

10 CFR 31.5 Certain measuring, gauging, or controlling devices.²

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(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 and provide written justification as to why it cannot comply.

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Dated at Rockville, Maryland, this 19th day of November, 1998.

For the Nuclear Regulatory Commission.

Malcolm R. Knapp,

Acting Executive Director for Operations.

[FR Doc. 98-32113 Filed 12-1-98; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AC42

Comprehensive Quality Assurance in Medical Use and a Standard of Care

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking; Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPRM) that requested public comments on questions related to comprehensive quality assurance and a standard of care in medical uses of byproduct material. The Commission has decided to withdraw this ANPRM because of the effective implementation of the "Quality Management Program and Misadministrations" rule and the NRC's current efforts in revising the existing regulation for medical uses of byproduct material into a more risk-informed and performance-based regulation.

²Persons possessing byproduct material in devices under a general license in 10 CFR 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR 31.5 in effect on January 14, 1975.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012-7082, telephone: (202) 512-2249.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6219, e-mail jmm2@nrc.gov.

SUPPLEMENTARY INFORMATION:

On October 2, 1987, the Commission published two notices in the **Federal Register** regarding medical use of byproduct material. The first notice was the proposed rulemaking entitled "Basic Quality Assurance in Radiation Therapy" (52 FR 36942), that proposed a requirement for medical use licensees to implement some specific basic quality assurance practices to reduce the number of therapy misadministrations involving byproduct material. The second notice was an ANPRM entitled "Comprehensive Quality Assurance in Medical Use and a Standard of Care" (52 FR 36949), that requested public comments on the extent to which a comprehensive quality assurance program requirement was needed. The NRC believed that this two-pronged approach to the misadministrations problem would provide the best balance between assuring public health and safety and avoiding inadvertent interference in the delivery of quality medical care.

On July 25, 1991 (56 FR 34104), the NRC published a final rule entitled "Quality Management Program and Misadministrations" (the QM Rule) which was based on the above-mentioned 1987 proposed rule. During the implementation of the final rule, the NRC decided to assess the effectiveness of the rule and, based on the results of the assessment, to determine the need for a rulemaking on comprehensive quality management.

Subsequently, a Commission SRM on SECY-97-115 dated June 30, 1997, approved subsuming several Part 35 rulemakings into one major revision to 10 CFR Part 35 rulemaking activity. The proposed rulemaking entitled "Medical Use of Byproduct Material," was published in the **Federal Register** (RIN 3150-AF74) (August 13, 1998; 63 FR 43516). The NRC is in the process of developing the final rule governing medical use of byproduct material into a more risk-informed and performance-based regulation. This overall revision includes a consideration as to whether

or not the regulation on the quality management program should be revised to become more risk-informed and performance-based. For this reason, the Commission is withdrawing the ANPRM.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98-32108 Filed 12-1-98; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AF04

Steam Generator Tube Integrity for Operating Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPRM) that was published to request public comment on the Commission's regulations pertaining to steam generator (SG) tube integrity. The proposed rule would have implemented a more flexible regulatory framework for steam generator surveillance and maintenance activities that would maintain adequate assurance of tube integrity while allowing a degradation-specific management approach. Because the NRC has concluded that the regulatory objectives set forth for this effort can be achieved by equally effective regulatory alternatives, the ANPR is being withdrawn.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012-7082, telephone: (202) 512-2249.

FOR FURTHER INFORMATION CONTACT: Tim Reed, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-1462, e-mail tar@nrc.gov.

SUPPLEMENTARY INFORMATION:

On September 19, 1994 (59 FR 47817), the Commission published an ANPRM that requested comments, advice, and recommendations from interested parties on the proposed steam generator rule. In response to the ANPRM, two

public comments were received. The primary comment was a coordinated industry response submitted by the Nuclear Energy Institute (NEI). The remaining comment, submitted by Virginia Power, endorsed the NEI comment. Subsequently, the NRC staff developed a draft rule and draft regulatory guide intended to implement a performance-based regulatory structure that provides for the development and implementation of appropriate measures to ensure the consistency and quality of inspection methods, repair criteria, and tube condition assessment, while giving appropriate consideration to risk. As part of the rulemaking process, the NRC staff estimated the risk associated with SG tube degradation and used the results to provide the insights required for performing a regulatory analysis of the proposed rulemaking approach.

In COMSECY-97-013, dated May 23, 1997, the NRC staff provided a risk assessment summary and major conclusions from a regulatory analysis. Based on these results, the NRC staff reassessed whether a rulemaking is the appropriate regulatory vehicle for addressing the problems associated with SG tube integrity. It should be recognized that the NRC staff found that the current regulations governing SG tube integrity provide an adequate basis to ensure public health and safety due to SG operation. However, the NRC staff concluded that further guidance is needed for the industry to continue to effectively meet these regulations. Issues involving a plant's technical specifications (TS) are amenable to a generic letter approach. Given these considerations, the NRC staff informed the Commission that it planned to pursue the following approach in lieu of a new steam generator rulemaking: (1) Complete development of a SG tube integrity regulatory guide which describes an acceptable performance-based program for ensuring adequate tube inspection, monitoring, and assessment; (2) request licensees, through a generic letter, to propose performance-based technical specification changes to address the issues regarding inspection, monitoring, and assessment of SG tube condition to ensure that SG tube integrity is maintained consistent with the plant licensing basis; (3) provide licensees with an option to change current SG tube repair criteria and implement a degradation-specific management approach, if it can be demonstrated that risk will be maintained at an acceptable level. An application-specific regulatory guide would provide guidance on

acceptable approaches for proposing changes to SG tube integrity criteria and assessing changes in risk associated with relaxation of tube integrity criteria. Licensees would not be able to implement alternate repair criteria until an appropriate risk assessment is submitted and found acceptable by the NRC staff; and (4) as part of the IPE follow-up program, the NRC staff will evaluate pressurized water reactors (PWRs) that appear to have a high potential for core damage sequences that can challenge SG tubes. Any additional requirements would be imposed consistent with the backfit requirements of § 50.109.

The SRM on COMSECY-97-013, dated June 30, 1997, approved the revised approach. The SRM also directed the NRC staff to seek industry input, as appropriate, in developing the technical basis for the proposed TS changes to ensure that the proposed changes are consistent with current steam generator tube degradation modes. In support of this commitment, the NRC staff developed a proposed generic letter that: (1) informs PWR licensees that plant TSs for maintaining SG tube integrity do not alone provide the needed assurance that SG tube integrity is being adequately monitored and maintained in accordance with NRC regulations and plant licensing bases; (2) advises licensees that they may request license amendments to their plant TSs to implement the model TSs attached to the generic letter for maintaining SG tube integrity, or justify alternate approaches for ensuring that SG tube integrity; and (3) requires that licensees submit to the NRC written responses that describe their ongoing or planned activities to monitor and maintain SG tube integrity. By letter dated December 16, 1997, the NRC staff was informed that the industry, through the NEI Nuclear Strategic Issues Advisory Committee, had voted to adopt NEI 97-06. The chief objective of the industry initiative is for PWR licensees to evaluate their existing SG programs and, where necessary, to revise or strengthen program attributes to meet the intent of the NEI 97-06 guidelines. The NEI 97-06 guidelines are intended to improve both the quality and the consistency of SG programs throughout the industry. Consistent with Direction Setting Issue (DSI) 13, the NRC staff's preferred approach is to endorse an industry initiative that addresses all NRC staff and stakeholder concerns, rather than issue a generic letter. As a result, the NRC staff has temporarily deferred issuing the proposed generic letter for public comment while it works

with industry to resolve issues associated with NEI 97-06, with the objective of endorsing NEI 97-06 in a regulatory guide.

Whether the NRC staff ultimately endorses the NEI 97-06 guidance or continues with its efforts to issue a generic letter addressing SG tube integrity, the NRC has concluded that equally effective regulatory alternatives to rulemaking are available to address the issue of SG tube integrity. Therefore, the proposed rule is not required and is being withdrawn.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AF33

Reporting Reliability and Availability Information for Risk-Significant Systems and Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing a notice of proposed rulemaking that solicited comments on proposed amendments to its regulations that would have required licensees for commercial nuclear power reactors to report to the NRC, plant-specific summary reliability and availability data for certain risk-significant systems and equipment. The proposed rule would have also required licensees to maintain onsite, and to make available for NRC inspection, records and documentation that provide the basis for the summary data reported to the NRC. The systems and equipment for which data would be provided are a subset of the systems and equipment within the scope of the NRC's maintenance rule. The Commission has decided to accept industry's proposed alternative to the rule to voluntarily provide reliability and availability information for risk-significant systems and equipment and, therefore, withdraws this rulemaking.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room