3.2.14 Document Control

The Topical Report describes Duke's Quality Assurance Program for all phases of Duke's Nuclear Power Plants. This document is certified to meet NRC Quality Assurance Regulations by the President and Chief Operating Officer. The Nuclear Policy Manual establishes the policies and instructions governing activities associated with Duke's nuclear stations and identifies the various departments performing these activities. This manual is approved by the President and Chief Operating Officer or designee. These manuals are considered controlled documents and numbered copies are distributed by

c) Measuring and test equipment information.

d) Responsibility for the inspection.

e) Acceptance or rejection criteria.

f) Identification of required procedures, drawings, specifications, etc..

g) Signature or initials of inspector.

h) Record of results of the inspection.

After inspection data is collected and reviewed by the inspector, the reports are technically reviewed by personnel designated to perform that quality assurance function.

Inspection activities involving the supplier quality assurance program are evaluated and approved by the Nuclear General Office, Supplier Verification Section.

17.3.2.13 Corrective Action

Station personnel are responsible for the implementation of the quality assurance program as it pertains to the performance of their activities. Specific to this responsibility is the requirement for informing the responsible supervisory personnel and/or for taking appropriate corrective action whenever any deficiency in the implementation of the requirements of the program is determined.

Procedures require that conditions adverse to quality be corrected. In the case of significant conditions adverse to quality (more significant events), the procedures assure that the cause of the condition is determined and action be taken to preclude repetition. Performance and verification personnel are to:

a) Identify conditions that are adverse to quality.

b) Suggest, recommend, or provide solutions to the problems.

c) Verify resolution of the issue.

Additionally, performance and verification personnel are to ensure that reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

For significant incidents occurring during operation which are, or could be, related to the nuclear safety of the station, reports are generated. These reports:

a) Contain a summary description of the information relating to the subject incident.

b) Contain an evaluation of the effects of the incident.

c) Describe corrective action taken or recommended as a result of the incident.

d) Describe, analyze and evaluate any significant QA Condition 1 implications of the incident.

Such reports shall be approved by the Manager, Safety Assurance and provided to the Site Vice President, the Plant Operations Review Committee, and to the Nuclear Safety Review Board. Outstanding corrective action commitments made with regard to such incidents are identified and periodically reviewed to assure that the identified corrective actions are properly completed and documented. An identified corrective action commitment is closed

qualified in accordance with applicable codes and standards, be utilized when the performance of such processes affects the proper functioning of a station's QA Condition 1 structures, systems, and components. These procedures shall provide for documented evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

Personnel performing such activities must be qualified in accordance with applicable codes and standards. Adequate documentation of personnel qualifications is required prior to performance of the applicable special process. Non-destructive examination personnel are certified to required codes and standards.

17.3.2.12 Inspection

In order to assure safe and reliable operation, a program of inspections for QA Condition 1 structures, systems and components is established at each nuclear station. The program addresses:

a) Inservice inspections required by Section XI of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code.

b) Inspections to verify compliance with cleanliness criteria.

c) Inspections to verify compliance with certain instrument and maintenance procedures.

d) Inspections to verify conformance of materials, parts, and components received at a nuclear station with applicable specifications and requirements.

e) Inspections to verify the integrity of QA Condition 1 structures, systems and components during and/or after maintenance and modification.

The personnel performing these inspections are examined and certified in their particular category. Current qualification and certification files are maintained for each inspector. Nondestructive examination inspectors are certified in accordance with American Society for Non-destructive Testing (SNT-TC-1A) recommended practice. Written procedures require the test and certification of inspectors in other categories such as Mechanical, Electrical, and Structural as described in the appropriate quality assurance manual. For cases where inspectors will perform limited functions within a category, they are tested and certified to those limitations. These inspectors are only allowed to perform inspections specifically defined in this limited certification.

Certification procedures and certifications are approved by Nuclear Generation or Electric System Support personnel responsible for these processes. These procedures comply with the requirements of applicable codes and standards.

Modifications, repairs and replacements are inspected in accordance with the original design and inspection requirements, or acceptable alternatives. Mandatory inspection hold points are included in the documents addressing the activities being performed, as necessary, and work does not proceed beyond such hold points until satisfactory completion of the required inspection, disposition of any item not meeting the acceptance criteria, and any required reinspection. Inspection procedures, instructions, and checklists contain the following information or require this information on inspection reports:

a) Characteristics to be inspected.

b) Method of inspection.

Installed instrumentation is subject to the requirements of the Technical Specification and is not subject to the tagging requirements discussed in (c) and (d) above. The Nuclear General Office, Regulatory Audits Section verifies implementation of the calibration program through periodic audits.

The basis for this exception on the installed Technical Specification required equipment is the PMPT, Preventive Maintenance Periodic Testing program. This is a computerized scheduling program that automatically schedules PMPT using SWR's, Standing Work Requests. When devices have been acceptably calibrated, the clock starts for the next calibration due date. The indication that the device is within calibration specifications and identification of the individual who was responsible for performing the calibration is documented within the calibration procedure for the device. If the device fails to meet calibration specifications, it will be repaired, replaced and/or engineering involvement will be requested to further evaluate. The PMPT program along with the calibration procedures address all the requirements in Topical Report Section 17.3.2.9 c and d. Therefore, there is no need to place tags on the devices to identify the calibration status.

17.3.2.10 Inspection, Test, and Operating Status

In order to assure that equipment status is clearly evident, and to prevent inadvertent operation, the operational quality assurance program requires QA Condition 1 structures, systems and components which are in an other than operable status to be identified as such. This identification may be means of tags, labels, stamps or other suitable methods. Where appropriate, an independent verification of the correct implementation of such identification measures is performed. When tags, labels or stamps are utilized for the identification of equipment status, the issuance and removal thereof is documented in order to assure proper control of such identification measures. Also, procedures require that the operability of an item removed from operation for maintenance or testing be verified prior to returning the item to normal service.

Inspections and tests required by the written approved procedures which address work activities are infrequently, temporarily deferred. When such a deferral does occur, a discrepancy is considered to exist and documentation of the acceptable completion of the affected work activity is not performed until the discrepancy is resolved.

Measures taken to identify equipment inspection and test status by Nuclear Generation Department personnel are controlled by the Nuclear Generation Department. Measures taken by Electric System Support Department personnel, during the performance of required inspections and quality control activities, to identify equipment status are controlled by the Electric System Support Department.

17.3.2.11 Special Process Control

The Nuclear Station Manager is responsible for directing the organization and performance of the station's program for the control of special processes, and for assuring the necessary qualified personnel are available.

Electric System Support and Nuclear Generation are responsible for furnishing qualified personnel, performance of and documentation of Non Destructive Examination (NDE).

The operational quality assurance program contains or references procedures for the control of special processes such as welding, heat treating, non-destructive examination, coatings, crimping, and cleaning. The program requires that approved, written procedures,

test results is conducted to determine the cause, required corrective action, and retest as necessary.

In addition to the above, after maintenance to, or modification of, QA Condition 1 structures, systems and components certain proof tests, electrical tests, operational tests or other special tests are performed and documented as required to verify the satisfactory performance of the affected items.

17.3.2.9 Measuring and Test Equipment Control

The organizations performing QA Condition 1 work activities have the responsibility to assure the required accuracy of tools, gauges, instruments, radiation measuring equipment, non-destructive testing equipment and other measuring and test devices affecting the proper functioning of QA Condition 1 structures, systems and components and that a program of control and calibration for such devices is provided. This program includes the following:

a) Devices are assigned permanent, identifying designations.

b) Devices are calibrated at prescribed intervals, and/or prior to use, against certified equipment having known, valid relationships to nationally recognized standards. The calibration interval for a device is based on the applicable manufacturer's recommendations. If experience dictates that the manufacturer's recommendations are not appropriate, the calibration interval is changed as necessary.

c) Devices that have been acceptably calibrated are affixed, where practical, with a tag, or tags, showing the date of calibration, the date the next calibration is due, an indication that the device is within calibration specifications and the identification of the individual who was responsible for performing the calibration. When attaching tags is not practical, the device is traceable by unique identification to the applicable calibration records.

d) Devices which fail to meet calibration specifications are affixed with a tag, or tags, showing the date of rejection, the reason for rejection and the identification of the individual rejecting the device. "Accepted" and "Rejected" calibration tags are sufficiently different to preclude confusion between them.

e) Items and processes determined to be acceptable based on measurements made with devices subsequently found to be out of calibration are re-evaluated.

f) Devices stored under conditions which are in accordance with, or more conservative than, the applicable manufacturer's recommendations.

g) Devices are issued under the control of responsible personnel so as to preclude unauthorized use.

h) Devices are shipped in a manner that is in accordance with, or more conservative than, the applicable manufacturer's recommendations.

i) Records are maintained on each device which identify such items as the device designation and the calibration frequency and specifications. Records are maintained to reflect current calibration status.

j) As a rule, the calibration program achieves a minimum ratio of 4-to-1 calibration standard accuracy to measuring and test equipment accuracy unless limited by the state of the art; however, when an accuracy ratio of less than 4-to-1 is utilized, an evaluation of the specific case is made and documented.

Nonconforming items are identified, segregated, or otherwise controlled in such a manner as to preclude their inadvertent substitution for and use as conforming materials parts and components.

17.3.2.8 Test Control

The operational quality assurance program addresses both preoperational and periodic (surveillance) testing. The program requires that such testing associated with QA Condition 1 structures, systems and components be accomplished in accordance with approved, written procedures and that schedules be provided and maintained in order to assure that all necessary testing is performed and properly evaluated on a timely basis.

Test controls include requirements on the review and approval of test procedures, and on the review and approval of changes to such procedures, as discussed in Section 17.3.2.14, "Document Control." Also, specific criteria are established with regard to procedure content. Examples of items which must be considered in the preparation and review of procedures include:

a) References to material necessary in the preparation and performance of the procedure, including applicable design documents.

b) Tests which are required to be completed prior to, or concurrently with, the specified testing.

c) Special test equipment required to perform the specified testing.

d) Limits and precautions associated with the testing.

e) Station, unit and/or system status or conditions necessary to perform the specified testing.

f) Criteria for evaluating the acceptability of the results of the specified testing, compatible with any applicable design specifications.

Test procedures contain the following information or require this information be documented:

a) Requirements and acceptance limits contained in applicable Design and procurement documents.

b) Instructions for performing the test.

c) Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of the item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

d) Mandatory inspection hold points.

e) Acceptance and rejection criteria.

f) Methods of documenting or recording test data and results.

g) Provisions to assure test prerequisites have been met.

Requirements are also established for verification of test completion and for determining acceptability of tests results. Test results are reviewed and accepted by the testing organization and the organization responsible for the item being tested. In the event that test results do not meet test acceptance criteria, a review of the test, test procedure and/or

e) Sufficient precautions will be taken to preclude identifying materials in a manner that will affect the function or quality of the item being identified.

Control of material, parts and components is governed by approved procedures. Specific control requirements include:

a) Nonconforming or rejected materials, parts, or components are identified to assure that they will not be inadvertently used.

b) The verification of correct identification of material, parts, and components is required prior to release for assembling, shipping and installation.

c) Upon receipt, procedures require that materials, parts or components undergo a receipt inspection to assure they are properly identified and that the supporting documentation is available as required by the procurement requirements/specifications. Items having limited shelf or service life are identified and controlled.

d) Each organization which performs an operation that results in a change in the material, part or component is required to make corresponding revisions and/or additions to the documentation record as applicable.

Following QA receipt inspection, materials, parts and components which are determined to be acceptable are assigned an identifying designation such as a unique tracking number in order to provide traceability of each item. This traceability is maintained for QA Condition items. In the event that the identification of an item becomes lost or illegible, the item is considered nonconforming and not utilized until proper resolution of the nonconformance. When a designated item is subdivided, each subdivision is identified in accordance with the above requirements. Where physical identification of an item is impractical or insufficient, physical separation, administrative controls or other appropriate means are utilized.

17.3.2.7 Handling, Storage, and Shipping

The quality assurance program requires that QA Condition 1 materials, parts and components be handled, stored, issued and shipped in such a manner that the serviceability and quality assurance traceability of an item is not impaired. Handling, storage and shipping of an item is in accordance with any special requirements identified in documents pertaining to the item. Such requirements may include special handling tools and equipment, special protective coverings and/or special protective environments. Items are to be marked or labeled to preserve the item's integrity and indicate the need for any special controls. Procedures identify predetermined requirements for handling, preservation, storage, cleaning, packaging, issuing and shipping and are utilized by suitably trained individuals.

Conforming QA Condition 1 materials, parts and components are stored in controlled, segregated areas designated for the storage of such items. Inspections and examinations are performed on a periodic basis to assure that recommended shelf life of chemicals, reagents, and other consumable materials is not exceeded. Hazardous items are stored in suitable environments with controls to prevent contamination of QA Condition 1 structures, systems, or components.

As required by procurement criteria, in order to assure that material and equipment are fabricated in accordance with applicable requirements, supplier review, audit and surveillance are performed by the Nuclear General Office, Supplier Verification Section. The review, audit and surveillance may include witnessing of tests, observation of fabrication checkpoints, and documentation review. Evaluation of overall supplier performance is performed at intervals and to a depth consistent with the item or service's importance to safety, complexity, and the quantity and frequency of procurement.

Procedures are established which implement the surveillance program for suppliers. This assures that items and services procured for use in nuclear QA Condition 1 applications are in compliance with applicable procurement requirements/specifications.

These procedures provide for surveillance of those characteristics or processes to be witnessed, inspected or verified. Surveillance activities assure that the supplier complies with all quality requirements outlined in the procurement document(s). The surveillance report becomes a part of the Nuclear General Office, Supplier Verification Section files. The surveillance representative has the authority and responsibility to stop work when the required quality standards are not met.

Upon receipt, QA Condition 1 materials, parts and components are placed in a controlled, designated area and are subjected to a receipt inspection. This inspection is intended to determine whether or not each item received conforms with applicable procurement requirements. Such inspections and the subsequent determination of conformance or nonconformance are documented by means of reports, which are retained on file and as appropriate, by tags attached to the items. Until a determination of conformance is made, a QA Condition 1 material, part or component cannot be issued and installed.

17.3.2.6 Identification and Control of Items

Control of materials, parts, and components at nuclear sites is the ultimate responsibility of the Senior Vice President, Nuclear Generation Department with responsibilities delegated to each nuclear Site Officer.

Identification requirements for materials, parts and components important to nuclear safety are stated in specifications, drawings and purchase documents. Specific identification requirements are as follows:

a) Materials, parts, components, assemblies, and subassemblies shall be identified either on the item or records traceable to the item to show that only correct items are received, issued and installed.

b) Some components, such as pressure vessels are identifiable by nameplates as required by applicable codes, or Duke specifications. Materials, parts, and components are traceable from such identification to a specific purchase order to manufacturer's records and to quality assurance records and documentation.

c) When required by procurement documents, materials are identified by heat, batch or lot numbers which are traceable at receipt. When several parts are assembled, a list of parts and corresponding numbers is included in the documentation.

d) When required by specifications or codes and standards, identification of material or equipment with the corresponding mill test reports, certifications and other required documentation is maintained throughout the life of the material or equipment by a unique tracking number.

If verification of a critical characteristic is to be by supplier survey, Supplier Verification is responsible for verifying the acceptability of the supplier control of the identified critical characteristic.

Procurement of materials, parts, components and services associated with a station's QA Condition 1 structures, systems, and components is controlled during the operational life of the station so as to assure the suitability for their intended service and that the safety and reliability of the station are not compromised.

Each procurement information for materials, parts, and components associated with QA Condition 1 structures, systems and components is identifiably designated as such. The procurement requirements applicable to each item are determined by a cognizant individual. This determination is reviewed by another cognizant individual who may be from the same organization as the individual/group making the determination. Procurement information must include or reference other documents such that to assure sufficient information is fully identified to specify the items being procured. Subsequent to preparation, procurement information is approved by the Procurement Engineering Manager or designee who is qualified by experience and training for the function.

Procurement information for QA Condition 1 materials, parts and components is reviewed to assure that quality assurance, technical and regulatory requirements including supplier documentation requirements are adequately incorporated into the purchase document(s). Significant changes to the content of such purchasing information are reviewed and approved in a manner consistent with the original.

Where necessary, procurement documents require that QA Condition 1 materials, parts, and components be acquired from suppliers determined to be acceptable by the Nuclear General Office, Supplier Verification Section - see Section 17.3.3.2.7. Determination of acceptability requires that a supplier provide Duke the right of access to the supplier's facilities and records for inspection and audit.

Except for some commercial grade items each shipment of items procured from a supplier must be accompanied by a certificate of conformance (or equivalent) which identifies the applicable procurement documents and item(s). The supplier documention specifies that the item meets the procurement requirements and includes repair records and a description of any deviations. This documentary evidence must be on site (any location under the QA Program) and all procurement, inspection, and testing requirements satisfied before the item is placed in service or used.

Nuclear Generation Department or Electric System Support Department personnel will review and approve this documentary evidence of item conformance with procurement requirements.

17.3.2.5 Procurement Verification

The approved procurement documents along with all quality and technical requirements are provided to the supplier by the Nuclear Generation and/or PSM Department. Procurement information is provided to the Supplier Verification Section and the receiving location.

holds an appropriate ASME Certificate of Authorization or Quality Systems Certificate issued by the ASME. When QA Condition 1 basic components and services are procured from an ASME supplier whose quality performance has not been verfied by an audit or survey, additional assurance of product quality shall be obtained by supplier surveillance, inspection or test.

The Supplier Verification Manager may place a supplier on the Approved Suppliers List following review, approval and acceptance of an audit performed by another licensed nuclear utility, or following review, approval and acceptance of a joint utility audit of a supplier. Licensed operating US nuclear utilities may be placed on the Approved Suppliers List by the Supplier Verification Manager without an audit or survey.

The Supplier Verification Section shall complete a satisfactory re-evaluation of a supplier every 12 months in order to maintain the supplier on the Approved Suppliers List. Annual re-evaluations may be extended by 3 months, from 12 to 15 months, with written approval of the Supplier Verification Manager. Additionally, suppliers shall be re-evaluated by means of an audit at least triennially, if initial approval was by audit or survey. The triennial audit requirement may be extended by 6 months, from 36 to 42 months, with written approval of the Supplier Verification Manager.

Materials, parts and components shall be procured to specified technical and quality requirements at least equivalent to those applicable to the original equipment or those specified by a properly reviewed and approved revision. As required by the applicable purchase documents, suppliers furnish documentation which identifies the material and equipment purchased and the specific procurement requirements met by the items. Also, as required by the applicable purchase documents, suppliers will provide documentation which identifies any procurement requirements which have not been complied with, together with a description of any deviations and repair records. Supplier evaluation and re-evaluation are done in accordance with procedures to assure their documentation is valid.

When QA Condition 1 products/services are not supplied as a basic component and meet the definition of commercial grade, the item may be procured without the performance of a supplier qualification audit or the existence of a documented supplier Quality Assurance Program. These commercial grade items used in QA Condition 1 applications require evaluation, dedication and approval by Nuclear Generation Department personnel. Supplier selection for commercial grade items is the responsibility of the responsible engineering personnel. These items are subject to the same verification and checking process for suitability of application as other QA Condition 1 items.

Critical characteristics for the dedication of Commercial Grade Items are determined by engineering technical sponsors and approved by the responsible engineering personnel based on the manufacturer's published specifications and the intended safety function for the items. Critical characteristics used for acceptance and dedication of commercial grade items are selected to provide reasonable assurance that the items will meet their catalog or manufacturer specifications and will perform the necessary safety functions in the intended applications. Verification of critical characteristic acceptability will be by manufacturer/supplier survey, manufacturing surveillance, receipt tests or inspections, or post installation testing. Historical data, when documented, may be used to supplement the other acceptance methods. Dedication will not be based purely upon historical data unless such data represents industry wide experience.

e) Materials, parts and components required in order to implement the modification.

f) Drawings revised and/or requiring revision.

g) FSAR revision(s) and/or Technical Specifications amendment(s) necessary.

h) Whether or not the modification involves an unreviewed safety question.

The reviews of the proposed modification, including applicable implementing procedures associated therewith, certifies that quality assurance requirements have been met and determines inspection requirements prior to implementation of the modification. Modifications which are determined to involve an unreviewed safety question are reviewed by the Nuclear Safety Review Board and must be authorized by the Nuclear Regulatory Commission prior to implementation.

17.3.2.4 Procurement Control

Duke's Quality Assurance Program requires the control of QA Condition 1 items or services purchased from a supplier, subsupplier or consultant.

The Quality Assurance Program supplements appropriately the ASME QA requirements with the regulatory guides listed in Table 17-1, with the clarifications or alternatives stated therein.

Procurement of QA items is to the quality program requirements in effect at the time of purchase.

Nuclear Generation or Electric System Support is responsible for the technical qualification of suppliers and control of the initial procurement of all QA Condition 1 items and services. Procurement requirements/specifications are prepared, checked, and approved by appropriate personnel and forwarded to the PSM Department, who prepares an inquiry and forwards it to approved suppliers. The Nuclear General Office, Supplier Verification Section is responsible for qualification of supplier's quality assurance programs.

QA Condition 1 material, equipment and services procured as basic components may only be procured from qualified suppliers. Supplier qualification is accomplished by a Supplier Verification Section evaluation of the supplier's quality assurance program. An audit or pre-award survey is performed by the Supplier Verification Section when required. The audit or pre-award survey is carried out in accordance with a comprehensive audit checklist to determine the ability of the supplier's quality assurance program and manual(s) to meet applicable criteria of 10CFR50, Appendix B, the ASME Code when required, and any other codes and standards determined to be appropriate for the prospective scope of supply. The audit or survey includes a review of the supplier's QA program manuals. The audit team prepares a formal audit report which states whether or not the supplier is qualified to supply the specific items or services. The audit report is reviewed and approved or disapproved by the Supplier Verification Manager. Approved suppliers of basic components will then be included on the Approved Supplier's List. Technical qualifications are determined by engineering personnel. Commercial qualification is determined by the PSM Department following evaluation of bids from qualified suppliers. Bid evaluation includes evaluation of the technical, quality and commercial qualifications of the prospective suppliers.

The Supplier Verification Manager may place a supplier on the Approved Suppliers list without the performance of an audit or pre-award survey when the prospective supplier

other design input. The individuals assigned to perform the check and review of a QA Condition 1 document have full authority to withhold approval of the document until every question concerning the work has been resolved. If required, the matter can be carried up to the Senior Vice President, Nuclear Generation Department by individuals in Nuclear General Office or to the Site Officer by individuals in Site Engineering for resolution. The checker verifies calculations by checking or by alternate computations. Analytical models, theories, examples, tables, codes, computer programs, etc., used as bases for design must be referenced in the design document and their application verified during check and review. Model tests, when required, to prove the adequacy of concept or design are reviewed and approved by the responsible engineer. The tests used for design verification must meet all the requirements of the designing activity. Computer programs are controlled in accordance with the applicable Quality Assurance Manual whereby programs are certified to demonstrate their applicability and validity.

Design verification may consist of reviews, alternate calculations, and/or qualification testing. Design reviews are intended to verify the correctness of design inputs, logic, calculations, and analyses. Calculations by alternate methods provide assurance that, for instance, computer codes are performing as expected, and that no systematic error in calculation procedures exist. Qualification testing, when suitable, is guided by Duke Power's adoption of various regulatory guides which deal with qualification testing. Qualification testing will simulate the most adverse design conditions that are expected to be encountered. Design verification is performed by qualified individuals in accordance with approved procedures which identify the responsibilities, features and pertinent considerations to be verified such as verification method, design parameters, acceptance criteria, and documentation requirements. Design verification is required to be completed before relying on the item to perform its function and before its installation becomes irreversible. The use of the originator's immediate supervisor for verification is: 1) restricted and justified to special situations where the immediate supervisor is the only individual capable of performing the verification 2) the need is individually documented and approved in advance by the supervisor's management and 3) the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse.

The individual/organization assigned responsibility for evaluation and design of a modification performs a safety evaluation of the proposed modification. This evaluation provides the bases for the determination that the modification does or does not involve an unreviewed safety question. This evaluation is reviewed by an individual/group other than the individual/group performing the safety evaluation, but who may be from the same organization as the individual/group which performed the safety evaluation. This evaluation and the review thereof are documented.

Following completion of design and evaluation of a modification, the responsible individual/organization summarizes the modification design and identifies the design documents and information required for modification implementation. This addresses such items as:

a) A description of the modification.

b) References utilized in the evaluation and design of the modification, and necessary for the implementation of the modification.

c) Special installation instructions.

d) Operational, test, maintenance and inspection requirements.

In order to assure proper interface control, the responsibilities of the various individuals/organizations involved in modifications are formally identified. The assignment of responsibility for the evaluation and design of a particular modification to a specific individual/organization is documented. Also, the written instructions addressing the control of modifications address the communication of information between involved individuals/organizations and, where appropriate, require documentation of such communications.

For each proposed modification, the individual/organization assigned responsibility for evaluation and design of the modification considers the following in the design of the modification:

a) Necessary design analyses, e.g., physics, stress, thermal, hydraulic, accident, etc.

b) Compatibility of materials.

c) Accessibility for operation, testing, maintenance, inservice inspection, etc.

d) Necessary installation and periodic inspections and tests, and acceptance criteria therefor.

e) The suitability of application of materials, parts, components, and processes that are essential to the function of the structure(s), system(s) and/or component(s) to be modified.

Final approval prior to implementation of each station modification shall be by the Station Manager or the Manager of Engineering; or for the Station Manager by the Operations Superintendent, the Maintenance Superintendent, the Work Control Superintendent, or the On-Duty Emergency Coordinator as previously designated by the Station Manager. Modifications are then executed in accordance with approved checklists, instructions, procedures, drawings, etc., appropriate to the nature of the work to be performed. These checklists, instructions, procedures, drawings, etc. include criteria for determining the acceptability of the modification.

Errors and deficiencies noted in the design of a modification are corrected by means of a variation notice or a revision to the modification. The control measures applied to each such modification revision or variation notice are equivalent to the control measures applied to the modification originally. Each modification revision or variation notice and the review and approval thereof, is documented.

Prior to a modification being declared operable and returned to service, all procedures governing the operation of the modification are reviewed and revised as necessary. If the modification significantly alters the function, operating procedure, or operating equipment, then additional training is administered as necessary.

Adequate identification and retrievable documentation of station modifications is retained for the life of the station.

Computer programs are controlled in accordance with appropriate department procedures, whereby programs are certified to demonstrate their applicability and validity.

17.3.2.3 Design Verification

During the check and review, of design documents, particular emphasis is placed on assuring conformance with applicable codes, standards, SAR design commitments, and

17.3.2 PERFORMANCE/VERIFICATION

17.3.2.1 Methodology

The Duke Power Company operational quality assurance program is described in various Company manuals. Procedures and work instructions necessary to implement the requirements of the operational quality assurance program are developed and approved by the organization responsible for the activity. These procedures and instructions may be contained in manuals, station procedures and directives, administrative instructions and/or other documents. These documents identify the criteria to determine acceptable quality for the activity being performed. On-site implementation of procedures and work instructions is the responsibility of the Site Officer. Verification of quality against these documents is performed by means of inspections, tests, audits, and reviews. Procedures for such inspections, audits and reviews are developed and approved by the responsible implementing manager.

The program receives on-going review and is revised as necessary to assure its continued effectiveness.

17.3.2.2 Design Control

In order to provide for the continued safe and reliable operation of a nuclear station's QA Condition 1 structures, systems and components, design control measures commensurate with those applied to the original design are implemented during the operational phase to assure that the quality of such structures, systems and components is not compromised by modifications.

Duke has assigned the responsibility for design activities during the operational phase of nuclear stations to the Nuclear Generation Department.

The operational quality assurance program establishes procedures and instructions for implementation and assurance of design control during the operational phases for QA Condition 1 items. These procedures and instructions assure the design is performed in accordance with approved criteria, and that deviations and nonconformances are controlled.

Each QA Condition 1 design document, such as a calculation, specification, or drawing, is prepared by a qualified individual who specifies and includes the appropriate codes, standards, SAR commitments, and other design input within the design documents. The preparer notes any deviations or changes from such standards within the design documentation package. Each design document is then checked by another individual qualified in the same discipline and is reviewed for concept and conformity with applicable codes standards, and other design inputs (as specified within the design documentation package). The document is approved by the individual having overall responsibility for the design function. A review of each specification is made to assure incorporation of necessary quality assurance information. The entire review process is documented.

Prior to the release of any QA Condition 1 design document, it is reviewed to assure coordination of disciplines. If the document clearly involves no coordination with the other disciplines, this review may be waived by the sponsor, with documented concurrence by the other disciplines.

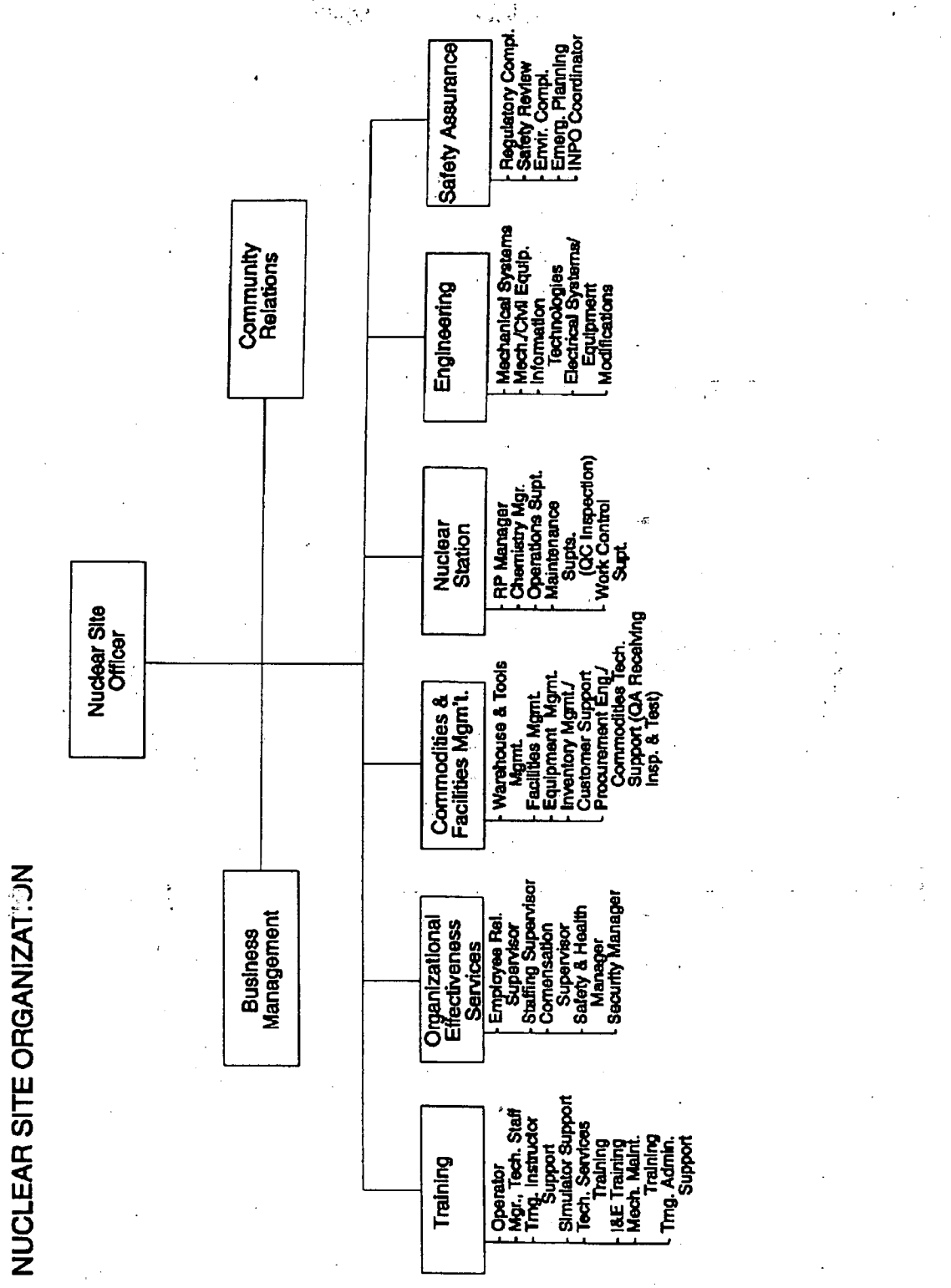

Figure 17-4. Nuclear Site Organization

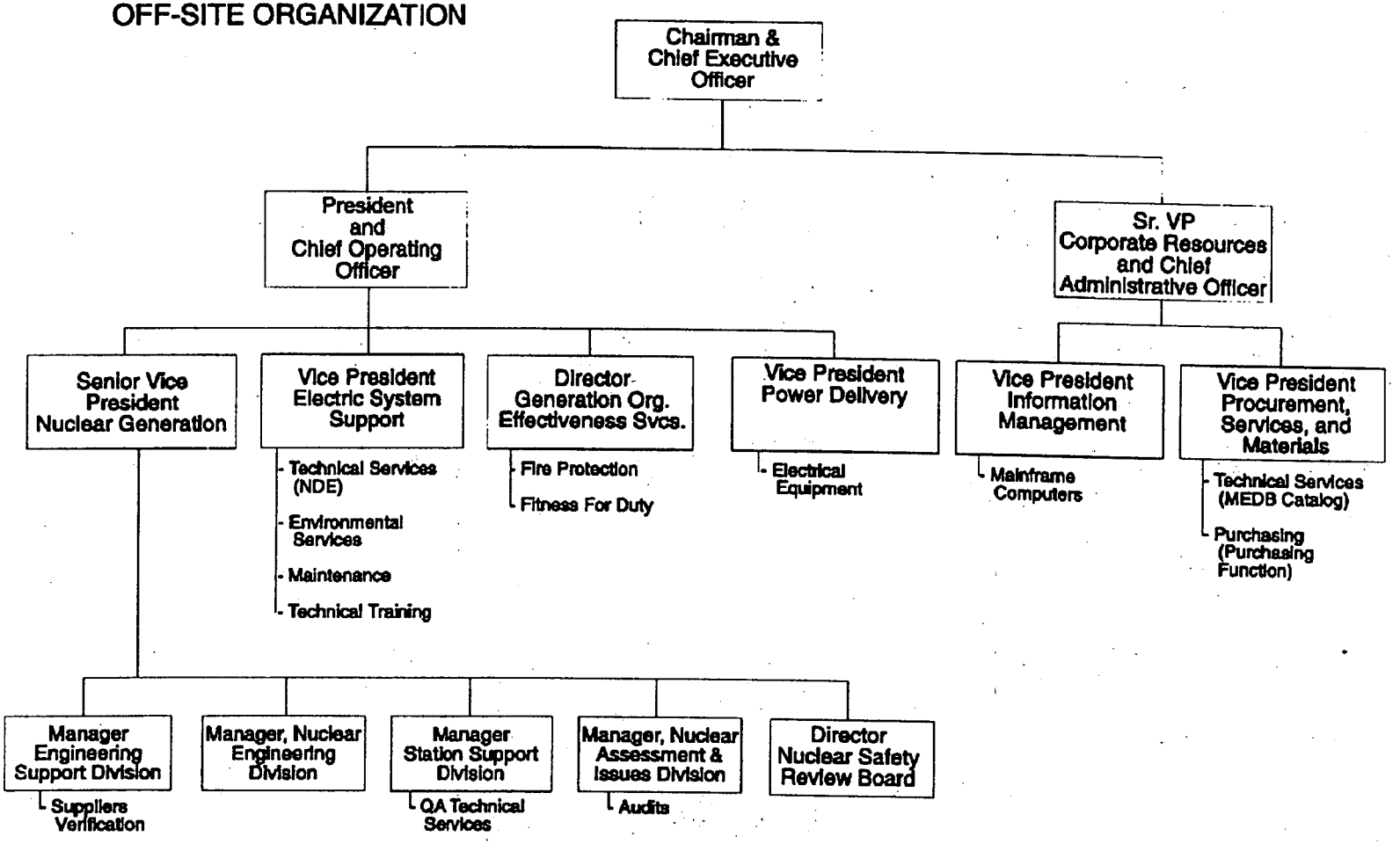

Figure 17-3. Off-Site Organization

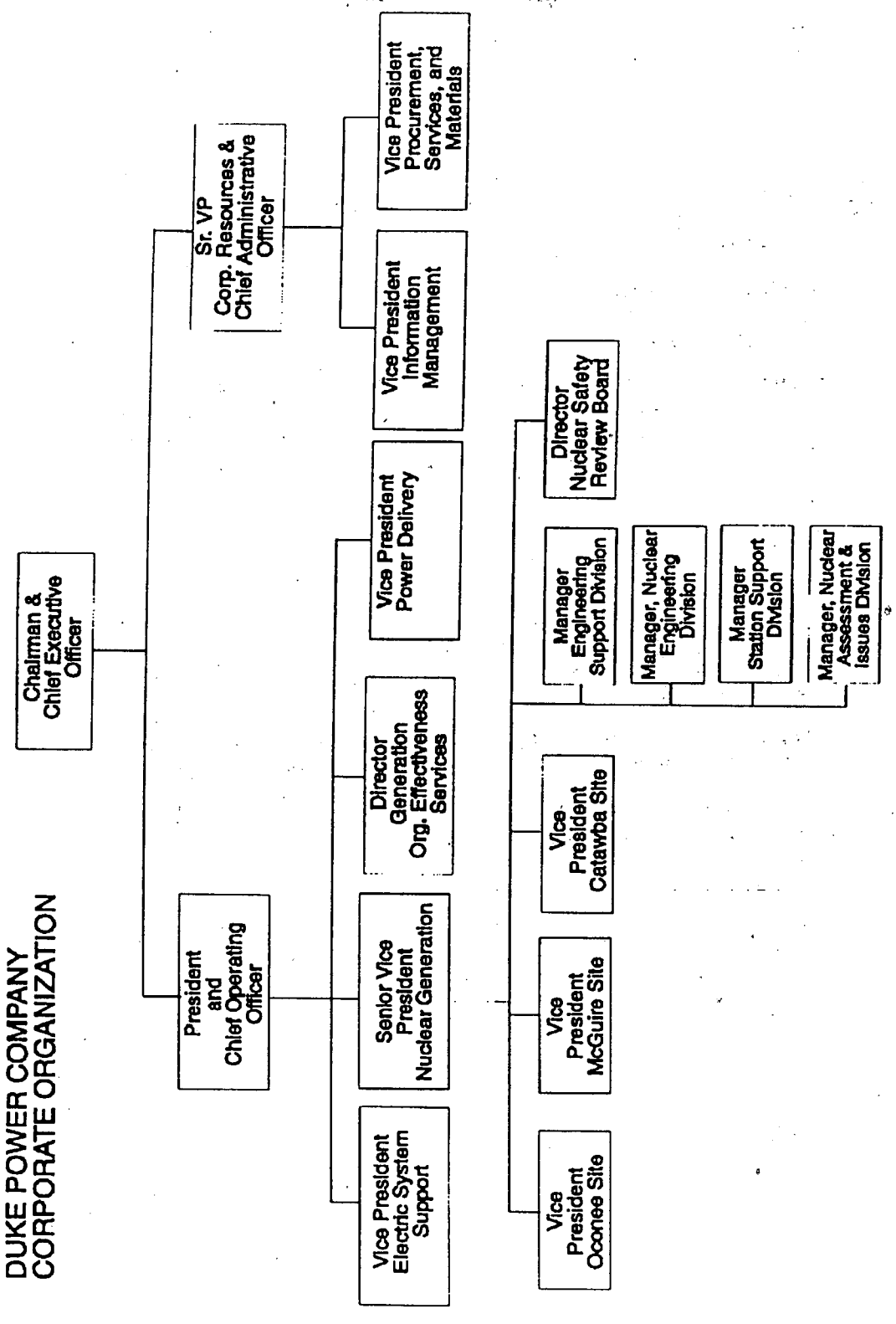

Figure 17-2. Duke Power Company Corporate Organization

Duke Power Company
422 South Church Street
Charlotte, NC 28242-0001

William H. Grigg
Chairman and
Chief Executive Officer

DUKE POWER

December 1, 1994

DUKE POWER COMPANY
QUALITY ASSURANCE PROGRAM
POLICY STATEMENT

Duke Power Company has developed a comprehensive quality assurance program, described in the Topical Report, to answer our needs and the regulatory requirements established by the Nuclear Regulatory Commission and other jurisdictional authorities for the safe and effective design, construction, operation, and modification of nuclear stations. This program has my unqualified support and is to be followed at all times.

The authority and responsibility to administer the quality assurance program is assigned to the President and Chief Operating Officer.

This quality assurance program is documented in quality and administrative manuals prepared by the involved departments and approved by the responsible department heads. These manuals delineate the action taken by Duke Power Company personnel during the design, construction, operation, testing, refueling, maintenance, repair and modification of its nuclear stations.

The department heads of all company departments engaged in nuclear activities are responsible for implementing procedures required by the quality assurance program.

Duke Power Company personnel are given authority commensurate with their responsibility, including the authority to stop work which does not conform to established requirements. This stop-work authority must be exercised in accordance with approved procedures.

All matters concerning quality which cannot be resolved at the normal interfaces among departments shall be referred to the President and Chief Operating Officer. Matters that cannot be resolved at this level will be referred to me for final resolution.

W. H. Grigg

TOPICAL REPORT
QUALITY ASSURANCE PROGRAM
AMENDMENT 18

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Figure 17-1. Duke Power Company Quality Assurance Policy Statement

training of replacement personnel and for periodic retraining, reexamining, and/or recertifying as required to assure that personnel remain proficient. Personnel receive formal orientation training in basic quality assurance policies and practices.

Personnel receive additional formal training, as appropriate, which addresses specific topics such as NRC regulations and guides, quality assurance procedures, auditing and applicable codes and standards. Special training of personnel in quality assurance related matters, particularly new or revised requirements, is conducted as necessary. Training and qualification records are maintained for each employee. Documentation of formal training includes the objectives, content of the program, attendees, and date of attendance.

17.3.1.6 Corrective Action

Duke Power has established a corrective action process whereby all personnel are to assure conditions adverse to quality are promptly identified, controlled, and corrected. This process is administered to correct the problem and its cause rather than establish blame or fault. This process also provides for trending of problems to detect adverse trends in quality performance, including reporting of results to appropriate levels of management. This process is discussed in Section 17.3.2.13, "Corrective Action."

17.3.1.7 Regulatory Commitments

Duke management is committed to applicable quality assurance regulations, codes, and standards as identified in Section "Quality Assurance Standards and Guides" of this report.

17.3.1.2.8 Department Interfaces

Quality related activities are performed by Nuclear Generation, Electric System Support, Generation Organizational Effectiveness Services, Procurement Services and Materials, Information Management. Departmental interfaces are identified in the quality assurance program manuals associated with these areas. Quality related activities performed by the Power Delivery Department are identified by and conducted in accordance with approved departmental interface agreements.

Organization charts for these departments are maintained in appropriate manuals for the respective departments.

17.3.1.3 Responsibility

The individuals who constitute the Duke Corporate Organization have full personal and corporate responsibility to assure nuclear power plants are designed, constructed, maintained, tested and operated in a manner to protect the public health and safety; and to assure the effectiveness of the Quality Assurance Program.

Corporate audits are initiated and directed by the Senior Vice President, Nuclear Generation. This audit is performed annually to assess the adequacy of the Quality Program. This audit is discussed in greater detail in Section 17.3.3.2.5.

Applicable procedures are developed, approved by the responsible implementing manager, issued for use, with sufficient personnel available and trained with necessary resources prior to performing quality affecting activities.

17.3.1.4 Authority

Anyone involved in quality activities in the Duke organization has the authority and responsibility to stop work if they discover deficiencies in quality. Personnel performing quality assurance and quality control functions have the authority and responsibility to stop unsatisfactory work and to assure the item/activity is controlled to prevent further processing, delivery, installation, or use until authorized by appropriate management. If a member of the group performing the work disagrees, they are instructed to take the matter to their management. The disagreement may either be resolved at this level or at any level up to and including the Chief Executive Officer.

17.3.1.5 Personnel Training and Qualification

A training program is established for each nuclear station and support organization to develop and maintain an organization qualified to be responsible for operation, engineering, testing, inspection, maintenance, modification and other technical aspects of the nuclear station involved. The program is formulated to provide the required training based on individual employee experience and intended position. The program is in compliance with Nuclear Regulatory Commission licensing requirements, where applicable. The training program is such that trained and qualified operating, maintenance, engineering, inspection, testing, technical support and supervisory personnel are available in necessary numbers at the times required. In all cases, the objectives of the training program shall be to assure safe and reliable operation of the station.

The training program is kept current to reflect station modifications and changes in procedures. A continuing effort is used after a station goes into commercial operation for

and regulatory audits. The Regulatory Audits Section has the authority and organizational freedom to:

1) Identify quality problems

2) Initiate, recommend or provide solutions to quality problems through designated channels.

3) Verify the implementation of solutions to quality problems.

4) Ensure cost and schedule do not unduly influence decision making involving quality.

If significant quality problems are identified by Regulatory Audit personnel, the Manager, Nuclear Assessment and Issues Division or designee, has the responsibility and authority to notify management to direct the affected work activity to cease pending satisfactory resolution of the identified problem.

17.3.1.2.3 Electric System Support Department

The Electric System Support Department provides centralized services to the Power Generation Group in areas such as environmental engineering, NDE, measuring and test equipment calibration, craft support, and others. The Electric System Support Department is directed by the Vice President, Electric System Support who reports to the President and Chief Operating Officer.

17.3.1.2.4 Generation Organization Effectiveness Services

The Generation Organization Effectiveness Services provides input to Power Generation Group in such areas as fire protection and Fitness For Duty. The Generation Organization Effectiveness Services is directed by the Director, Generation Organization Effectiveness Services who reports to the President and Chief Operating Officer.

17.3.1.2.5 Procurement, Services and Materials (PSM) Department

PSM is responsible for the Materials and Equipment Database (MEDB), which is the computer database containing necessary attributes for purchase of a commodity; and the purchasing function. These activities in PSM are directed by the Manager- Business & Technical Services, and the General Manager, Corporate Materials Management respectively, who report to the Vice President, Procurement Services and Materials. PSM is responsible for operation of any central storage facilities not directly assigned as part of a nuclear site. The Nuclear Site Organization administers, implements and assesses the Quality Assurance Program at these locations storing QA Condition 1 items.

17.3.1.2.6 Information Management (IM) Department

IM is responsible for the development and maintenance of mainframe computer software and data which supports QA Condition activities. These activities in IM are directed by managers and directors reporting to the Vice President, Information Management.

17.3.1.2.7 Power Delivery Department

The Power Delivery Department provides maintenance and testing services to the nuclear station for selected electrical equipment. These services are directed by the Vice President, Power Delivery who reports to the President and Chief Operating Officer.

assigned the responsibility of performing the activity. The verification of quality is assigned to qualified personnel independent of the responsibility for performance or direct supervision of the activity. The degree of independence varies commensurate with the activity's importance to safety.

The policies described in this document are implemented through departmental program manuals and procedures, and are, therefore, transmitted to all levels of management.

Organization charts for various departments/locations are contained in Chapter 13 of the respective Station Final Safety Analysis Report.

17.3.1.2.2 Nuclear Generation Department

The Nuclear Generation Department has direct line responsibility for all Duke Power Company nuclear station operations. The Nuclear Generation Department is responsible for achieving quality results during engineering, preoperational testing, operation, testing, maintenance and modification of the Company's nuclear stations and with complying with applicable codes, standards and NRC regulations. The functions of Nuclear Generation are directed by the Senior Vice President, Nuclear Generation.

The Senior Vice President, Nuclear Generation formulates, recommends, and carries out plans, policies, and programs related to the nuclear generation of electric power; and reports to the President and Chief Operating Officer. The Senior Vice President, Nuclear Generation is informed of significant problems or occurrences relating to safety and quality assurance through established administrative procedures, and participates directly in their resolution, where necessary.

a) Nuclear Site Organization

The Nuclear Site Vice Presidents (Site Officer) report to the Senior Vice President, Nuclear Generation. The Site Officer is also responsible for the administration, implementation, and assessment of the quality assurance program as it applies to station operation. In the discharge of their responsibilities, the Site Officers direct the activities of the station organizations.

Reporting to the Site Officer for each nuclear station, is a Manager, Nuclear Station who is assigned the direct responsibility for the safe operation of the facility. The qualification requirements for the Manager, Nuclear Station are in accordance with the provisions of ANSI N18.1-1971 and are presented in each station's FSAR.

b) Nuclear Generation Department, Nuclear Generation Office

The Nuclear Generation Department, Nuclear General Office, is divided into four divisions. The activities of each division are directed by a manager who reports to the Senior Vice President, Nuclear Generation. The divisions within the Nuclear General Office are: (1) Engineering Support, which provides technical support to the stations in procurement, supplier verification, maintenance and engineering; (2) Nuclear Engineering, which provides support to the stations in severe accident analysis, safety analysis, nuclear design, and fuels/core management; (3) Station Support, which provides technical support to the stations in work control and human performance, chemistry, radiation protection, steam generator maintenance, quality assurance services, inservice inspection and special projects such as license renewal, RM&C, and steam generator replacement; and (4) Nuclear Assessment and Issues, which provides technical and business support to the stations in operating experience assessment, operations assessment, business/financial support, regulatory/industry affairs, NSRB,

17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

17.3.1 MANAGEMENT

17.3.1.1 Methodology

The President and Chief Operating Officer is the corporate executive responsible for quality assurance and is the highest level of management responsible for establishing Duke's quality assurance policies, goals, and objectives. The Duke Power Company Quality Assurance Program Policy Statement, issued by the Chief Executive Officer as shown in Figure 17-1, assigns this responsibility and requires development of and compliance with procedures in all QA Condition 1 matters. All organizations performing quality affecting activities are bound by this Policy Statement. The Quality Assurance Program has been developed in accordance with this Policy Statement.

The individuals who constitute Duke Power Company have full personal and corporate responsibility to assure that nuclear power plants are designed, constructed, tested and operated in a manner to protect the public health and safety. The comprehensive program to assure this begins with initial design and continues throughout the life of the station. The Duke Power Quality Assurance Program must assure that the necessary quality requirements for QA Condition 1 structures, systems, components and materials are achieved. All special equipment, environmental conditions, skills and processes that are determined to be QA Condition 1 will be provided within the scope of the Quality Assurance Program.

A controlled listing of QA Condition structures, systems, and components is approved, issued, and periodically updated. Each Nuclear Site Vice President is responsible for approval and issuance after issuance of the operating license.

This program applies to the QA Condition 1 portions of the plant but may also be optionally applied, in whole or in part, to other selected items necessary for reliable operation. Section 17, "Quality Assurance" identifies those items currently included under Duke Power's Quality Assurance Program.

17.3.1.2 Organization

17.3.1.2.1 Corporate Organization

The Duke Corporate organization is shown in Figure 17-2. The Chairman and Chief Executive Officer has overall responsibility for Design, Construction, and Operation of generation and transmission facilities. Reporting to the Chairman and Chief Executive Officer is the President and Chief Operating Officer, who has the overall authority and responsibility for the quality assurance program, and who directs several activities including the Nuclear Generation, Electric System Support, Generation Organizational Effectiveness Services, and Power Delivery Departments. Also reporting to the Chairman and Chief Executive Officer is the Senior Vice President, Corporate Resources and Chief Administrative Officer, who directs several activities, including the Procurement, Services and Materials Department and the Information Management Department through their respective vice presidents.

Duke's organization reflects the concept of quality assurance as an interdisciplinary function involving various groups. As such, the attainment of quality rests with those

17.2 OPERATIONAL QUALITY ASSURANCE

Deleted

17.1 QUALITY ASSURANCE DURING DESIGN AND CONSTRUCTION

Deleted

Table 17-1 (Page 7 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
10CFR 21	Conforms	-------
Regulatory Positions 2 & 4 of Branch Technical Position CMEB 9.5-1	Conforms	Fire protection controls are in accordance with the intent of regulatory positions 2 & 4 of Branch Technical Position CMEB 9.5-1 as stated in the Safety Evaluation Reports for the respective nuclear stations.
Generic Letter 89-02, NCIG-07.	Conforms	-------

Table 17-1 (Page 6 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.152 Rev (0) - Criteria For Programmatic Digital Computer System Software In safety-Related Systems of Nuclear Power Plants	Not applicable	Regulatory Guide does not apply to plants prior to 11/85
Regulatory Guide 4.15 Rev (1) - Quality Assurance For Radiological Monitoring Program (Normal Operations) - Effluent Streams and the Environment	Adopted	Adopted at Oconee, McGuire, and Catawba via various site procedures that meet the intent of the Regulatory Guide.
Regulatory Guide 7.10 Rev (1) - Establishing Quality Assurance Programs For Packaging Used In The Transport of Radioactive Material	Alternative	Duke Program conforms to the intent of this Regulatory Guide as addressed in each Station's FSAR
Criteria 1 of Appendix A to 10CFR 50	Conforms	------
10CFR 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants	Conforms	------
10CFR 50.55a - Licensing of Production and Utilization Facilities (ASME Boiler and Pressure Vessel Code, Section XI - Rules for Inservice Inspection of Nuclear Reactor Coolant Systems)	Conforms	10CFR 50.55a Specifies ASME Section XI code dates. The Duke program conforms to 10CFR 50.55a with the specific editions and addenda of Section XI specified in the Duke Power Inservice Inspection Plan for each station.
10CFR 55 - Operators Licenses	Conforms	-------
10CFR 55, Appendix A - Requalification Programs for Licensed Operators of Production and Utilization Facilities	Conforms	-------
10CFR 50.55(e) - Conditions of Construction Permits	Conforms	-------

Table 17-1 (Page 5 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.143 Rev (1) - Design Guidance For Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants	Conforms	-----
Regulatory Guide 1.144 Rev (1) - Auditing of Quality Assurance Programs for Nuclear Power Plants	Alternative	RG 1.144 Rev (1) incorporates ANSI N45.2-12, (1977). Duke Program conforms to ANSI N45.2.12-1977 for internal/external audits except Section 4.4.6. In lieu of making recommendations for correcting program deficiencies we will identify the deficiencies to the audited organization. For external audits, the results of the audit will be provided to the audited organization in lieu of the audit report. Also, the re-evaluation may be extended to 15 months as described in Section 17.3.2.4, "Procurement Control." Self Initiated Technical Audits (Section 17.3.3.2.6, "Self-Initiated Technical Audits") shall require a response describing corrective action and implementation schedule as requested by the audit report but not to exceed sixty days of receipt of the audit report.
Regulatory Guide 1.146 Rev (0) - Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	Duke Program conforms to ANSI/ASME N45.2.23 - 1979 except section 2.3.4. In lieu of prospective Lead Auditors participating in a minimum of five quality assurance audits within a period of three years prior to date of certification, the prospective Lead Auditor shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. Upon successful demonstration of the ability to effectively lead audits, licensee management may certify the individual as a lead auditor.

Table 17-1 (Page 4 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.88 Rev (2) - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Alternative	RG 1.88 Rev (2) Incorporates ANSI N45.2.9-1974. The Duke Program conforms to RG 1.88 except the records storage facilities have a minimum 3-hour rating. A qualified Fire Protection Engineer will evaluate record storage areas (including satellite files) to assure records are adequately protected from damage. The fire protection engineer shall be a graduate of an engineering curriculum of accepted standing and shall have completed not less than 6 years of engineering attainment indicative of growth in engineering competency and achievement, 3 years of which shall have been in responsible charge of fire protection engineering work.
Regulatory Guide 1.94 Rev (1) - Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Alternative	RG 1.94 Rev (1) Incorporates ANSI N45.2.5-1974. Duke program for McGuire and Catawba conforms to ANSI N45.2.5-1974 except the length of bolts shall be flush with the outside face of the nut.
Regulatory Guide 1.116 Rev (0-R) - Quality Assurance Requirements for Installation, Inspections, and Testing of Mechanical Equipment and Systems	Conforms	RG 1.116 Rev (0-R) Incorporates ANSI N45.2.8-1975
Regulatory Guide 1.123 Rev (1) - Quality Assurance Requirements for control of Procurement of Items and Services for Nuclear Plants	Conforms	RG 1.123 Rev (1) Incorporates ANSI N45.2.13-1976

Table 17-1 (Page 3 of 7). Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.58 Rev (1) - Qualification of Nuclear Power Plant Inspection, Examination and Testing Personnel	Alternative	RG 1.58 Rev (1) incorporates ANSI N45.2.6-1978 for both construction and operation. Duke nondestructive examination personnel will meet the qualification requirements of SNT-TC-1A-1980. Duke operational/functional testing personnel will meet the requirements of ANSI N18.1-1971 rather than ANSI N45.2.6. Also, Duke's Level I inspectors receive a minimum of 4 months experience as Level I before being certified as Level II, in lieu of one year experience recommended by ANSI N45.2.6. Inspectors are only assigned tasks for which they have been qualified.
Regulatory Guide 1.64 Rev (2) - Quality Assurance Requirements for Design of Nuclear Power Plants	Adopted with Clarification	RG 1.64 Rev (2) Incorporates ANSI N45.2.11-1974. The use of the originator's immediate supervisor for design verification shall be restricted to special situations where the immediate supervisor is the only individual capable of performing the verification. Advance justification for such use shall be documented and signed by the supervisor's management. And the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse. The supervisor will not be the design verifier on work for which he is the actual performer / originator.
Regulatory Guide 1.74 Rev (0) - Quality Assurance Terms and Definitions	Conforms	RG 1.74 Rev (0) Incorporates ANSI N45.2.10-1973. Some definitions used by Duke are worded differently than those in this standard; however, the general meanings are the same.

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DUKE POWER

July 11, 1996

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

SUBJECT: McGuire Nuclear Station Units 1 & 2
Docket Nos. 50-369, 50-370

Catawba Nuclear Station Units 1 & 2
Docket Nos. 50-413, 50-414

Oconee Nuclear Station Units 1, 2, & 3
Docket Nos. 50-269, 50-270, 50-287

Duke Nuclear Quality Assurance Program

Pursuant to 10 CFR 50.54(a)(3) please find attached Amendment 21 to the Duke Power Company Topical Report Duke-1-A, Quality Assurance Program. Amendment 21, which has been implemented pursuant to 10 CFR 50.54(a)(3), contains: 1) A major revision of the sections which address procurement, identification, control, handling, storage, and shipping of materials items; 2) Changes to the qualifications for lead auditor certification; 3) A deletion of the section addressing the Integrated Safety Assessment; and 4) Other clarifications and additions to the Duke Quality Assurance Program. The changes contained in Amendment 21 have been determined to not reduce the commitments currently in the Duke Quality Assurance Program. The contents of Amendment 21 are listed and discussed in Attachment 1 and identified by indicator bars on the left margin of Attachment 2.

Please direct questions on this matter to J. S. Warren at (704) 382-4986.

Very truly yours,

M. S. Tuckman

M. S. Tuckman

IE52 1/,

MST/JSW

Attachment 1: Listing and Discussion of the Changes Contained in Amendment 21 (9 Pages)

Attachment 2: Amendment 21 of Topical Report Duke-1, Quality Assurance Program (Title Page through Page 17-46)

xc w/encl: Document Control Desk (3 Copies)

S. D. Ebneter
Regional Administrator, Region II
ATTENTION : C. Casto (2 Copies)

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ATTACHMENT 1
Duke Power Company Topical Report, Duke-1
Quality Assurance Program, Amendment 21
Listing and Discussion of Amendment 21 Contents

Item 1
Pages: xi, xii, xiii
Section: List of Effective Pages and List of Amendments
Description of Change: Updated List of Effective Pages and List of Amendments to include Amendment 21.
Reason/Basis: The List of Effective Pages (Pages xi and xii), and the List of Amendments (Page xiii) are revised as necessary for the implementation of Amendment 21.

Item 2
Page: 17-3
Section: 17. Quality Assurance, Definitions
Description of Change: Added software development as an additional example of supplier activities listed under the definition of "Services".
Reason/Basis: This addition recognizes that software is now an example of supplier-provided services procured by Duke Power. This change only updates the Topical Report to include software. This change does not affect the existing quality programs for software.

Item 3
Page: 17-8
Section: Table 17-1, Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides
Description of Change: Revised the qualifications for the Fire Protection Engineer contained in Table 17-1 in the *Remarks* column for Regulatory Guide 1.88 Rev (2).
Reason/Basis: To provide consistency with the personnel qualifications contained in NUREG-800, Standard Review Plan, for the position responsible for the formulation and implementation of the fire protection program. Conformance with the referenced standard (ANSI N45.2.9-1974) is maintained.

Item 4
Page: 17-9
Section: Table 17-1, Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides
Description of Change: Revised an incorrect reference from 17.3.3.2.8, Suppliers, to 17.3.3.2.6, Self-Initiated Technical Audit in the Remarks column for Regulatory Guide 1.144 Rev (1).
Reason/Basis: This is an administrative change being made to clear an incorrect reference.

Item 5
Page: 17-9
Section: Table 17-1, Conformance of Duke Power Program to Quality Assurance Standards, Requirements and Guides
Description of Change: Changed the Conformance Status for Regulatory Guide 1.146 Rev (0) from "Conforms" to "Alternative" as described in the *Remarks* column.
Reason/Basis: The proposed change continues to require demonstrated performance by the individual prior to certification as a lead auditor, but provides management the flexibility to certify the individual once skills have been demonstrated. This is considered to be consistent with 10CFR50, Appendix B, Criterion XVIII, *Audits*, which requires audits to be performed by appropriately trained personnel. This flexibility will allow management to assign personnel possessing significant nuclear experience to the audit function in a more timely manner. This is considered an enhancement to the audit program.

Item 6
Pages: 17-14, 17-16, 17-17, 17-20, 17-21, and 17-37
Sections: 17.3.1.2.1, Corporate Organization; 17.3.1.2.6, Information Technology Services (ITS) Department; 17.3.1.2.8, Department Interfaces; Figure 17-2, Corporate Organization; Figure 17-3, Off-Site Organization; and 17.3.2.14, Document Control
Description of Change: Changed Information Technology Services (ITS) Department to Information Management (IM) Department.
Reason/Basis: This is an administrative change only affecting organizational considerations. There is no impact on the quality assurance program since the change only addresses the title of the organization that is designated to perform the covered activities. The personnel qualifications remain the same.

Item 7
Page: 17-16
Section: 17.3.1.2.5, Procurement, Services and Materials (PSM) Department
Description of Change: Changed General Manager Purchasing to General Manager, Corporate Materials Management and changed Manager, Technical Services to Manager, Business & Technical Services. Added discussion of responsibility related to central storage facilities.
Reason/Basis: This change updates the Topical Report to be consistent with the current Duke organization. This is an administrative change that only affects organizational considerations for the, Procurement, Services and Materials Department. There is no impact on the quality assurance program.

Item 8
Page: 17-16
Section: 17.3.1.2.7, Power Delivery Department
Description of Change: Revised the department responsibility and reportability description.
Reason/Basis: This is an administrative change that only affects organizational considerations for the Power Delivery Department. There is no impact on the quality assurance program.

Item 9
Page: 17-17
Section: 17.3.1.2.8, Department Interfaces
Description of Change: Added a description of the control of interfaces used for quality related activities performed by the Power Delivery Department.
Reason/Basis: This is considered an administrative change that only affects the description of the organizational interface agreements with the Power Delivery Department. The quality of affected manuals or procedures is not lessened by this change.

Item 10
Page: 17-22
Section: Figure 17-4, Nuclear Site Organization
Description of Change: Revised the Commodities and Facilities Management organization chart.
Reason/Basis: This is an administrative change only being made in order to correctly illustrate the current organization in the sites' commodities and facilities organization. There are no quality assurance program implications related to this change.

Item 11
Page: 17-24
Section: 17.3.2.2, Design Control
Description of Change: Added the On-Duty Emergency Coordinator to the list of positions authorized to approve station modifications for the Station Manager.
Reason/Basis: This is an administrative change granting approval authority to a position equivalently qualified as those positions already listed. The addition of the On-Duty Emergency Coordinator will provide the sites with more flexibility to obtain desired approvals during emergency situations and off-hours during the absence of the Station manager. There is no impact on the quality assurance program since the personnel qualifications are equivalent.

Item 12
Pages: 17-26 through 17-31
Sections: 17.3.2.4, Procurement Control; 17.3.2.5, Procurement Verification; 17.3.2.6, Identification and Control of Items; and 17.3.2.7, Handling, Storage, and Shipping
Description of Change: These sections have undergone extensive revision and have been rewritten to better describe the Duke procurement process. Changes deemed to warrant individual discussion are listed in the Basis for this proposed change.
Reason/Basis: These changes primarily address organizational, responsibility, and procedural aspects of procurement activities and material control activities. Specific changes/bases are:

a. In Section 17.3.2.4 (Pages 17-26 and 17-27), the description of the program for basic components commercial grade items was revised. The basis for this change is to provide consistency with the current version of 10CFR21.

b. In Section 17.3.2.4 (Page 17-27), the requirements for placement on the Duke approved Suppliers List are being changed to permit placement to occur without performance of an audit by Duke or a pre-award survey. The placement is to be based on acceptance of an audit performed by another licensed nuclear utility (or a joint utility audit), supplier possession of appropriate ASME certification or other assurance of product quality, and management review of information and approval.

c. In Section 17.3.2.4 (17-27), an addition is made to permit a six-month grace period (with management approval) in the requirements/frequency for supplier re-evaluation. The present triennial audit requirement may be extended by six months (to 42 months) with written management approval. The purpose of this change is only to provide scheduling flexibility and is not intended to become standard practice or to be repetitively applied.

Item 13
Page: 17-36
Section: 17.3.2.13, Corrective Action
Description of Change: An addition was made stating that Duke now uses electronic means to track, trend, and facilitate the

Item 13 (Continued)
resolution of problems and to measure and classify nuclear performance.
Reason/Basis: For this section, this is considered an administrative change which provides a description of the media used to process information in the Duke corrective action programs. This change/addition is considered an enhancement since it replaces outdated techniques previously used in this area. The addition also supports the deletion of Section 17.3.3.2.6, Integrated Safety Assessments, as discussed in Item 26 of this document.

Item 14
Page: 17-36
Section: 17.3.2.13, Corrective Action
Description of Change: Changed Nuclear Services to Safety Assurance
Reason/Basis: This is an administrative change only affecting organizational considerations. There is no impact on the quality assurance program since the change only addresses the title of the organization that is designated to perform the covered activities. The personnel qualifications remain the same.

Item 15
Page: 17-37
Section: 17.3.2.14, Document Control
Description of Change: Changed "cover letter" to "distribution indices".
Reason/Basis: This is an administrative change only affecting the accompanying mechanism used to distribute/mail manual copies. It does not affect the determination of the recipients of the manuals or the control of the distribution process.

Item 16
Page: 17-37
Section: 17.3.2.14, Document Control
Description of Change: Deleted the reference to the Regulatory Audits Section Procedures Manual.
Reason/Basis: This information is now contained in the Nuclear Policy Manual, which is appropriately approved, as described in the newly added subsequent paragraph addressing the Assessment Organization. There is no impact on the quality assurance program.

Item 17
Page: 17-37
Section: 17.3.2.14, Document Control
Description of Change: Deleted the reference to the Nuclear Safety Review Board Procedures Manual.
Reason/Basis: This information is now contained in a nuclear system directive and is appropriately approved, as stated in the revised paragraph. There is no impact on the quality assurance program.

Item 18
Page: 17-38
Section: 17.3.2.14, Document Control
Description of Change: Deleted the reference to the Power Delivery Department Manual.
Reason/Basis: This is considered an administrative change. Procedures contained in these manuals are now located in the Nuclear Policy Manual or the ESS functional area manuals. There is no impact on the quality level since there are existing quality controls for these alternative manuals as discussed in Section 17.3.2.14 of the Topical Report.

Item 19
Page: 17-38
Section: 17.3.2.14, Document Control
Description of Change: Changed Nuclear Services to the Nuclear General Office.
Reason/Basis: This is considered an administrative change which only affects an organizational unit designation. Nuclear Services has been superseded by the Nuclear General Office in designation only. This is consistent with a previous amendment to the QA Topical Report.

Item 20
Page: 17-41
Section: 17.3.2.15, Records
Description of Change: Changed "preview" and "Purview" to "purview".
Reason/Basis: This change corrects typographical errors.

Item 21
Page: 17-43
Section: 17.3.3.2.1, Nuclear Safety Review Board
Description of Change: Changed Senior Vice President Power Generation Group to Senior Vice President Nuclear Generation
Reason/Basis: This is an administrative change. This change is consistent with the current Duke organization and is consistent with previous amendments made to the Topical Report and the stations' Technical Specifications.

Item 22
Page: 17-43
Section: 17.3.3.2.1, Nuclear Safety Review Board
Description of Change: Added "other events and trends of nuclear safety significance."
Reason/Basis: This addition describes the Nuclear Safety Review Board's re-emphasized role in the assessment of site performance from a nuclear safety point of view. This addition also supports the deletion of Section 17.3.3.2.6, Integrated Safety Assessments, the basis for which is discussed in Item 26 of this document.

Item 23
Page: 17-44
Section: 17.3.3.2.3, Internal Audits
Description of Change: Deleted, "for compliance with NSRB requirements".
Reason/Basis: This is considered an administrative change which is being made to more accurately describe the review function performed by the NSRB staff on the scope of audits. The scope of audits is defined by the stations' Technical Specifications and the audit reports are provided to the individual NSRB members for detailed review. This change has no impact on the covered activities or the quality assurance program.

Item 24
Page: 17-44
Section: 17.3.3.2.3, Internal Audits
Description of Change: Changed Integrated Safety Assessment to periodic performance trend summaries.
Reason/Basis: Section 17.3.3.2.6, Integrated Safety Assessment is being deleted, the basis for which is described in Item 26. This change is being made in support of this deletion and further demonstrates the updated manner in which assessment information is now being communicated to management.

Item 25
Page: 17-45
Section: 17.3.3.2.5, Corporate Audit
Description of Change: Revised the description of the process used to determine the minimum scope of corporate audits.
Reason/Basis: The scope of future internal audits is to be determined by the Senior Vice President, Nuclear Generation and the audit team. This change is intended to improve the wording of the affected paragraphs and has no substantive impact on the Corporate Audit process.

Item 26
Page: 17-45
Section: 17.3.3.2.6, Integrated Safety Assessment
Description of Change: This section is being deleted.
Reason/Basis: Although the Integrated Safety Assessment (ISA) has been effective in the past, the present process has been replaced by more real-time and modern information systems now used by Duke Power to assess plant performance. The processes listed below are currently being used in place of the ISA to conduct the assessment function in a more efficient and timely manner and these items form the basis for this change to the Topical Report.

a. A nuclear system events report is processed by the Nuclear Engineering Division on a monthly basis and measures nuclear performance. The report is issued to senior management and classifies any nuclear event or potential nuclear event on a systematic basis. The report is published electronically for all nuclear employees. This report is also provided to NSRB members for review. This process is referenced in Section 17.3.2.13.

b. NSRB meetings are now performed more frequently, and this contributes to Duke's ability to more accurately assess current nuclear performance at the three sites. Senior management is now more involved in the NSRB activities. Identified station specific and generic problems are discussed in the NSRB meetings. Additionally, the NSRB has become more involved in the assessment of each station's events and trends of nuclear significance. This process is described in Section 17.3.3.2.1.

Item 26 (Continued)

c. Duke has updated the investigative and corrective action processes to electronically track and trend site problems. Problems identified in this process are also considered for generic implications. Reports on problem activities are reported to senior management and the NSRB on a monthly basis. This process is referenced in Section 17.3.2.13.

d. Data obtained from internal audits is now being provided to management through periodic trend summaries as discussed in Section 17.3.3.2.3.

Item 27
Page: 17-45
Section: 17.3.3.2.7, Self-Initiated Technical Audits
Description of Change: This section is being renumbered to 17.3.3.2.6 to account for the deletion described in Item 26.
Reason/Basis: This is an administrative change only and is required to support the implementation of Amendment 21.

Item 28
Page: 17-45
Section: 17.3.3.2.8, Suppliers
Description of Change: This section is being renumbered to 17.3.3.2.7 to account for the deletion described in Item 26.
Reason/Basis: This is an administrative change only and is required to support the implementation of Amendment 21.