July 18, 1978 SECY-78-394

Secy 78-394

COMMISSIONER ACTION

For: The Commissioners

From: Saul Levine, Director
Office of Nuclear Regulatory Research

Thru: Executive Director for Operations

Subject: PLAN TO INVESTIGATE THE ADEQUACY OF QUALITY ASSURANCE PRACTICES IN RES-SPONSORED PROGRAMS

Purpose: To obtain Commission approval of a plan to investigate the adequacy of quality assurance practices in NRC safety research programs

Discussion: Background

On April 13, 1978, the Commission issued a memorandum and order that included ten required staff actions resulting from a petition from the Union of Concerned Scientists, dated November 4, 1977. This paper addresses staff action #7 which states:

> "Develop a plan to investigate the adequacy of quality assurance practices for NRC-sponsored confirmatory research programs and provide recommendations to the Commission. This plan is to be developed as a coordinated effort among appropriate NRC offices to include RES, NRR, IE and SD. Consultation with the Department of Energy and appropriate national laboratories is suggested. The plan is to be completed within six weeks."

The proposed plan is included as Enclosure 1.

Development of Plan

In response to this request, a meeting of RES, NRR, IE, SD and DOE headquarters personnel was held on April 28, 1978 to determine the best approach to develop the plan. Using comments and suggestions from this meeting, RES agreed to take the lead in developing the plan.

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On May 11, 1978, representatives from RES, NRR, IE, SD, DOE, the Idaho National Engineering Laboratory, Argonne National Laboratory, Sandia Laboratories, Oak Ridge National Laboratory and Battelle Columbus Laboratories met to review the draft plan. Based on the comments and suggestions given during this meeting, the proposed plan (Enclosure) was developed.

Plan

Central to the proposed plan is a Review Team to be composed of NRC and DOE headquarters personnel and supplemented, as needed, by appropriate DOE field office personnel. The NRC members of the Review Team will come from RES, NRR and IE with SD providing on-call advice and assistance. SD will be kept informed of the activities of the Review Team but will not participate in the review because of manpower limitations. Of the NRC Review Team members, NRR and IE have the requisite quality assurance expertise so these two offices will be the most heavily involved in the investigation.

The actual investigation will proceed in a systematic, step-by-step manner of meeting with DOE personnel, reviewing quality assurance documents and meeting with RES program managers to determine the specific technical and programmatic requirements for adequate quality assurance practices. It is recognized at the outset that RES sponsored programs are quite diverse, ranging from such large, complex experiments as LOFT to simple, straightforward laboratory-scale experiments. Consequently, the formality and level of detail in the quality assurance practices must vary with the program. To meet a reasonable schedule for completing the investigation, it is planned that the focus of the review be on INEL, ORNL and Sandia where RES has most of its funding. The initial portion of the investigation will be done by reviewing quality assurance documents from these three laboratories. If the need arises, the Review Team may wish to go into more detail with other laboratories or contractors.

After briefing the RES program managers on the results of the review of quality assurance documents, the Review Team plans to visit INEL, ORNL and Sandia to study selected programs in more detail. Other laboratories may be visited as necessary to do sampling studies.

Upon completion of the investigation, the Review Team will prepare a report of its findings to RES. This report will include input from the involved offices of DOE. RES will review the report and determine from RES programmatic and technical needs if the existing quality assurance practices are adequate. RES will then transmit the report to the Commission along with any comments or recommendations. RES will be responsible for following up on any recommendations.

Schedule and Resources

The plan calls for completion of the review within nine months of Commission approval. It is expected that RES, NRR and IE will each have to commit the equivalent of approximately five man-months of full-time effort to this review. Special travel funds of at least $5,000 will have to be set aside for field visits. The estimates for schedule, personnel resources and travel funds are based on the assumption that the Review Team will concentrate on the principal programs and will selectively sample the others.

Recommendations: That the Commission approve the proposed plan.

Coordination: This paper has been concurred on by NRR, IE and SD.

Saul Levine, Director
Office of Nuclear Regulatory Research

Enclosure:
Plan to Investigate the
Adequacy of Quality Assurance
Practices for NRC-Sponsored
Confirmatory Research

Commissioners' comments should be provided directly to the Office of the Secretary by close of business Tuesday, August 1, 1978.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT July 26, 1978, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE

PLAN TO INVESTIGATE THE ADEQUACY OF QUALITY ASSURANCE PRACTICES FOR NRC-SPONSORED CONFIRMATORY RESEARCH PROGRAM

1. SCOPE

In a Memorandum and Order[1] issued by the NRC Commissioners on April 13, 1978, the NRC staff was directed to:

> Develop a plan to investigate the adequacy of quality assurance practices for NRC-sponsored confirmatory research programs and provided recommendations to the Commission.

In developing the plan, the Commissioners requested a coordinated effort among appropriate NRC offices and suggested consultation with DOE and appropriate laboratories.

This document sets forth the plan to investigate the adequacy of quality assurance practices for NRC-sponsored research programs. The plan includes the formation of an NRC/DOE Review Team to determine the status and effectiveness of existing DOE quality assurance practices.

As used in this plan, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that the products of NRC's research programs (for example, computer programs, experimental data or test article performance data) will meet the intended aims of the programs and that the results are not biased nor otherwise unacceptable through defects in the conduct of the research program.

2. CATEGORIES OF QUALITY ASSURANCE

NRC has a broad spectrum of research programs covering all facets of the nuclear fuel cycle at the experimental and analytical level. In experiments the emphasis is generally on obtaining data about some physical phenomenon (e.g., water flow) or on some particular test article (e.g., fire protective coatings). The facilities,

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1 U.S. Nuclear Regulatory Commission, "Memorandum and Order in the Matter of Petition for Emergency and Remedial Action," April 13, 1978.

themselves, are merely tools used to obtain this information. Thus, the NRC confirmatory research programs generally fall under one of two categories or levels for quality assurance. These are:

Category 1 - Research programs which involve demonstration test articles as related to their use in commercial power plants. In general, a demonstration test article is an item which is intended to perform in a research program as a comparable item would perform in a commercial nuclear power plant.

Category 2 - Research programs which are important to the successful resolution of a licensing technical issue, and which do not involve demonstration test articles.

3. DISCUSSION

Through definition of programmatic and technical requirements, RES will be responsible for establishing the category of quality assurance and overall level of detail, and the contractor is responsible for implementing a quality assurance program commensurate with the specified requirements. In particular, Cagegory 1 programs will be subject to the applicable requirements of 10 CFR 50, Appendix B, as defined by RES. RES will review the quality assurance program as appropriate to confirm that it is consistent with the relative importance of the information to be derived from the research program. For programs at DOE laboratories, the categories will be specified in the Statement Of DOE Work (SOEW), NRC Form 173. For non-DOE RES programs, the categories will be specified in the interagency agreement (for other government agencies) or in the contract (for private organizations). Quality assurance for research performed for NRC in other countries will have to be established by RES through mutual agreement. To complete this investigation in a reasonable length of time it will be necessary to concentrate on large research programs (>$250K) and to only randomly sample small research programs. Attachment 1 is a preliminary assignment of the Category 1 programs. The remaining research programs are considered to be Category 2.

In general, the level of quality assurance needed for a given research program will be tailored to the application of the results. For example, where test components being studied at a DOE laboratory are not necessarily considered as being of a specified standard, assurance with specific quality assurance provisions will be requested from the responsible DOE field office or others involved in the test program that the DOE laboratory or project quality assurance program is sufficient to furnish all relevant data on the test component necessary

for test interpretation. In such a case, the specific quality assurance provisions would be reviewed by RES for consistency with RES data requirements established on that program.*

For those tests where RES specifies that it is significant to the purposes of the test that certain well-defined components be qualified to specified standards, RES will require that these components be purchased using the specified quality assurance standards.

Computer code and model development programs are currently subjected to several layers of quality assurance under a formal process which is monitored by RES. This process is considered to be adequate to meet the needs of the code users. Typically, a computer code is subjected to checkout and data comparisons by the code developers. Next, an independent group is assigned to conduct a performance assessment of the code through comparisons with different sets of data. Finally, the code is checked out by the Argonne Code Center before being publicly released. This general process has been considered and is periodically reviewed by various research review groups. Thus, there appears to be no specific need to investigate the computer code and model development programs; however, continued monitoring will be performed by the RES technical monitor(s) assigned to such programs and the Review Team will sample the adequacy of the quality assurance procedures used in developing and checking the codes.

Similarly, RES has reviewed and accepted existing DOE quality assurance practices for the construction and operation of DOE facilities in support of NRC programs. Quality assurance practices for any proposed new NRC-related facilities at DOE laboratories would be established by NRC and DOE through consideration of such factors as importance and schedular needs for the program/data requirements to meet the test objectives. Operational safety of the facility is a consideration and will be the responsibility of DOE. With the exception of LOFT, there are no major NRC-related facilities which have not been accepted by RES for research use. Therefore, any quality assurance of facilities is tied to the experimental program itself (e.g., calibration of test instrumentation, quality of data, etc.) and not to the facilities per se. In the case of LOFT, IE has already assisted RES in assuring that adequate quality assurance records exist prior to NRC indication of facility acceptability for the performance of the NRC nuclear experimental program.

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* RES may elect to seek the services of other NRC offices for support in the review of quality assurance practices.

4. APPROACH TO EVALUATION

One of the first steps in evaluating the adequacy of quality assurance practices for NRC-sponsored research programs will be to have the RES program managers specify, through programmatic and technical considerations, what level of quality assurance is appropriate for a given research program. Consistent with RES program manager guidance, the following aspects will be addressed by the Review Team in consultation with the RES program in order to assess the quality assurance practices.

a. Existence and basis of quality assurance program and practices at a level appropriate to the assigned category of the program to ensure research results which meet the intended objective of the program.
b. Effectiveness of the execution of the quality assurance activities at the appropriate level.
c. Contractor proficiency in quality assurance procedures and practices for the assigned category
d. Review procedures instituted by the contractor to ensure useful safety research results.
e. Involvement and committment of contractor management to quality assurance program to the extent required by the assigned category. (This includes consideration of resources and manpower.)

5. QUALITY ASSURANCE REVIEW

To carry out the investigation of the adequacy of current quality assurance practices, a systematic, step-by-step approach will be used. The various phases of the investigation are described in the following subsections. Because most of the RES funding is at DOE laboratories, the phases are keyed to DOE activities; however, a similar all-NRC review process will be used on a selected sampling of non-DOE RES contractors.

Phase 1 - Organization of Review Team

An NRC/DOE Headquarters Review Team supplemented by appropriate DOE field office personnel will be formed to determine the status and effectiveness of the existing DOE quality assurance practices. (An all-NRC review team will be involved in the review of non-DOE contractors working on NRC programs.) This formation could be completed within two weeks following Commission approval

of this plan. The NRC representatives will come from RES, IE and NRR.* The bulk of the review work will be done by IE, NRR and DOE with RES providing guidance, through definition of programmatic and technical requirements, on the level of detail required in the investigation of any given program.

Phase 2 - Headquarters Level Review of DOE Quality Assurance Policies

The Review Team will meet with appropriate DOE personnel to obtain background information on certain DOE laboratory quality assurance practices. This phase of the investigation will also include the review of documents to be submitted by the DOE field offices and laboratories in order to assess the degree of procedural control relative to the criteria and categories of programs. This review will also provide background information prior to any visits to the laboratories. This review is expected to take three months.

Phase 3 - Review with RES

At appropriate stages in the review of DOE/laboratory quality assurance documents, the review team will meet with the RES project managers to discuss the acceptability of existing practices in terms of program requirements. Emphasis will be placed on practices and procedures required to obtain useful and applicable research results. To establish a consistent level of requirements within a given research program element, it is advisable that the cognizant Branch Chief and the RES member of the Review Team (or their designated alternates) participate in these reviews. Obviously, Phases 2 and 3 are not strictly sequential; there will be a continuous interaction between the Review Team and the program managers.

Phase 4 - Field Assessment of Quality Assurance Practices

Based upon the Phase 2 review and RES programmatic or technical guidance, the review team will perform a field assessment study of selected aspects of the Category 1 programs and a sampling of the principal Category 2 programs. The focus of attention will be on the Category 1 programs and the research at INEL, ORNL and Sandia (where most of the RES funding is). Each field

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* The Office of Standards Development will be kept informed of the activities of the Review Team but does not plan to participate in the review because of manpower limitations.

visit is expected to be no more than two or three days' duration. Allowing for scheduling and uncertainties in detail, this review is expected to take three months.

Phase 5 - Report of Investigation

Within one month of completing the investigation, the review team will prepare a report to RES on its investigation along with suggestions for improvement, if any. This report will include the results of field assessments and discussions with the involved offices of DOE. RES will review the report and then transmit the report to the Commission along with any comments or recommendations. RES will be responsible for following up on Commission-approved recommendations.

It is expected that IE and NRR will each have to commit the equivalent of approximately five man-months of full-time effort to this review.

ATTACHMENT 1

List of RES Category 1 Programs or Test Hardware

(Note: All other RES programs are Category 2)

Fire Protection

Qualification Testing Evaluation

PBF Test Train Fuel Rods

Instrumented Fuel Assemblies for Halden

Intermediate Test Vessel Experiments

} only where demonstration test articles are used