



UTILITIES

March 18, 1996

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NG-96-0096

Mr. William T. Russell, Director  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Mail Station P1-37  
Washington, DC 20555-0001

Subject: Duane Arnold Energy Center  
Docket No. 50-331  
Operating License DPR-49  
Reporting of Changes to the Quality Assurance Program  
Description, U.S. SAR 17.2

Reference: 1) January 30, 1996 letter from Stephen D. Floyd of the Nuclear  
Energy Institute to Suzanne C. Black of the Nuclear Regulatory  
Commission.

File: A-116, A-365, Q-98

Dear Mr. Russell:

This letter transmits two changes to Revision 16 of the IES Utilities Inc. Quality Assurance Program Description (QAPD) for the Duane Arnold Energy Center in accordance with the requirements of 10 CFR Section 50.54(a)(3).

This submittal includes the following changes, none of which is a reduction in commitment:

- Regulatory Guide 1.144 (ANSI N45.2.12 - 1977) requires suppliers to be evaluated annually. This submittal replaces the annual supplier evaluation with an ongoing supplier evaluation process.
- ANSI N45.2.23-1978 requires an auditor to participate in a minimum of five (5) audits prior to certification as a lead auditor. This submittal recognizes the performance attributes required for an individual to be considered for lead auditor certification. This performance based approach to lead auditor certification may require more than, or less than five (5) audits for certification.

These two changes were discussed between the Nuclear Energy Institute Staff and the NRC Staff on November 8, 1995, and were submitted to the NRC for information per Reference 1.

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An IES Industries Company

Mr. William Russell

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Attachment 2 to this submittal discusses the changes in the QAPD, and the reasons for the changes, and states the bases for concluding that the program continues to satisfy the criteria of 10 CFR Part 50, Appendix B.

These two changes will be incorporated into Revision 17 of the IES Utilities Inc. QAPD as part of the next UFSAR update in accordance with 10 CFR 50.71e.

Very truly yours,



John F. Franz

Vice President, Nuclear

*KEP*  
JJF/KEP/JMG/hjf

- Attachments: 1) Affected pages from the DAEC UFSAR, Chapter 17.2, Revision 17, date to be determined.
- 2) Discussion of Changes in the Quality Assurance Program Description.

cc: L. Liu  
D. Mineck  
K. Peveler  
H. Miller, (NRC - Region III)  
G. Kelly (NRC - NRR)  
NRC Resident Office  
DOCU

***DAEC UFSAR 17.2 AFFECTED PAGES***

Section	Page	Paragraph	Change
Appendix A	A-13	18.5	Added new paragraph
Appendix A	A-14	19.3	Added new paragraph

- 18.2 Section 1.1, "Scope", and Section 1.2, "Applicability", of ANSI N45.2.12-1977 reference ANSI N45.2. IES Utilities Inc. is committed to ANSI N18.7-1976 for the operational phase, consistent with its commitment to Regulatory Guide 1.33.
- 18.3 Regulatory Position C.3.b(1) states that external audits, after the award of a contract, are not necessary for procurement actions where acceptance of the product is in accordance with Section 10.3.2, "Acceptance by Reviewing Inspection", of ANSI N45.2.13-1976. The suppliers of products that meet this requirement are included on the IES Utilities Inc. external audit schedule and are audited on a triennial basis.
- 18.4 ANSI N45.2.12, Section 4.3.1 "Pre-Audit Conference"

For internal audits, a "pre-audit planning meeting" may be substituted for the "pre-audit conference." The pre-audit planning meeting should accomplish the following:

- 1) The Lead Auditor to present the proposed audit plan and an opportunity for the audited organizations to provide input to the proposed audit plan.
  - 2) Introduce the Lead Auditor and identify proposed audit team members. Those audit team members available will be introduced. Note: Non-utility team members are usually not available at these meetings.
  - 3) Counterparts are invited to these audit planning meetings as part of the planning process.
  - 4) The audit schedule is presented, including a tentative exit date. The final exit date is announced separately during the audit period.
  - 5) The channels of communication are opened at the audit planning meeting through participation in the audit planning process.
  - 6) Following the audit planning meeting, the Lead Auditor will finalize the audit plan.
- 18.5 Regulatory Position C.3.b(2) states that a documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, non-conformance notices, and corrective actions, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits. In lieu of performing a documented evaluation of the supplier annually, the information described above is reviewed as it becomes available. This may result in some supplier evaluations being performed more frequently than annually to address the operating experience and other information identified above. In other cases, due to the lack of new information, documented supplier evaluations may be extended.

19.0 REGULATORY GUIDE 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants"

COMMENTS AND CLARIFICATIONS:

IES Utilities Inc. complies with the Regulatory Position of this Regulatory Guide with the following clarifications:

- 19.1 The IES Utilities Inc. commitment is to Regulatory Guide 1.146, August 1980, and to ANSI N45.2.23-1978 which it endorses.
- 19.2 ANSI N45.2.23 Section 1.2 references ANSI N45.2. For IES Utilities Inc., the entities subject to audit are defined in 10 CFR 50 Appendix B and ANSI N18.7-1976. This is consistent with IES Utilities Inc.'s commitment to Regulatory Guide 1.33 which endorses ANSI N18.7-1976, in lieu of ANSI N45.2.
- 19.3 ANSI N45.2.23 Section 2.3.4 states that the prospective Lead Auditor shall have participated in a minimum of five (5) Quality Assurance audits within a period not to exceed three (3) years prior to the date of qualifications, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification. In lieu, of the existing Section 2.3.4 in ANSI N45.2.2.3, the following is implemented: "Prospective Lead Auditors 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.

20.0 REGULATORY GUIDE 1.155, "Station Blackout"

COMMENTS AND CLARIFICATIONS:

IES Utilities Inc. complies with Appendix A, "Quality Assurance Guideline for Non-Safety Systems and Equipment," to Regulatory Guide 1.155, Revision 1, August 1988.

21.0 REGULATORY GUIDE 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment"

COMMENTS AND CLARIFICATIONS

IES Utilities Inc. complies with the Regulatory Position in Regulatory Guide 4.15, Revision 1, February 1979.

**Discussion of Changes  
in the Quality Assurance Program Description**

**1. Page A-13, Position 18.5 on Regulatory Guide 1.144**

**Background:**

DAEC has a commitment to Regulatory Guide 1.144 which endorses ANSI N45.2.12-1977 and states:

"A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, non-conformance notices, and corrective actions, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits."

Since this commitment was made, DAEC has implemented significant improvements to the supplier assessment program. DAEC's ongoing assessments and reviews, including self assessment, encompass the same activities as the four issues in Regulatory Guide 1.144. The subsequent paragraphs describe alternative and equivalent approaches for assessing suppliers.

**Regulatory Guide, 1.144 Guidance:**

"A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier furnished documents such as certificates of conformance, non-conformance notices, and corrective actions."

**Alternative Approach:**

Supplier-furnished documents are reviewed as part of the receipt inspection process for purchased items and services, and any deficiencies or concerns are documented at that time. Deficiencies are documented and the supplier is notified as necessary, on a real time basis for correction. Repetitive deficiencies are identified through trending of supplier performance. Supplier-furnished documents are reviewed as they are received. There is no benefit in reviewing the documents a second time in order to perform an annual supplier evaluation for these items.

**Regulatory Guide 1.144 Guidance:**

"A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account .. (2) results of previous source verifications, audits, and receiving inspections."



**Discussion of Changes  
in the Quality Assurance Program Description**

**Alternative Approach:**

Supplier QA personnel perform source verifications (as needed on applicable purchases), perform audits and review third party audits. They are kept informed of concerns and/or deficiencies from the receipt inspection process through the corrective action program which captures documentation deficiencies as well as nonconformances of hardware at the time of occurrence. As appropriate, the respective supplier performance records are updated at this time. Performing an additional evaluation at an annual anniversary would only report the real time, ongoing evaluations performed previously.

**Regulatory Guide 1.144 Guidance:**

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account ... (3) operating experience of identical or similar products furnished by the same supplier.

**Alternative Approach:**

The DAEC's corrective action program captures concerns related to product performance. In today's operating environment, the predominant procurement activities are related to spare and replacement parts. New hardware may also be purchased as part of a modification process for obsolete equipment, or replace poorly performing equipment. These equipment change-out activities are performed in accordance with DAEC procedures, including corrective action (address equipment deficiencies) and design change process (for upgrades or equipment replacement). Industry reliability programs are available which provide information to DAEC personnel on the performance of safety related hardware throughout the nuclear industry. The DAEC also has an industry operating experience review program. Supplier concerns identified through the industry's operating experience programs are addressed at the time of identification and, if necessary, are reported (e.g., 10 CFR Part 21 reports, NRC Information Notices, NRC Generic Letters, INPO SOERs, INPO SERs, Supplier reported bulletins, etc.). In addition, the industry has established a bulletin board through the Nuclear Procurement Issues Committee (NUPIC) which shares real time data regarding supplier performance from audits, surveillances, and other information regarding supplier performance experienced by the nuclear utilities. Such information and DAEC reviews allow for quick action, investigation and transmission of common problems to each licensee. An annual supplier evaluation provides no additional value because the operating experience reviews are performed on an on-going basis.

**Regulatory Guide 1.144 Guidance:**

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account ... (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

**Discussion of Changes  
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**Alternative Approach:**

Since the issuance of Regulatory Guide 1.144 Revision 1 in September of 1980, the industry has matured and, as described in the discussion in Item 3 above, licensee's (including DAEC) have developed programs to share operating and vendor information. DAEC reviews and trends this information, including NRC inspection reports of vendors, as part of ongoing routine activities. As necessary, DAEC takes action based on reviews, when a concern is identified, not as a result of an annual review. An additional annual review of these activities is not necessary because the original purpose of the review is being accomplished in a different and more effective manner.

**Identification of Change:**

DAEC shall review the above information described in Regulatory Guide 1.144 Revision 1, 1980, as it becomes available through its receipt inspection and operating experience programs instead of performing an annual evaluation.

**Reason for the Change:**

DAEC has developed more effective and efficient practices for conducting the reviews recommended in Regulatory Guide 1.144 Revision 1, 1980. The DAEC's operating experience and the operating experience of other licensee's is included in supplier evaluations (as applicable). As a NUPIC member the DAEC receives significant information as a result of audits performed by other members. This significant information is included in the supplier evaluation process on a real time basis. An additional annual review is an unnecessary resource burden because the function and purpose of the review has already been accomplished. Reliance for effective control over supplier quality is better placed on real time evaluations than by deferring reviews to one selected time frame.

These activities may result in some supplier evaluations being performed more frequently than annually to address the operating experience, etc. (categories of information identified above), and for some suppliers the evaluation period may be extended, commensurate with actual procurement activity.

**Basis for Concluding the Change Continues to Comply with 10 CFR 50 Appendix B and Previous Commitments:**

10 CFR 50 Appendix B, Criterion VII, "Control of Purchased Material, Equipment and Services", requires:

"The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."



**Discussion of Changes  
in the Quality Assurance Program Description**

This requirement continues to be met through the performance of an on-going evaluation system versus a delayed process of an annual evaluation. Existing DAEC practices are performing the function described in Regulatory Guide 1.144 Revision 1, 1980 more effectively and efficiently through an on-going evaluation process.

This change is not a reduction in commitment. The function is being performed in a more efficient, effective and productive manner that enhances safety through a more expedient assessment of potential deficiencies.

**Discussion of Changes  
in the Quality Assurance Program Description**

**2.0 Page A-13; Position 19.3 on Regulatory Guide 1.146**

**Background:**

The process of becoming a Lead Auditor is defined by ANSI N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants" as endorsed by NRC Regulatory Guide 1.146 of August 1980. This standard also incorporates the requirements of ANSI N45.2.12 which defines the process by which audits are performed.

As defined by ANSI N45.2.23, the process of becoming Lead Auditor certified is essentially composed of three parts:

- Candidate's prior education and experience, professional accomplishments, and some discretion by management in regards to the candidate's maturity, etc., to achieve 10 or more points within the system defined by section 2.3.1
- Candidate receives, or is evaluated and found to already have, knowledge of quality assurance program requirements as defined by section 2.3.3. This section addresses knowledge and understanding of ANSI N45.2 standards, and other applicable standards, general understanding of 10 CFR 50 Appendix B, auditing techniques, and audit planning. Then as stated by section 2.3.3.5, on-the-job training is required to demonstrate an understanding of the audit process. The lead auditor candidate is also required to take an examination to evaluate the candidate's knowledge of these requirements.
- The candidate is required to demonstrate their capabilities by participation in the performance of audits as defined by section 2.3.4.

From the above chronology, the process of lead auditor qualification is composed of prior knowledge and experience, knowledge obtained in the quality assurance processes, and demonstrated performance. This approach to lead auditor qualification is a systematic approach and ensures an individual has demonstrated their ability to lead audits prior to being lead auditor certified. Section 2.3.4, "Audit Participation" currently states: "The Prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification." In addition, there are other approaches that address the same objective, based on the candidate being able to demonstrate competency as a lead auditor.

**Identification of Change:**

Section 2.3.4 is replaced with:

"Prospective Lead Auditors 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."

## **Discussion of Changes in the Quality Assurance Program Description**

### **Reason for the Change:**

Currently, section 2.3.4, ANSI N45.2.23 for Audit Participation does not ensure a lead auditor has the necessary skills prior to certification. The standard requires "participation" in five audits and does not require the prospective lead auditor to demonstrate their skills as a lead auditor during the five audits in which they "participate". An individual may have related experience and be capable of demonstrating their skills to lead an audit in less than five audits, but the standard does not permit a licensee to certify such an individual until the individual had "participated" in at least five audits. The objective of this section of the standard is for the prospective lead auditor to demonstrate the ability to lead audits. The prospective lead auditor may need less than, or more than, five audits to demonstrate adequate on-the-job performance for certification depending on the abilities of the individual.

As the nuclear industry moves into the performance based regime for audits, many utilities have established rotation programs, or similar programs to broaden personnel experience by working in different areas, e.g., auditing. These individuals are generally capable of demonstrating their ability to effectively lead audits in less than five audits, but because of the restrictive nature of section 2.3.4 of ANSI N45.2.23, they must continue to be supervised to comply with these provisions. This is unnecessary and is not an effective utilization of licensee resources.

Licensee management should be permitted to assess the performance of the prospective lead auditor against the knowledge and performance criteria described in the ANSI standards: knowledge of the audit process, knowledge of licensee's quality assurance program, knowledge of the requirements of 10 CFR 50 Appendix B, knowledge of applicable and pertinent sections of industry standards, the candidates demonstrated performance in implementing the audit process (including leading), demonstrated oral and written communication skills, and demonstrated interpersonal skills interacting with other departments within the Company or supplier organizations.

### **Basis for Concluding the Change Continues to Comply With 10 CFR 50 Appendix B and Previous Quality Assurance Program Commitments:**

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 the skills have been demonstrated. This is consistent with 10 CFR 50 Appendix B, criterion II, Quality Assurance Program, which requires a program be defined for the indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. This is also consistent with 10 CFR 50 Appendix B, criterion XVIII, Audits, which requires audits to be performed by appropriately trained personnel.

This change is not a reduction in commitment.