April 22, 1992

Responses To February 19, 1992
NRC Request For Additional Information
Duke Power Company Quality Assurance Topical Report
Amendment 15

1. Reference the Regulatory Guides found in NUREG-0800 in the text rather than in a footnote. Either eliminate or relegate to a footnote the reference to the "Rainbow Books." The commitments to the quality assurance (QA) guides and standards have not been updated per Section 17.3 of NUREG-0800. For example, the topical report does not address the substitution of NQA-1 and NQA-2 for N-45.2 and its daughter standards. This should be clarified in the abstract of the topical report where it states that Section 17.3 of the topical report "follows the format of Section 17.3 of NUREG-0800 (A.7.b)

Response
Section 17.0.2 was revised to reference the regulatory guidance found in NUREG-0800. The footnote was eliminated. The reference to the "Rainbow Books" was eliminated. Table 17.0-1 was expanded to include all of the applicable regulatory guidance contained in A.7.a and A.7.b (Sections VI.a and VI.b) of NUREG-0800. The Abstract was revised to say that Duke QA Program is based on ANSI N18.7-1976 in lieu of NQA-1 and NQA-2.

2. The alternative to Regulatory Guide 1.58 in Table 17.0-1, states that Duke may certify inspectors as Level II after only four months experience as a Level I. Clarify that inspectors are only assigned tasks for which they are qualified. (A.5.a)

Response
In Table 17.0-1, the remarks section was expanded to include the statement "Inspectors are only assigned tasks for which they are qualified".

3. In the clarification to Regulatory Guide 1.64 in Table 17.0-1, clarify that a supervisor will not provide the "independent design review" of the supervisor's input to (or work on) the design or justify not providing such a commitment. (A.7.b)

Response
In Table 17.0-1, the remarks section was expanded to include the statement "The supervisor will not be the design verifier on work for which he is the actual performer / originator".

4. The alternative to Regulatory Guide 1.144 precludes auditing organization from making recommendations for correcting program deficiencies and precludes reports of external audits from being given to the audited organization. Provide justification for these exceptions or delete them. (A.7.b)

Response

This does not represent a change to our program. Recommendations for correcting internal program deficiencies or improving the quality assurance program are provided by the audit report when deemed appropriate. We believe that much forethought must go into such recommendations for corrective action - because by nature, it places the auditing organization in an in-line configuration and reduces its independence in determining if corrective action was appropriate, adequate, and effective in resolving deficiency. We believe also that the audited organization is for the most part, in the best position to identify the appropriate action to be taken - which represents quality improvement at its lowest level.

Audit reports of external organizations (e.g. suppliers) contain our subjective evaluation in addition to the findings identified. We therefore, believe it would be counter productive and not in the best interest of the business purpose to provide these organizations with these reports. We do, however, provide them with audit findings needing corrective action.

5. The first paragraph of Section 17.3.1.1 indicates that the Executive Vice President, Power Generation Group is responsible for establishing Duke's QA policies. Briefly describe the Duke quality (or QA) policy in the topical report. Also clarify that procedures and activities reflect the policy. (A.1.a and A.3.f)

Response

The wording of Section 17.3.1 and the Abstract have been revised to address. The Duke Power Company Policy Statement on Quality Assurance has been added to the Topical as Figure 17.3-1.

6. Section 17.0 indicates that the topical report describes the QA program for safety-related items and activities and that it provides a method of applying a graded QA program to some nonsafety-related items and activities. The nonsafety-related items (listed as QA Condition 2,3, and 4: radioactive waste, fire protections and Seismic Category II items) should also include items such as nonmetallic insulation for austenitic stainless steel (per RG 1.36) and protective coatings (per RG 1.54). Clarify the scope of Duke's graded QA program. Provide a commitment to ensure the quality of items to an extent consistent with their complexity and importance to safety. Also, in this regard, consider replacing "nuclear safety-related" and similar limiting

terms in the topical report with "QA Condition" or some other term that better describes the scope of the Duke QA program. (A.1.c, A.1.d, and B.1.c)

Response

Section 17.0 (3rd paragraph) was revised to equate QA Condition 1 to nuclear safety related. QA Conditions 2, 3, and 4 clarification statement has been added to the "non-safety related" discussion in this Section. New statement added: "The quality of systems, components, items, and services within the scope of QA Conditions 1, 2, 3, and 4 is assured commensurate with the system's, component's, item's, or service's importance to safety." Regulatory Guides 1.36 and 1.54 were added to Table 17.0-1 as a result of question #1. All references to Nuclear Safety Related or Safety Related within the Topical were changed to "QA Condition 1".

7. Describe (in Section 17.3.1.2.2b) the activities/responsibilities of the Nuclear Services organization. (A.2.a)

Response

Section 17.3.1.2.2 (b) has been revised to read: The Nuclear Generation Department, Nuclear Services Division, is divided into various groups. The activities of each group are directed by a manager who reports to the General Manager, Nuclear Services. The General Manager, Nuclear Services reports to the Senior Vice President, Nuclear Generation. The groups within Nuclear Services include: Engineering Maintenance Support, which provides technical support to the stations in procurement, maintenance and engineering. Nuclear Engineering, which provides support to the stations in severe accident analysis, safety analysis, nuclear design, and fuels / core management. Operations, Performance, and Automation Services, which provides support in generation scheduling, thermal analysis, automation, generation reliability, and performance. Nuclear Technical Services, which provides support for dosimetry, radiation protection, radwaste processing, and nuclear chemistry. Safety Assurance which provides support in nuclear licensing, operational event analysis, emergency planning, ISI plans / reports, and quality assurance program and procedure development and maintenance."

8. Identify the organizational entities that are on site and those that are off site. Also, include (in Section 17.3.1.2/Figure 17.3-1) the activities/responsibilities, location, and reporting relationships of the organizational entities first identified after Section 17.3.1.2. Examples include the Verification Manager, Suppliers; the Site Safety Assurance Manager; the Commodities and Facilities Management Group; the Regulatory Compliance Group; the Environmental Compliance Group; and the Emergency Preparedness Group. (A.2.a)

Response

Figure 17.3-3, showing the reporting relationships of the off-site organizations performing quality functions, has been added to the Topical Report. Figure 17.3-4, showing the site organization, and reporting relationships, has been added to the Topical Report. References to Emergency Preparedness within the Topical have been changed to Emergency Planning due to a group name change since Amendment 15 was originally submitted for review.

9. Inspections and tests are verification activities, and Acceptance Criterion A.2.b of the SRP states there is to be independence between performing personnel and verification personnel. The criterion goes on to state that the degree of independence may be commensurate with the inspection or test's relative importance to safety. Since on site inspections and tests are not the responsibility of the Quality Verification Department, clarify Duke's position regarding the "independence" of on site inspectors and testers. (A.2.b)

Response

The basic philosophy employed during the reorganization was to divide the functional areas of the previous QA department into areas of Verification, Safety Review, Quality Control and QA Technical Services. The Quality Verification Department reports directly to the Executive Vice-President, Power Generation Group and includes the independent offsite Nuclear Safety Review Board plus the group that performs independent audits to insure QA program requirements are consistently met. QA Surveillance personnel were moved to the independent onsite Safety Review group which reports directly to the Manager of Safety Assurance. This group performs independent reviews in all areas of plant operations to ensure that all appropriate quality requirements are met. This group is totally independent of the execution groups that report under the Station Manager. The Quality Control inspectors were placed under the managers of the execution groups but maintain their identity as fully qualified QC inspectors under all requirements of ANSI N45.2.6. The QC inspectors maintain independence from personnel involved in daily work execution activities. The execution managers have the responsibility to ensure that all quality requirements are met and that QC inspectors have full authority to carry out their responsibilities including authority to stop work activities if

necessary. The QA Technical Support area is centrally located in the Nuclear Services Group and provides detailed technical support in areas of ISI, ASME Section XI inspections, and procurement of QA parts and services. They also maintain consistent procedures for various aspects of the QA program and procedures used by site quality personnel.

10. Clarify whether management positions under the Manager, Quality Verification, have been established at the Duke nuclear power plant sites. If not, discuss why such positions are unnecessary. (A.2.d)

Response

Site management positions equivalent to the positions under the Manager, Quality Verification, have not been established. The Quality Verification Department is totally independent of on-site groups and conducts independent audit activities including the site implementation of quality program requirements. This provides the independent assessment of site activities which would include assessment of the implementation of the quality program by the site execution managers. Quality Verification is informed of the day-to day activities at the stations through computerized daily status reports - provided by each site, document reviews and on-site audits and NSRB meetings. Nuclear Generation has a site assessment role through the position of Safety Assurance Manager on site. Independent reviews are performed in all areas of plant operations to ensure that all appropriate quality requirements are met.

The Duke Nuclear Safety Review Board (NSRB), which reports organizationally to the Manager, Quality Verification Department (as Director of the NSRB), does not have an onsite management position. The NSRB, which is Duke's independent offsite nuclear safety review board established in accordance with the stations' Technical Specifications, maintains management independence from the nuclear site organization. A close working interface is established with the site Safety Assurance Manager, but there is no reporting relationship with the Manager, Quality Verification Department. This is consistent with the NSRB's function as an independent review committee.

11. Clarify whether the delegation of work (that has an importance to safety) to organizations outside Duke Power Company is controlled by the procurement controls described in the report. (A.2.e, A.3.b, and A.4.a)

Response

It is not our current practice to delegate MAJOR WORK to participants outside the company. (A.2.e)

It is not our current practice to delegate the ACTIVITIES of planning, establishing, and implementing the overall QA program to others. (A3.b)

It is not our current practice to delegate the AUTHORITY for planning, establishing, or implementing any part of the overall QA program. (A.4.a)

For these reasons, these issues are not addressed in the Topical Report.

The procurement controls discussed in Sections 17.3.2.4 and 17.3.2.5 are applied to all vendors supplying QA Condition 1 items or services to Duke Power Company.

12. Clarify whether Duke's corrective action program ensures that corrective actions are not inadvertently nullified by later actions. (A.6.b)

Response

Corrective actions generally result in some procedure or plant change. These are then controlled via the 50.59 process which requires a thorough assessment of any subsequent changes. Subsequent changes may require that corrective actions be revised. In any case the as-changed result should still be acceptable by virtue of the 50.59 review that has been conducted at the time of change.

13. Section 17.3.1.6 and the last paragraph of Section 17.3.2.13 of the topical report address trend analyses. Clarify whether significant trends are reported to the appropriate levels of management. (A.6.e)

Response

Significant trends will be / are reported to appropriate levels of management. This commitment will be contained in the Nuclear Policy Manual.

14. The topical report should include a commitment to comply with 10CFR21, Criterion 1 of Appendix A to 10CFR50, Regulatory Guide 1.26, Regulatory Guide 1.29, Regulatory Guide 1.152, Regulatory Guide 4.15, Regulatory Guide 7.10, and Generic Letter 89-02 as part of the overall QA program. (A.7.a, A.7.b, and A.7.c)

Response

Table 17.0-1 has been expanded to include our position on all of these commitments.

15. Clarify whether, for Section III ASME B&PV Code items, the Code QA requirements are supplemented appropriately with the guidance of the regulatory guides listed in Table 17.0-1 of the report. (A.7.d)

Response

Duke's program does supplement appropriately the ASME QA requirements with the regulatory guides listed in Table 17.0-1, with the clarification's or alternatives stated therein.

16. The fourth paragraph of Section 17.3.2.4 addresses the qualification of vendors using experience/historical data. Clarify that, in accordance with Generic Letter 89-02, such vendor qualification is not used for commercial grade products used in safety-related application. Also describe any special provisions required to verify the acceptability of product important to safety from a vendor so qualified. (B.3.4.b)

Response

The 4th paragraph of Section 17.3.2.4 has been revised to include the following words: "This provision for vendor qualification based upon historical evidence shall not form the sole basis for procurement of commercial grade items unless:

a. The established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended QA Condition 1 application; and

b. The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable).

When QA Condition 1 products are procured from a vendor whose quality performance has not been verified by an audit, additional assurance of product quality shall be obtained by vendor surveillance, inspection or test."

17. The fifth paragraph of Section 17.3.2.4 addresses the reevaluation of approved vendors. Clarify whether, in accordance with Regulatory Guide 1.28, vendors are audited triennially. (B.3.4.c)

Response

The 5th paragraph of Section 17.3.3.2.4 has been revised to include the following words: "Additionally, vendors shall be reevaluated at least triennially by means of an audit."

18. Clarify whether procurements are subject to Duke's QA program requirements that are in effect at the time of purchase. (B.4.h)

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

19. The seventh paragraph of Section 17.3.2.4 addresses the procurement of commercial grade items. Discuss the determination and verification of critical characteristics of these items. (B.4.i)

Response
Critical characteristics for Commercial Grade Items are determined by technical sponsors and approved by the responsible engineers based on the manufacturer's published specifications and the intended safety function for the items. Specific characteristics used for acceptance or dedication of the items are selected based on providing reasonable assurance that the items will meet their catalog or manufacturer specifications and will perform the functions intended which are based on those specifications. Verification of acceptance requirements 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.

20. Clarify Section 17.3.2.5 to indicate whether the quality of purchased items and services is verified at intervals and to a depth consistent with the item or service's importance to safety, complexity, and quantity and the frequency of procurement.

Response
The last sentence in the 2nd paragraph of Section 17.3.2.5 has been revised to add the following words: "... 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."

21. Clarify that traceability is maintained to an extent consistent with each item's importance to nuclear safety. (B.6.b)

Response
As discussed in the last paragraph of Section 17.3.2.6, after receipt inspection, acceptable QA Condition materials, parts, and components are assigned appropriate identification in order to provide traceability of the item. This traceability is maintained for QA Condition items.

22. Clarify that nondestructive examination equipment is also controlled in accordance with the commitments in Section 17.3.2.9 of the QA topical report. (B.9.b)

Response

Nondestructive examination is controlled in accordance with the commitments in Section 17.3.2.9. This section has been revised to include the words: "non-destructive testing equipment".

23. The last paragraph of Section 17.3.2.9 states that installed equipment, subject to Technical Specification requirements, is not subject to Duke's tagging commitments for other measuring and test equipment. Provide justification for this exception. (B.9.d)

Response

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.

24. The first sentence of Section 17.3.2.10 states that items that are "in other than operable status" are so identified. Clarify that this includes nonconforming items as well. (B.10.a)

Response

Non-conforming items are addressed in Section 17.3.2.13, including identification.
Operations maintains status of all inoperable equipment required by the Technical Specifications and assures that action is taken per Technical Specification Action Statements.

25. The sixth paragraph of Section 17.3.2.12 limits the Quality Verification Department's evaluation and approval of inspection activities to those involving the vendor QA program. Clarify that these evaluations extend to in-house inspection activities as well or justify this apparent lack of program verification. (C.2)

Response

As discussed in paragraph 17.3.3.2.2, Duke's Quality Assurance Program requires a comprehensive system of planned and periodic internal audits for all phases of station operations and supporting activities - of which inspection activities are an integral part. The absence of such a statement in this section is not to be misconstrued to imply otherwise. The statement addressing vendor quality assurance programs was to clarify to the reviewer that vendor inspection activities are evaluated and approved.

26. Clarify whether personnel responsible for carrying out the self-assessment function are cognizant of day-to-day activities and that they act in a management advisory capacity. (C.1.a)

Response

Quality Verification audit personnel have access to the site for audit evaluation meetings and are frequently on site for follow-up activities involving corrective action. Awareness of day-to-day activities is through access to computer generated data bases and the review of pertinent correspondence. Quality Verification acts in a management advisory capacity through publishing of audit reports, the Approved Supplier List, participating in commercial grade evaluations, through direct communication with management during audit exit meetings, and through Integrated Assessment input.

The NSRB members receive reports of all significant nuclear safety related events or activities occurring at the nuclear stations. The NSRB also meets at each site location at least once every six months. In addition the NSRB holds separate technical specification change approval meetings, on a usual frequency of once per month. Several members of the NSRB are experienced Duke management personnel. These personnel, the internal NSRB members, hold key positions within Duke's nuclear organization and are cognizant of and/or involved with the station's day-to-day activities. The NSRB is also responsible for conducting and/or evaluating reviews, audits, plant interface sessions, and investigations to further determine that all nuclear safety related aspects of the nuclear stations are being adequately assessed and considered. The NSRB, as required by the nuclear stations' Technical Specifications, is responsible for advising the Executive Vice-President, Power Generation Group, and the Senior Vice-President, Nuclear Generation Department directly.

Additionally, the NSRB advises the senior nuclear site management of its recommendations and concerns at the conclusion of each NSRB meeting held on site.

Personnel assigned to the nuclear stations, in the Safety Assurance function, are cognizant of the day-to-day operations of the station and act in a management advisory capacity.

27. Duke's response to Standard Review Plan Section 17.3 acceptance criteria C.2.c, d, e, and f is given under some specific sections in Part 17.3.3 of the topical report. Since these criteria should be generic to the assessment process, consider revising Part 17.3.3 of the topical report such that the response to these criteria applies to each of the assessment functions.

Response

Consideration has been given to a generic reference to Standard Review Plan 17.3, criteria C.2.c, d, e, and f in the Self Assessment section. We have concluded that because certain of our self assessment functions are not performing an audit activity, Standard Review Plan 17.3, criteria C.2.c, d, e, and f would not apply. For example, our Integrated Safety Assessments and Site Safety Assurance functions would not incorporate all of these criteria. Therefore, we believe the more appropriate way to address these criteria is in the specific sections where they do apply, as we have done.

R B Priory being duly sworn states that he is Executive Vice President, Power Generation Group, of Duke Power Company; that he is authorized on the part of said company to sign and file with the Nuclear Regulatory Commission this amendment to its Topical Report, Duke-1-A; and that all statements and matters set forth herein are true and correct to the best of his knowledge.

R B Priory

ATTEST:

Phyllis T Simpson

Phyllis T. Simpson, Assistant Secretary

Subscribed and sworn to me this 22nd day of April, 1992

Willie P. Bailey

Notary Public

My Commission Expires May 5, 1996

My commission expires: _____

Date