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NUCLEAR REGULATORY COMMISSION SECY-78-95 WASHINGTON, D. C. 20555

# INFORMATION REPORT

UNITED STATES

For: The Commissioners

From: Edson G. Case, Acting Director, Office of Nuclear Reactor Regulation

Thru:

Executive Director for Operations Curt Duch

PLANNED STAFF ACTIONS WITH RESPECT TO THE SANDIA STUDY OF Subject: THE NRC QUALITY ASSURANCE PROGRAM

To inform the Commission of planned staff actions regarding Purpose: the recommendations of subject program.

Discussion: On May 4, 1976 in SECY-76-254, we informed the Commission of our plans to procure an independent study of the NRC quality assurance activities regarding nuclear power stations. Authorization to conduct the study was issued to the Sandia Laboratories. The study has been completed and a final report thereof entitled, "A Study of the Nuclear Regulatory Commission Quality Assurance Program." was provided to us in August 1977 and has been published as NUREG-0321.

> The report of the study contains 16 recommendations that the study team believes will enhance the quality assurance activities of the NRC and the nuclear power industry. The staff has considered these 16 recommendations and has developed a planned course of action. A condensed status report of the planned action regarding each recommendation is contained in Enclosure 1 and a more detailed discussion of the recommendations and planned action is contained in Enclosure 2.

With respect to 12 of the 16 recommendations, the staff has in progress, or has completed, actions that are consistent with each study recommendation; in almost all cases, these actions were underway prior to receipt of the Sandia report. For three of the study recommendations, the staff has concluded that further study is necessary in order to determine the appropriate action and has initiated such study. For the remaining study recommendation, no staff action is planned.

Contact: D. J. Skovholt, NRR 49-27492

8207120269 820625 PDR FOIA MCMURRA82-176 PDR Although the staff actions discussed herein are responsive to the study recommendations, the need for these actions had already been determined by the staff and they were underway. The results of the study are considered confirmatory in this regard. Usually, the need for a certain action is determined and confirmed by staff review of the experience within the industry. For example, both Sandia's Recommendation No. 13 and the recent experience with failures of electrical cable connectors provide independent confirmation of the need for the current staff activities to further define requirements and guidance regarding qualification testing.

Coordination:

This has been concurred in by the Offices of Inspection and Enforcement and Standards Development. The Office of the Executive Legal Director has no legal objection.

> Edson G. Case, Acting Director Office of Nuclear Reactor Regulation

Enclosures:

1. Status Report

2. Detailed Discussion

DISTRIBUTION: Commissioners Commission Staff Offices Exec. Dir. for Opers. Secretariat ENCLOSURE 1 Status Report

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# Enclosure 1

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# STATUS REPORT

# PLANNED STAFF ACTIONS

Recommendation	Action Completed	Action is a Continuing Effort	Action In Progress	Action to be Determined by Further Study	No Action Planned
1			x		
2			Х		
3	х				
4	X				
5	X				
6				X	
7		Х			
8					X
9			Х		
10			Х		
11			Х		
12			X		
13			Х		
14		Х			
15				X	
16				X	

# ENCLOSURE 2

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Detailed Discussion

# Enclosure 2

# Discussion of Planned Staff Actions

#### Recommendation #1

"The NRC strengthen, through its communications to industry, recognition of the Standard Review Plan as the basic source of guidance on quality assurance requirements."

Status: Action in Progress

### Discussion:

It has been the objective of NRR to assure that Chapter 17 of the Standard Review Plan (SRP) identifies all guidance relevant to licensing activities concerning quality assurance requirements, either through inclusion or reference, and that industry thoroughly understands the purpose of the SRP in the licensing process. While this objective has been largely accomplished, the fact that some elements of the SRP are no longer up-to-date has resulted in some limitation of its usefulness as a basic source of guidance. However, a number of actions have been initiated which have strengthened this activity since discussions with Sandia personnel during the summer of 1976.

The SRP identifies: (a) what will be reviewed by NRR, (b) who will perform the review, (c) what acceptance criteria will be employed, and (d) what finding will be made by the staff. Thus, the SRP will either contain specific control and acceptance criteria or will reference pertinent documents, such as regulatory guides and industry standards, which must be considered and addressed in the applications. The SRP, in conjunction with its sister document, the Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, are the mechanisms by which documents produced by the Office of Standards Development and actions identified by the Office of Inspection and Enforcement are appropriately identified and incorporated into the licensing process. In this manner, a controlled, consistent, and documented review process is assured.

Over the past year, the following actions have been initiated with regard to the QA section of the SRP (Chapter 17).

(a) The industry and other NRC offices were asked to comment on the SRP QA guidance. As a result, extensive comments were received from AIF, IE and Standards.

- (b) The role and importance of the SRP continue to be highlighted in speeches and meetings with industry. For example, this subject was discussed in formal presentations at: the Third and Fourth Annual Conferences of the ASQC Nuclear Division in San Francisco in October 1976 and in Washington, D. C. in October 1977, the ASME Conference on Quality Assurance in Miami in September 1976, and the AIF Workshops in Atlanta in December 1976 and in Boston in October 1977.
- (c) NRR has initiated a program for the updating of the SRP on a consistent basis. Chapter 17 on QA has been extensively revised and updated and is now undergoing management review.
- (d) Actions have been initiated to assure that Regulatory Guide 1.70 covering the Format and Content of Safety Analysis Reports and the SRP are consistent.

Based upon the above, the thrust of the Sandia recommendation has been and is being carried out. NRR certainly concurs in the objective of the recommdation and will continue to seek additional vehicles to strengthen the communication with industry on the SRP.

# Recommendation #2

"10 CFR, Appendix B, be used in the regulation of all areas of power reactor design, construction, and operation which are judged to have sufficient importance to safety to fall under other NRC regulation. The selective application of QA elements now applied to safety-significant items not interpreted as falling under Appendix B should be replaced by an approach in which the degree to which the 18 criteria of Appendix B are applied would reflect the safety-significance of the item."

Status: Action in Progress

#### Discussion:

We agree that there is need for additional guidance in determining what structures, systems, and components, important to safety fall within the requirement of Appendix B to 10 CFR Part 50. We also agree that Appendix B requires a graded approach to implementing quality assurance practices such that the degree to which the 18 criteria of Appendix B are applied should reflect the safety-significance of the item. The Office of Standards Development has a regulatory guide (RS Task 704-4) presently under development concerning the applicability of the quality assurance criteria of Appendix B to 10 CFR Part 50 to structures, systems, and components of nuclear power plants. It is expected the guide will be issued for public comment in mid calendar 1978.

#### Recommendation #3

"The Transfer of Lead Responsibility Memo be revised (or that some supplemental means be established) to provide a schedule for completion of activities and a status reporting mechanism, for problems requiring action by both the Office of Inspection and Enforcement and the Office of Nuclear Reactor Regulation."

Status: Action Completed

#### Discussion:

At the time of the discussions with Sandia personnel in the summer of 1976, it was indicated that the formal guidelines covering lead responsibilities and interfaces between NRR and IE were out of date and, as a result, there were some uncertainties. The previous formal procedures on this subject were established via a December 29, 1972 memo from L. Manning Muntzing to J. F. O'Leary and F. E. Kruesi.

A revised agreement between NRR and IE was documented in a memorandum to Lee V. Gossick from Ben C. Rusche and Ernst Volgenau dated March 21, 1977, subject: Agreement on NRR/IE Interface and Division of Responsibility. This memorandum recorded the general areas of responsibilities of each office and specific agreement on the division of responsibility between the Offices in those areas where interfaces or overlaps existed in the functions assigned to each organization.

A schedular and status-reporting mechanism for items involving both NRR and IE was established via a memorandum for Lee V. Gossick from Edson G. Case, Ernst Volgenau and William G. McDonald dated July 1, 1977, subject: Plan for Tracking of IE-Oriented Items Impacting NRR Licensing Activities. This memorandum discussed the Interoffice Action Items and the suggested improvements in the present NRR procedures and management information tracking system, particularly the Blue and Pink Books, to identify for management attention, each such item, the date of transfer or action request, the responsible branch and individual, the completion date and the current status. This memorandum also noted that procedures had been developed to track the IE-originated items (Interoffice Action Items) and to clarify the internal NRR interface between DPM and DOR on items affecting CPs, OLs and ORs.

In addition, monthly NRR/IE interface meetings continue to be held to resolve any questions regarding implementation of the policies and procedures regarding NRR/IE interfaces.

In sum, the need for action on this recommendation was recognized and implemented prior to submittal of the Sandia report. The actions noted above responded to each aspect of the Sandia recommendation, and thus, this item has been classified as completed. Further improvements in these procedures will be made as the need and our experience dictate.

#### Recommendation #4

"The NRC take steps to assure that each vendor inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) is aware of the continuing responsibility and authority of the licensee with respect to vendor quality assurance."

Status: Action Completed

#### Discussion:

Substance of recommendation is published in the White Book, Licensee Contractor and Vendor Inspection Status Report (Forward and Sample Confirming Letter). The White Book is updated quarterly and distributed to all vendors listed in the document.

To further emphasize vendor notification of licensee responsibility, the IE cover letter to each vendor inspection report has been modified to include a standard paragraph with the recommended information.

# Recommendation #5

"IE headquarters clarify responsibility for inspection of quality assurance activities of utility-run architect-engineers as belonging either to the regular inspection and enforcement program or to the Licensee Contractor and Vendor Inspection Program (LCVIP)."

Status: Action Completed

#### Discussion:

Responsibility assignment for the inspection of independent architect engineering firms (LCVIP) and the utility who performs its own inhouse architect engineering (Region) was stated in the early draft MC-2720, Architect Engineer Inspection Program. A subsequent redraft, reidentified as MC-2710, includes the responsibility assignment. It is currently also designated in MC-2500 of the IE Manual, pages 2500-4 and 5, dated January 1, 1977.

#### Recommendation #6

"Vendors to be inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) be selected on a basis which ensures that every vendor has some likelihood of being inspected."

Status: Receiving further study.

# Discussion:

The criteria used for selecting vendors for inspection must continue to be based primarily upon safety considerations. Since vendor work volume is constantly changing proportionate to overall nuclear industry activity, the vendor population is not fixed at any given time. Further, the majority of vendors are small, single item suppliers, or suppliers of equipment which may or may not be used in a safety important system. It is, therefore, not practical to ensure that every vendor is inspected at some point in time nor is the expenditure of limited NRC resources for inspection of vendors justified under any circumstances if the vendor is not supplying safetyrelated products or services.

IE will review implementation of present criteria applied for the selection of vendors for inspection to assure as broad a coverage as possible.

#### Recommendation #7

"IE inspection of material produced under the ASME Code provisions be eliminated, but only if the ASME requirements are expanded to include operation. Since efforts in this direction are underway, this recommendation is intended to encourage such efforts."

Status: Action is a Continuing Effort

#### Discussion:

Use of the word "material" in the recommendation is unclear since the ASME Code covers the design, manufacture, assembly of parts and components as well as providing rules specific to materials. From the text preceding the recommendation, we assume that material is meant to mean all "products and services" provided a nuclear facility in accordance with ASME Code rules.

In response to the recommendation, as stated, efforts are underway to utilize the ASME vendor certification and inspection system to supplement direct NRC inspections. NRC recognition and utilization of the ASME certification and inspection system is contingent upon two things: (1) development and application of ASME standards that are equivalent to NRC requirements and (2) extension of ASME rules to include all parts of dynamic-type components (e.g., pumps, valves) rather than simply their pressure boundary. Assuming that these conditions are satisfied, the NRC will have a basis for reducing direct NRC inspection of ASME certified vendors. Part of current NRC resources used to inspect ASME vendors will be redirected to the auditing of the ASME certification and inspection system.

A two-year trial program for evaluating the ASME certification and inspection system for supplementing NRC inspections is currently underway. This program will continue to receive priority attention.

#### Recommendation #8

"The Inspection and Enforcement staff strengthen its review of the inspectability and enforceablity of Technical Specification requirements."

Status: No Action Planned

# Discussion:

In accordance with existing procedures, all Standardized Technical Specifications were reviewed for inspectability and enforceability by both IE Headquarters and the Regional Offices. All facility Technical Specifications are reviewed for inspectability and enforceability by the appropriate Regional Offices.

Isolated examples may occasionally be identified where requirements are unclear causing some difficulty in inspection. However, if these oversights have significant safety impact, internal procedures are available for achieving clarification and correction.

In IE's view, sufficient effort is currently allocated to this subject area. No further action is deemed necessary.

#### Recommendation #9

"Routine direct NRC inspection and testing of hardware be increased, and that data pertinent to quality decisions made in the construction and operation of a plant be evaluated by the NRC on a routine basis. (This includes the evaluation, for example, of radiographic and ultrasonic test data.)"

Status: Action in Progress

#### Discussion:

The principle of direct inspection and testing of hardware and work activities has been recognized as a valid technique for not only measuring the effectiveness of quality assurance programs but for confirming the adequacy of designs. One of the major offices (Office of Nuclear Regulatory Research) authorized by the Reorganization Act of 1974 was specifically established to provide the NRC with a capability for performing confirmatory research and product qualification.

IE currently has two major efforts underway, utilizing private contractors, for the prime purpose of identifying and evaluating specific activities where direct NRC inspection and/or testing could be applied. Also, IE inspectors routinely examine and evaluate test data (radiographs, ultrasonic results) on a sample basis covering product quality. These examinations are not performed to provide "product acceptance" for the licensee but are performed as a technique for evaluating QA program effectiveness.

A third initiative underway which will provide further implementation of this recommendation is the Resident Inspection Program. This program will provide additional IE capability for the surveillance of all licensee activities including the direct inspection and testing of hardware and fabrication-construction.

We plan to carry out to completion the contracts for evaluating possible techniques for independent test and measurement by IE and to implement proposals as practical. We shall also continue and expand inspector activities relating to direct observation of hardware and examination of test data.

#### Recommendation #10

"IE inspections for QA program implementation during construction (Modules 35700B through 35736B of the IE Manual) be conducted more frequently during the period of personnel turnover prior to operation."

Status: Action in Progress

# Discussion:

The major portion of the Construction Inspection Program is focused on implementation of the QA program and fully reflects the content of modules 35700B - 35736B. It should be noted that the referenced modules were specifically designed for operational readiness determination. Frequency of conduct is not germane to assuring readiness for operation. It appears inappropriate to recommend actions by module num er. In this specific case, modules 35700B - 35736B were superseded by other inspection procedures on 10/1/76.

Initiation of the Resident Inspection Program will provide additional IE surveillance capability of all licensee activities, including the transition period between construction and operation. This program, in conjunction with the current inspection programs, is designed to permit additional observation and surveillance of licensee activities and will meet the intent of the specific recommendation. The Resident Inspection Program is expected to start in early 1978 with the assignment of inspectors to eight selected sites. Full implementation is scheduled for FY 1982. Revisions to the inspection modules for the Resident Inspection Program have been prepared.

#### Recommendation #11

"Qualification testing be required for design verification when practicable."

Status: Action in Progress

#### Discussion:

As noted in the report, Appendix B to 10 CFR Part 50, and Regulatory Guide 1.64 which endorses ANSI N45.2.11, indicates that qualification testing is one method of performing design verification, but not the only method. Other methods are by means of design reviews and alternate calculations. NRC has established and is continuing to establish guidelines for qualification test programs (see discussion for Recommendation #13). These guidelines indicate qualification testing methods which NRC considers to be an acceptable method of performing design verification. Other methods of design verification may be used where specifically justified.

It appears that Recommendation #11 on qualification testing has been somewhat amplified and clarified in Recommendation #13 wherein they recommended NRC establish requirements and guidelines for a comprehensive qualification and proof test program. The report notes in connection with Recommendation #13 on page 42 that, "Since the cost of testing is high, indiscriminate application of qualification and proof testing should not be required. Instead, the criteria for application should be carefully and clearly developed, as they have been for pre-operation and startup testing, inservice inspection, and surveillance, so that testing will be applied where it is practical and avoided where it is not." We agree with this recommendation and have developed and are continuing to develop guidelines for qualification testing as noted in the response to Recommendation #13.

# Recommendation #12

"IE inspections "QA Program (Receipt, Storage and Handling of Equipment and Materials)" (Module 25720B of the IE Manual) and "QA Program (Test and Measurement Equipment)" (Module 35736B) be conducted more frequently during construction."

Status: Action in Progress

Discussion:

The referenced modules are operational preparedness modules and do not relate to construction activities. The subject matter covered by the reference modules is fully covered by the construction inspection program in many modules, each related to the functional construction activities in progress.

Our plans are that more extensive observation of the activities described by the recommendation will be performed upon initiation of the Resident Inspection Program. (See Recommendation #10.)

#### Recommendation #13

"The NRC establish requirements and guidance for comprehensive qualification and proof test programs similar in detail to the requirements and guidance for preoperational and startup testing programs. The guidance should include criteria for practicability."

Status: Action in Progess

Discussion:

We agree with the recommendation that "the NRC establish requirements and guidance for comprehensive qualification and proof test programs similar in detail to the requirements and guidance for preoperational and startup testing programs." We have been and are continuing to implement this recommendation.

For the past several years, NRC has been establishing requirements and guidelines for comprehensive qualification test programs for equipment, starting with the basic criteria of IEEE 279-1968, "Proposed IEEE

Criteria for Nuclear Plant Protection Systems," which was incorporated by reference into the Commission's regulations. This standard, and its successor, IEEE Std 279-1971, require that type test data or reasonable engineering extrapolation based on test data be available to verify that equipment that must operate to provide protection system action will meet, on a continuing basis, the performance requirements determined to be necessary for achieving system requirements.

Regulatory guides delineating acceptable methods for qualifying specific kinds of equipment for LOCA, seismic, and normal ambient environments have already been developed and issued as follows:

- Regulatory Guide 1.40, "Qualification Tests of Continuous-Duty Motors Installed Inside the Containment of Water-Cooled Nuclear Power Plants"
- Regulatory Guide 1.63, "Electric Penetration Assemblies in Containment Structures of Light-Water-Cooled Nuclear Power Plants"
- Regulatory Guide 1.73, "Qualification Tests of Electric Valve Operators Installed Inside the Containment of Nuclear Power Plants"
- Regulatory Guide 1.100, "Seismic Qualification of Electric Equipment for Nuclear Power Plants"
- Regulatory Guide 1.131, "Qualification Tests of Electric Cables, Field Splices, and Connections for Light-Water-Cooled Nuclear Power Plants"

As part of NRC's continuing and comprehensive efforts in the area of qualification testing, the preparation of regulatory guidance is also planned for those vital electric equipments not subject to LOCA environments, such as cable fire stops, fire breaks, switchgear, batteries, motor control centers, modules (including sensors), battery chargers, inverters, transformers, and diesel generators. In the development of such guidance, the NRC will take into account all available empirical information and shall apply experience gained in prior activities, such as the recent qualification of electrical connectors. In addition, a general standard for qualifying mechanical, as well as electric, equipment is being prepared by IEEE. This standard, when published in acceptable form, will be endorsed by a regulatory guide.

Specific mechanical equipment qualification guides are also being developed including guides on snubbers, valve assemblies, and pumps.

#### Recommendation #14

"The NRC actively continue support of cooperative audit programs in the industry, especially programs for the sharing of audit data among licensees and contractors, and for the conduct of joint audits."

Status: Action is a Continuing Effort

### Discussion:

Redundant audits are a problem area which was identified and discussed by QAB with Sandia personnel in the summer of 1976. Accordingly, the Sandia recommendation is endorsed, and actions continue to be implemented along the lines suggested by Sandia.

The principal thrust of the Sandia recommendation is to encourage various approaches, such as cooperative audits, which offer the potential of reducing the audit burden without reducing the confidence that work is proceeding satisfactorily. Over the past year, the following actions have been initiated towards this objective:

- (a) The CASE (Coordinating Agency for Supplier Evaluation) concept which allows for sharing of audit findings for supplier evaluation through publication of a quarterly register has been endorsed by NRR (letter dated July 1977). The detailed topical report requires only minor revision before it will be accepted as an adequate basis for implementing and inspecting the CASE system. With NRC endorsement of this system, redundant pre-award audits by purchasers should be minimal or non-existent.
- (b) The NRC and the ASME have had a number of discussions over the past year on the possibility of the NRC endorsing the AMSE certification and inspection program as a "third party." If successful, the attainment of this objective should further reduce the need for pre-award audits and for yearly programmatic audits by purchasers. It should also greatly reduce the number of audits/inspections by NRC personnel. The initiation of a two-year trial program with the ASME was approved by the Commission in May 1977, and staff discussions are continuing. The ASME anticipates the submittal of a topical report to the NRC this year which would be a major milestone in this activity.

(c) The IE Licensee Contractor and Vendor Inspection Program (LCVIP) also has the potential of reducing the number of audits purchasers must perform on their subcontractors. The LCVIP is continuing to evolve, and greater benefit towards reducing audits may result from future program directions. A major milestone in this regard was the approval by the Commission of the LCVIP concept and program in May 1977.

The actions noted above reflect a continuing effort by NRC to eliminate redundant and unnecessary auditing. Actions already completed and those in progress should greatly aid in this regard. Additional actions will be initiated by NRR, working with IE and Standards, as the need is identified.

#### Recommendation #15

"The NRC adopt, for nuclear power plants, a more systematic, yet simple method of representing hardware and human performance characteristics that are significant to safety. This method should address the importance to safety of these characteristics and should also consider their unreliability modes and rates, in order that a more comprehensive quality assurance program can be applied. Toward this end, we recommend the use of simplified event models and equations within the industry and the NRC."

Status: Receiving further study.

#### Discussion:

Sandia strongly believes that the use of statistical reliability modeling, i.e., mathematical determinations of hardware and human performance reliablity, will provide an improved basis for defining, assessing and balancing quality assurance programs on a component and sub-systems level. It is suggested by Sandia (pages 56-59) that reliability models and related operating and test data should be included by applicants in the SARs (prepared in conjunction with the Chapter 15 accident analysis), and reviewed by NRC in the context of predetermined numeric probabilistic goals based upon "... system reliabilities appropriate to the task of protecting the public health and safety."

Sandia recognized that there would be impacts associated with this approach on the industry and the NRC, although Sandia believed the NRC SAR reviews could be performed with a staff increase of from one to two specialists. Sandia identified this recommendation as one of a longerterm nature.

Although the importance to safety and unreliability modes and rates are factors in determining quality assurance requirements for a particular item, these factors are not sufficient by themselves to allow such determinations. Other factors include the complexity and uniqueness of the item, the quality history of the item, the degree of standardization, and the degree to which functional compliance can be demonstrated by inspection and test. Simplified event models and equations as recommended by Sandia must be used in conjunction with other factors, and thus, engineering judgment must be used in structuring and assessing QA programs.

However, the overall usefulness of the reliability modeling methodology has been recognized and continues to be seriously investigated by the NRC. Starting with the initiation of the Reactor Safety Study (WASH 1400) in 1972 by the AEC, the methodology and results of this approach have been used by the AEC/NRC to assess the relative safety and critical failure modes of commercial reactors. As a result of this work, the NRC has continued to expand inhouse expertise on the applications and limitations of the pertinent assessment methodologies, and has initiated activities directed at: (1) expanding the application of these techniques from those currently being accomplished in the normal NRR review process, (2) expanding staff capability through intensive training courses, and (3) pursuing outside expert advice and recommendations on the application of these methodologies. The focus of these activities, however, has been broader in nature than just the potential quality assurance advantages. Rather, these efforts are part of a coordinated effort directed at defining how the NRC can best take advantage of these techniques. Although our plans have not been finalized, we believe that Sandia may have seriously underestimated both the difficulty and the resources required to conduct the recommended activities. For example, such mathematical determinations will require an extensive data base. This data base, presently being built from the Nuclear Plant Reliability Data System and associated Licensee Event Reports, is still in an early stage of development; many years of growth will be necessary before useful data are forthcoming. Therefore, while we believe that these techniques may give added insight and assistance in developing regulatory positions and assessing generic design features having critical safety signficance, we do not believe that application of this methodology along the lines of the Sandia recommendations to specific plant SARs is currently practical.

We recognize that these techniques should provide additional insight into such items as relative safety significance of components and subsystems, the importance of human performance in achieving satisfactory system function and the need for testing under worse-case environments. These aspects were discussed with Sandia personnel in the summer of 1976, and subsequent steps have been initiated to develop some inhouse capability along these lines. We plan to focus more specifically on such considerations in future reliability modeling investigations. The specific scope of this work will be defined in conjunction with the development of the NRC Probabilistic Safety Analysis Plan now targeted for approval by the end of the second quarter of FY 78. If appropriate, the assistance of the Office of Nuclear Regulatory Research may be requested through a specific research request.

In sum, we do not believe that the full scope of this recommendation should or can be adopted by the NRC without further work. We propose to initiate more focused efforts towards determining the usefulness of risk methodologies, but we see problems in application and in obtaining the necessary staff capability.

#### Recommendation #16

"The quality assurance planning and evaluation function in the NRC be assigned to a separate group. This function would include:

 Performing continuing reviews of all assurance measures in standards, Regulatory Guides and Standard Review Plans for consistency and adequacy,

- (2) Evaluating overall QA effectiveness (ultimately by comparing assessments of the reliability of reactor safety features from all plants with established goals) and recommending programmatic improvements when indicated, and
- (3) Developing and implementing quality assurance techniques."

Status: Receiving further study.

# Discussion:

Sandia observed the potential for inconsistencies to develop among the various NRC organizations (NRR-SD-IE) involved with QA for commercial reactors. Additionally, they believed an advantage would exist from an independent assessment and overview of QA activities from a separate group focusing on QA uniquely across the NRC. This group would have a broader perspective and charter than the rather specific QA responsibilities of the individual offices and would have the ability to balance QA measures, analyze results and problems, and recommend changes without regard to the office where improvements are needed.

The report is silent, however, on any specific examples or other bases which support the need for this recommendation. It makes no mention of existing coordinating and concurrence mechanisms established to assure consistency, such as regulatory guide review process, Interoffice QA Task Force, NRR-IE interface agreements and meetings, formal coordination on the development and interpretation of standards or the extensive discussion and coordination that occurs among the offices. Additionally, it fails to note that a number of independent organizations, such as the ACRS, individual licensing boards and the GAO have looked at QA activities from an overview perspective.

Further, it recommends that improved QA techniques be developed and implemented without specifying what these techniques should be or why they are needed (other than those proposed in part 2 of the recommendation). We are not aware that improved techniques are in fact needed or that if a need is identified, a separate group should be responsible for their development and implementation.

The present organizational arrangement involving QA responsibilities has proven to be practical and workable. Of course, improvements may be possible and the Sandia recommended organizational change warrants consideration, but the overall need for an additional "review" group without specific responsibilities for defining, applying or assuring QA activities in terms of CPs and OLs is not readily apparent. In fact, IE also notes that the present organization arrangement has proven to be satisfactory, and in view of no identifiable deficiencies by Sandia, believes that this recommendation should not be adopted.

On the other hand, we are aware that inconsistencies in QA provisions can and have developed among the various offices. For the most part, these have been or are being resolved through existing mechanisms. Additionally, the Sandia recommendation is largely based upon having the capability to evaluate QA effectiveness through reliability studies and, as noted in our response to Recommendation 15, the need for this capability remains to be fully evaluated. Thus, the information will not exist in the foreseeable future to fully evaluate the worth of an organization change in terms of this important aspect of the recommendation. Thus, we propose to defer action on this recommendation until the results of work associated with Recommendation 15 (dealing with mathematical reliability modeling) are available.