Ref: SA/KNS

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ALL AGREEMENT STATES

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NRC INFORMATION NOTICE NO. 88-62: RECENT FINDINGS CONCERNING IMPLEMENTATION OF QUALITY ASSURANCE PROGRAMS BY SUPPLIERS OF TRANSPORT PACKAGES

Enclosed for your information is a copy of the NRC Information Notice No. 88-62 which discuss the results of recent NRC inspections of the implementation of NRC-approved Quality Assurance (QA) programs by persons who fabricate and supply packages to users.

If you have any questions, please contact Kathleen Schneider at 301-492-0320.

cristen sted by:

Donald A. Nussbaumer Assistant Director for State Agreements Program State, Local and Indian Tribe Program

Enclosure: As stated

9306230012 /30503 PDR COMMS NRCC CORRESPONDENCE PDR

UNITED STATES NUCLEAR REGULATORY COMMISSION OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS WASHINGTON, D.C. 20555

August 12, 1988

NRC INFORMATION NOTICE NO. 88-62: RECENT FINDINGS CONCERNING IMPLEMENTATION OF QUALITY ASSURANCE PROGRAMS BY SUPPLIERS OF TRANSPORT PACKAGES

Addressees:

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All holders of NRC quality assurance program approval for radioactive material packages.

Purpose:

This notice is provided to inform addressees of the results of NRC inspections of the implementation of NRC-approved Quality Assurance (QA) programs by persons who fabricate and supply packages to users. It is suggested that addressees review the information for applicability to their operations, and institute corrective action, as may be appropriate. However, suggestions contained in this notice do not constitute NRC requirements; therefore no specific action or written response is required.

Description of Circumstances:

NRC inspections of suppliers of transport packages have found various degrees of failure to fulfill NRC-approved QA programs, including cases of complete failure to implement the programs. The most severe cases resulted in NRC withdrawal of the QA program approvals. This action can have serious effects on the package supplier's continued operations, as well as the operations of users of the package.

Discussion:

NRC regulations require holders of NRC-approved QA programs to document the implementation of their programs through written procedures and instructions. The inadequacies of these programs appear to be the result of lack of adherence to this requirement. This has been confirmed by recent inspections which have identified instances of inadequate documentation in all areas of the QA program. Examples of QA program requirements for which written procedures or activities were found deficient are set forth below:

 a) independence of personnel who verify that an activity is performed correctly;

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- b) qualification of personnel who perform special processes such as welding:
- assurance that procurement documents contain appropriate requirements relating to the applicable requirements of Subpart H of 10 CFR Part 71 and 10 CFR Part 21;
- e) corrective action systems;
- f) training and indoctrination of personnel performing activities affecting quality;
- g) control of documents, including review and approval of changes by authorized personnel;
- h) assurance that sufficient records are available to furnish objective evidence of activities affecting quality. (As a minimum, records should include operating logs; results of inspections, tests, and audits; qualification of personnel procedures and equipment; and design, procurement, and fabrication data.)
- i) performance of aucits and qualification of auditors.

NRC-approved QA programs applicable to user-licensees may only cover activities related to procurement, maintenance, repair and use. NRC recognized that other QA activities are performed by suppliers of packages, including design, fabrication, assembly, test and modification that are required to be controlled under Subpart H of 10 CFR Part 71. In such cases, user-licensees should assure themselves that those activities are conducted in accordance with the suppliers' NRC approved QA program by obtaining appropriate certification from the supplier.

If you have any questions about this matter, please contact the individual identified below.

Robert F. Burnett, Director Division of Safeguards and Transportation, NMSS Office of Nuclear Material Safety and Safeguards

Technical Contact: C.E. MacDonald, NMSS (301) 492-3384

Attachment: List of Recently Issued NRC Information Notices

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LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
88-61	Control Room Habitability - Recent Reviews of Operating Experience	8/11/88	All holders of OLs or CPs for nuclear power reactors.
88-60	Inadequate Design and Installation of Matertight Penetration Seals	8/11/88	All holders of OLs or CPs for nuclear power reactors.
88-04, Supplement 1	Inadequate Qualification and Documentation of Fire Barrier Fenetration Seals	8/9/88	All holders of OLs or CPs for nuclear power reactors.
88-59	Main Steam Isolation Valve Guide Rail Failure at Waterford Unit 3	8/9/88	All holders of OLs or CPs for nuclear power reactors.
88-58	Potential Problems with ASEA Brown Boveri ITE-51L Time-Overcurrent Relays	8/8/88	All holders of OLs or CPs for nuclear power reactors.
88-57	Potential Loss of Safe Shutdown Equipment Due to Premature Silicon Controlled Rectifier Failure	8/8/88	All holders of OLs or CPs for nuclear power reactors.
88-56	Potential Problems with Silicone Foam Fire Barrier Penetration Seals	8/4/88	All holders of OLs or CPs for nuclear power reactors.
88-55	Potential Problems Caused by Single Failure of an Engineered Sarety Feature Swing Bus	8/3/88	All holders of OLs or CPs for nuclear power reactors.
88-54	Failure of Circuit Breaker Following Installation of Amptector Direct Trip Attachment	7/28/88	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License CP = Construction Permit

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UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

NRC INSPECTION MANUAL

NMSS

TEMPORARY INSTRUCTION 2800/15

"ESTABLISHMEN" OF REGIONAL TRIAL PROGRAM FOR EARLY IDENTIFICATION OF MATERIAL LICENSEES NEEDING MORE NRC ATTENTION "

2800/15-01 PURPOSE

The purpose of this procedure is to establish, in each Region, a one-year program to identify, early, licensees with the potential for degraded safety performance. NRC Regional management can take appropriate action with the identified licensees to adjust the situation <u>before</u> significant degradation occurs. If successful, this program will result in improved overall performance of licensees, reduction in violation of NRC requirements, and reduction in the attendant need for enforcement action. This one-year program will emphasize the use of performance symptoms or performance evaluation criteria in assessing licensee performance.

2800/15-02 BACKGROUND

An NRC license to possess nuclear materials is issued on the premise that the licensee management will diligently ensure that requirements of NRC regulations and license conditions are met. This premise is necessary because NRC representatives cannot visit facilities frequently. The most important factor in ensuring proper control of licensed material for most categories of materials licensees is that licensee staff follow or perform procedures properly. However, there are some categories of materials licensees, such as irradiators and fuel facilities, where control equipment performs certain safety functions, e.g., interlocks, automatically. Basically, good licensee management performance is the key to good performance, through efforts to ensure adequate procedures, well designed and maintained equipment, sufficient numbers of qualified and trained personnel, adequate management audits and reviews, and correction of causes of identified deficiencies. We have observed the ability of experienced reviewers and inspectors to detect signs of slipping management performance before trouble occurs. We are now seeking to have all inspectors systematically look for these early signs of degraded performance so that Regional management can initiate corrective actions before serious problems develop.

2800/15-03 PROGRAM GUIDANCE

The ability of the WRC to promote high quality licensee performance, and, conversely, to prevent deterioration of that performance, requires coordinated licensing and inspection efforts. Before granting a license, NRC

licensing officials try to determine if the licensee understands his responsibilities, is fully qualified, understands what kind of performance NRC expects, and what actions NRC will take if violations occur. Once the license is granted, there are periodic inspections to identify violations of regulatory requirements, and also to identify early indications of degraded performance. Based on these inspections, Regional management determines when particular licensees show the kind of symptoms that indicate that NRC should pay closer attention to them.

NRC Regional management should judge what the appropriate action is for each individual situation. However, there is a range of actions that can be considered, including: telephone contacts; meetings with licensee management; special inspections tailored to emphasize certain aspects; additional management comments in letters forwarding inspection reports; or Confirmatory Action Letters. A follow-up inspection in such situations is also warranted. The purpose of these additional actions is to focus on licensee management and assure that he understands any concerns NRC may have about the symptoms and potential for degraded performance and that he takes action to correct underlying causes.

Each Region should develop and use a list of "performance factors" that may indicate the potential degraded performance. The term "performance evaluation factors" is being used in relation to the nuclear materials program, to differentiate this effort from the reactor program, where the term is "performance indicators." Although the objective of the reactor program is also to assist in improving performance, the type of information available in the materials area is not trend information on performance and not data-intensive information on equipment. Rather, the kinds of information available are the primary early subjective warnings or precursors of degraded performance of the licensee operations.

2800/15-04 RELATIONSHIP TO "PROBLEM" LICENSEES

Licensees whose performance has already degraded to the extent that serious incidents have occurred, or escalated enforcement actions have become necessary, are, by definition, problem licensees. There should be fewer of these than those for whom their performance symptoms indicate a need for increased NRC and licensee management attention. "Problem" licensees demand extensive immediate attention. Licensees with symptoms of degraded performance may in the future become "problem" licensees, unless actions are taken to improve performance.

2800/15-05 FACTORS OF DEGRADED PERFORMANCE

The specific performance each Region uses should be patterned after the attached exhibit, and added to as necessary by each Region. However, the factors that the Regions use should cover the areas of: licensee management oversight and control; quality of procedures and operations; adequacy of personnel staffing and training; and audits and feedback mechanisms to correct causes of deficiencies.

2800/15-06 TRACKING OF LICENSEE PERFORMANCE

Each Region should assign responsibilities to enhance its ability to track the performance of licensees and categories of licensees. One way to accomplish this is to assign Regional project officers to keep abreast of licensing and inspection information on each category of licensees and to keep management aware of problems and need for action.

2800/15-07 REPORT ON ONE-YEAR USE OF PERFORMANCE FACTORS

Each Region is to conduct an assessment, after one year, of its use of degraded performance criteria and symptoms and its Regional action with licensees, identifying the usefulness, difficulties, ideas for improvement that are instituted or planned, and innovations that are particularly useful. A report should be submitted in May 1989. NMSS will convene a meeting with the Regions to discuss lessons learned and future program guidance.

2800/15-08 EXPIRATION

This Temporary Instruction will remain in effect until June 30, 1989.

2800/15-09 STATISTICAL DATA REPORTING

Budgeting for FTE's has already been implemented. The time should be charged to NRC Inspection Procedure 87100.

END

Exhibit

PERFORMANCE EVALUATION FACTORS

Enforcement History - Point system depending on the number and types of violations.

Points Examples (may be added to by each Region, as appropriate). Failure of Isotope Committee (or certain key members there-25 а. of) to meet or discuss meaningful issues for a Broad Scope type license. 25 b. RSO too busy with other assignments (RSO spending less than 25% of time). 15 Excessive customer complaints from major manufacturers or с. distributors. 50 d. Excessive allegations which have been substantiated. 15 Significant number of diagnostic misadministrations e. (greater than 10"3 per procedure). 20 f. High man-rem levels (greater than 50% of workers requiring NRC Form 4). 20 g. Frequent or excessive contamination within the restricted area (greater than 10 x NMSS guidance for release to unrestricted areas). 15 Excessive missed surveillances (leak testing, inventory, h. surveys, etc., greater than 50% per year). 1. 50 Financial instability of licensee (shoe string operations. one or two-man operation such that cost of cleanup is significant to continued operations of the facility). Lack of involvement of senior management to oversee RSO 20 j. performance (management unaware of operations). Inadequate consultant service (consultant not finding any 20 k. problems but NRC does). 1. 15 Radiation Safety Committee (Broad Scope) gives "rubber stamp" approvals to users and/or issues user permits for indefinite periods of time. 20 Insufficient technologist/authorized user/radiation safety 20. staffing for licensed program workload. Excessive numbers of repeat violations (three or more). 75 r . 25 Frequent internal uptakes greater than 125 mrems, whole body 0. equivalent but less than 520 MPC/hr limits.

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