NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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APPOINTMENT OF COMMISSIONER JACKSON

On April 6, 1995, the United States Senate confirmed the appointment of Dr. Shirley Ann Jackson as a member of the Commission. Dr. Jackson succeeds Dr. Forrest J. Remick, whose term as Commissioner expired on June 30, 1994. In addition, Dr. Jackson will become the next Nuclear Regulatory Commission Chairman effective July 1.

Dr. Jackson brings to the Commission extensive experience in research and management in the areas of high-energy physics, nuclear physics, and condensed-matter physics, as well as high-level policy experience in business and higher education. Since 1991, she has been a Professor of Physics at Rutgers University, New Brunswick, New Jersey, and served as a consultant to AT&T Bell Laboratories, where she had previously worked from 1976–1991. In the mid-1970's, she was a research associate at the Fermi National Accelerator Laboratory in Batavia, Illinois, and a Visiting Scientist at the European Organization for Nuclear Research in Geneva, Switzerland. Dr. Jackson earned her Bachelor's degree in 1968 and her Ph.D. degree in 1973 from the Massachusetts institute of Technology (M. I. T.), where she became the first African-American woman to receive a doctorate from M.I.T. in any field. Dr. Jackson is a native of Washington, D.C.

Dr. Jackson's appointment to the Commission became effective on May 2, 1995. She and members of her transition staff can be reached at (301) 415–1820.

(Contact: Kevin Ramsey, NMSS, 301–415–7887)

NUCLEAR REGULATORY COMMISSION MATERIALS LICENSING BUSINESS PROCESS REENGINEERING

In October 1994, the NRC staff began to examine the process used to issue materials licenses, to identify ways to improve the process. The staff was directed to develop a new licensing process that would—

1. Maintain or raise the level of public safety;
2. Perform licensing reviews and associated tasks an order of magnitude faster than the current process;
3. Exploit modern information technology; and
4. Reduce the resources needed to carry out the licensing program.

The method used for this examination is called Business Process Reengineering (BPR). BPR is the process of fundamentally changing the way work is performed, to achieve significant improvements in speed, cost, and quality. In the first phase of this effort, a core team of people who work in licensing, administration, and information technology developed a generalized design of a new materials licensing process. Soon the core team and others will begin the detailed design, building, and testing of the new process. Implementation of NRC's new licensing process is scheduled to begin in 1996.

The core team found that today, licensing is being accomplished by a complex process that can involve anywhere from 54 to 94 handoffs among involved individuals and computer systems during a routine license review. On average, NRC takes 84 days to complete a licensing action. Yet only 2 days are actually needed to complete the technical safety review of a typical licensing request. During the remaining 82 days, paper is either in transit or a queue.

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Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:
E. Kraus
NMSS Licensee Newsletter Editor
Office of Nuclear Material Safety and Safeguards
Two White Flint North, Mail Stop 8–A–23
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555–0001

On June 16, 1995, the Commission directed the staff: (1) to proceed with the detailed design and testing of the new licensing process; (2) to coordinate its efforts closely with the Agreement States, licensees, and the public; (3) to separate the payment of fees from the process of issuing a license and continue streamlining fees; and (4) on a one-time basis, to extend qualified licenses for an additional 5 years.

Proposed New Licensing Process and Coordination Efforts:

The staff proposes to use a graded approach that matches the safety hazards associated with a license application. Applications for relatively simple actions would go through an automated review process. The automated review process uses artificial intelligence-assisted review scripts to help reviewers in rapidly determining if the application conforms with established NRC regulations and licensing policies. Any unanticipated circumstance or any improper or incomplete response would automatically alert the reviewer and require separate action for resolution. This system would significantly alter the current practice of using technical staff to review well-established and relatively low-risk uses of licensed materials.

Applications for more complex uses would be reviewed by trained technical reviewers, working either individually or in teams. The staff plans to develop a new set of tools for reviewers to facilitate consistent, high-quality reviews. These tools include a single, comprehensive licensing manual that consolidates all NRC regulations and guidance in one easily accessible form. This licensing manual will be made available to the Agreement States, the public, and licensees in both hard copy and electronic media (e.g., a bulletin board), when it is completed later this year.

The staff plans to hold various meetings and workshops to get input from Agreement States, licensees, and the public, and will issue announcements when these plans are finalized.

Streamlining Fees:

The staff is working on a proposal that would separate the collection of fees from the issuance of a license and would also streamline fee collection.

One-time Extension of Qualified Licenses:

To provide the resources needed to develop a consistent Nuclear Material Safety and Safeguards policy on the duration of licenses and certificates, carry out the detailed design and testing of the new process, and develop the licensing manual, the staff is proposing, on a one-time basis, to extend all qualified byproduct, source and some special nuclear material licenses by 5 years. Each extended license would include the same authorizations and limits that it does now. Licenses would be considered qualified for the extension if the authorized activities pose a low safety risk and the results of the most recent inspection are good. Licenses that fall into one or more of the following categories would not be considered for license extension: (1) Any license that requires an emergency plan; (2) Any license lacking acceptable decommissioning financial assurance; (3) Any license currently listed on the Site Decommissioning Management Plan list; (4) Any license for which an environmental assessment is needed or has been prepared; or (5) Any license subject to a significant enforcement action as a result of the most recent inspection (i.e., an Order, a Severity Level I, II, or III violation, a Confirmatory Action Letter, etc.). NRC will publish the proposed license extension criteria for comment soon.

(Contact: Donald A. Cool, NMSS, 301–415–7197)

STATUS OF THE ENHANCED PARTICIPATORY RULEMAKING

The U.S. Nuclear Regulatory Commission has been conducting an enhanced participatory rulemaking to establish radiological criteria for decommissioning. The proposed rule was published in the *Federal Register* (59 FR 43200; August 22, 1994) as proposed amendments to 10 CFR Part 20. The rulemaking was scheduled to be completed in June 1995. However, because of the substantial comments received on the proposed rule, the NRC staff now plans to submit the rulemaking package for Commission review in December 1995. Commenters raised a variety of concerns, including the justification for selecting 0.15 millisievert (15 millirem) per year as the dose limit for unrestricted use, and the large costs associated with remediation of contaminated soil and groundwater. The staff plans to conduct a multi-day public workshop in the Washington, DC, area in early September 1995, to discuss the issues raised by the comments, describe current staff evaluations based on real-world data, and explore alternative approaches that could be used to implement the final criteria. A *Federal Register* notice about the workshop should be published by July.

NRC staff is also cooperating with the U.S. Environmental Protection Agency (EPA) in that agency's development of residual radioactivity standards. EPA circulated a preproposal draft version of its standards in May 1994. Many of the same issues raised in the public comments on NRC's proposed rule were also raised about EPA's draft standards. The objective of the agency discussions is to allow EPA to find that NRC's requirements provide sufficient protection of the

public and the environment. Based on such a finding, EPA would exclude NRC and Agreement State licensees from the scope of its standards.

In the interim, until NRC promulgates radiological criteria for decommissioning in 10 CFR Part 20, NRC will continue to use the criteria identified in the "Action Plan to Compel Cleanup of Site Decommissioning Management Plan Sites," which was published in the *Federal Register* on April 16, 1992 (57 FR 13389).

(Contact: Michael Weber, NMSS, 301–415–7297)

BRACHYTHERAPY ISSUES PAPER

The U.S. Nuclear Regulatory Commission is currently in the process of reviewing the medical use of byproduct material for brachytherapy, with regards to the adequacy of existing regulations, standards, and procedures. The need for additional regulations and guidance for brachytherapy was discussed by the staff with NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI). The ACMUI advised the staff to solicit additional information from the regulated community to sufficiently identify and evaluate the problems and determine what additional regulations and guidance may be necessary to further prevent errors. On November 3, 1994, NRC published a *Federal Register* Notice (59 FR 55068) requesting comments from the medical community on a list of issues and questions regarding those areas of medical use of byproduct material, primarily brachytherapy, that are currently being reviewed by NRC, to determine if additional or modified regulations or guidance are warranted. In addition, NRC conducted symposia at the annual meetings of the Radiological Society of North America and the American Brachytherapy Society.

The staff has developed an issues paper to describe the background and issues that would be associated with efforts to address brachytherapy, either for future regulations and/or guidance. The issues are categorized into three major topic areas: all brachytherapy, remote afterloading (RAL) brachytherapy, and manual brachytherapy. Within these broad topic areas, the issues include modification of the specific listing of brachytherapy sources and uses in 10 CFR 35.400; specific licensing guidance and license conditions for high-dose-rate (HDR) RAL that are not explicitly addressed in the regulations; quality assurance checks and calibrations for RAL brachytherapy similar to teletherapy; computer treatment planning; review of current brachytherapy definitions; training and experience; pulsed-dose-rate brachytherapy; and mobile HDR brachytherapy. This paper was discussed in detail with the ACMUI in May 1995 and will be the basis for future discussions with professional societies and organizations.

(Contact: Patricia Holahan, NMSS, 301–415–7847)

ENFORCEMENT POLICY TASK FORCE REVIEW

On May 13, 1994, the Executive Director for Operations established a task force to assess the U.S. Nuclear Regulatory Commission enforcement program. The charter asked the task force to consider: (1) whether the defined purposes of the program are appropriate; and (2) whether NRC's enforcement practices and procedures are consistent with those purposes. Over the last year, meetings were held with NRC regional and Headquarters offices, and various Federal agencies. Relevant documents were reviewed, including applicable statutes and regulations, NRC policies and procedures, previous assessments, responses to requests for comment in the *Federal Register*, and policies of other Federal and State agencies.

On April 6, 1995, the Enforcement Policy Task Force provided its report and recommendations to the Commission for review and approval. The task force concluded that the existing NRC enforcement program, as implemented, is appropriately directed toward supporting the Agency's overall safety mission. The task force also found, however, that the existing program, at times, provides mixed regulatory messages to the licensees, and room for improvement exists in both the enforcement policy and its implementation. The task force recommended that the overall program should be clarified to: (1) emphasize the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified; (2) direct Agency attention to licensees with multiple enforcement actions in a relatively short period; and (3) focus on current performance of licensees. The report recommends significant changes in the methods and processes used to determine when civil penalties should be considered and how the amounts of civil penalties are calculated. The following specific recommendations were made:

Severity Levels – NRC should continue to use a graduated system of enforcement actions, in a manner that reflects the varying safety significance of different violations, and that can be adjusted based on the circumstances of the

violation. Severity Level (SL) V violations should be eliminated. Formal enforcement actions should only be taken for violations categorized at SL I to IV. Minor violations, if documented, should be treated as Non-Cited Violations.

Enforcement Conferences – Enforcement conferences should be considered when the Agency reasonably expects that an escalated enforcement action will result, and additional information is needed to make an enforcement decision. Enforcement conferences should normally be public meetings held in regional offices.

Civil Penalties – Applied with discretion and judgment, civil penalties (CPs) can provide an effective deterrent against future violations. With limited exceptions, the task force recommended maintaining the existing base CP amounts. Once a violation has been determined to be SL III or above, the CP assessment process should consist, at most, of four basic decisional points: (1) consideration of previous escalated enforcement action, (2) credit for identification, (3) credit for corrective actions, and (4) exercise of discretion. These four points are discussed below.

1. *Consideration of Previous Escalated Action* – When NRC determines that a non-willful SL III violation has occurred, and the licensee has not had a previous escalated action during the past 2 years or two inspections, the only consideration should be whether the licensee's corrective actions for the present violation may reasonably be considered prompt and comprehensive (see discussion under 3, below).

2. *Credit for Identification* – This decision requires considering who identified the problem, whether the problem resulted in an event, the ease of discovery, the degree of licensee initiative shown, whether prior opportunities existed to identify the problem, and other similar factors.

3. *Credit for Corrective Actions* – This factor encourages licensees to (1) take the immediate actions necessary, on discovery of a violation, that will restore safety and compliance with the requirement; and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but also prevent occurrence of violations with similar root causes. In assessing this factor, consideration will be given to the timeliness of the corrective action, the adequacy of the licensee's root-cause analysis, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern).

4. *Exercise of Discretion* – The ability to exercise discretion (in tailoring sanctions to the circumstances of each case) must be preserved. The recommended approach provides for the use of discretion to deviate from the normal approach where necessary to ensure that the sanction reflects the significance of the circumstances and conveys the appropriate regulatory message.

As of May 23, 1995, the Commission had not taken action on these recommendations. Copies of the task force report, "Assessment of the NRC Enforcement Program," can be obtained free, on written request, from the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(Contact: E. William Brach, NMSS, 301-415-7196)

CERTIFICATION OF RADIOGRAPHY EQUIPMENT

Paragraphs (a) and (d) of 10 CFR 34.20 provide that all newly manufactured radiographic exposure devices and associated equipment (manufactured after January 10, 1992) acquired by U.S. Nuclear Regulatory Commission licensees must meet the requirements specified in American National Standards Institute N432-1980 (ANSI-N432). Paragraph (e) of 10 CFR 34.20 provides that all equipment in use after January 10, 1996, meet ANSI-N432 requirements. One of the test criteria specified in ANSI-N432, Section 8.9, is a prototype endurance test of the entire radiography system and is intended to ensure the integrity of the radiography system (particularly the source assembly), and to ensure that the system will remain operational after 20,000 operating cycles.

However, it has recently come to our attention that this test criterion, as specified in ANSI-N432, may not be reasonably attainable. Specifically, the torque requirement specified in the ANSI test is not attainable for two reasons. First, it exceeds by a considerable amount the torque that an individual can likely exert on the radiography system. Second, it would require that the typically used drive cable (Type 187 teleflex cable) be operated beyond the working load recommended by the supplier of that component.

Four manufacturers of radiography exposure devices and/or sealed source assemblies have models ("newly-manufactured") approved and registered as complying with the requirement. However, even though the device/source assembly manufacturers indicated that the devices/source assemblies had been tested in accordance with the ANSI provisions, the manufacturers used a more attainable criterion. The staff is not aware of any device problems occurring as a result of the use of the alternative criterion. Nevertheless, because the device/source assembly models were not tested as specified in ANSI-N432, these newly manufactured devices/source assemblies (and the licensees who use them) are not in full compliance with the regulation.

NRC is publishing in the *Federal Register* a final rule revising 10 CFR Part 34 which becomes effective 30 days after publication. The amendment includes language that relieves (exempts) licensees from the requirement to comply with Section 8.9.2 of ANSI N432-1980 when an alternate and acceptable test criterion has been applied. The amendment also includes a provision that allows manufacturers to use engineering analysis to demonstrate that a modest change in an already approved design is acceptable without the need to perform additional prototype tests. The amendment is necessary to relieve licensees from compliance with an impractical and unnecessary test criterion that was required by reference to ANSI-N432. Until the effective date of the final rule, NRC staff has added a license condition, as needed, that exempts the licensee from the equipment torque test requirement. Because the license condition is superseded by the rulemaking action, the condition only remains in force until the final rulemaking effective date. Licensees who are authorized to use "newly-manufactured" equipment, identified as meeting 10 CFR 34.20 requirements, can continue to use the equipment without requesting the exemption license condition.

Any questions regarding the exemption condition or the rulemaking should be directed to Bruce Carrico, Office of Nuclear Material Safety and Safeguards (NMSS). For questions concerning the applicability of 10 CFR 34.20 to a particular device, contact Michele Burgess, NMSS.

(Contacts: Bruce Carrico, NMSS, 301-415-7826
Michele Burgess, NMSS, 301-415-5868)

TRANSMISSION SOURCE-HOLDING DEVICES USED IN SPECT IMAGING

Recently, Ohio Imaging submitted a request to the U.S. Nuclear Regulatory Commission for a sealed source and device review of a device used with SPECT imaging systems, referred to as a "STEP" device. The STEP device received 501(K) approval by the Food and Drug Administration (FDA), and NRC recently approved the STEP device for use as described below. The source-holding device is a shutter shield affixed to the rotating gantry of a tripleheaded scintillation-camera patient-imaging system and contains either a Technetium-99m, Cobalt-57, or Gadolinium-153 source, of various activities. The purpose of the device is to provide, during image acquisition, a photon beam of differing energy from that administered to the patient, to improve resolution loss caused by non-uniform absorption in the patient. In other words, it acts as a thickness compensator to improve image resolution. A similar device, manufactured by ADAC and referred to as "VANTAGE," is currently undergoing a 501(K) review by the FDA. The State of California is performing the sealed source and device review of the VANTAGE device. The STEP and VANTAGE devices function essentially the same; however, the VANTAGE devices use a higher-activity source.

Licensees are reminded that these devices do not meet the definition of either a calibration or reference source (authorized by 10 CFR 35.57) or a sealed source for diagnosis (authorized by 10 CFR 35.500). Therefore, if you are using the STEP or VANTAGE device, or a similar device, you must submit a request to amend your license to authorize the possession and use of such devices. If the device for which authorization is sought has not undergone a sealed source and device review by either NRC or an Agreement State, either the requesting licensee or manufacturer of the device must submit the required information, for a sealed source and device review to occur. Once the sealed source and device review is completed and the device is registered, either by NRC or an Agreement State, the license will be amended to authorize its possession and use.

(Contact: Janet Schlueter, NMSS, 301-415-7894)

SEMI-ANNUAL MEETING OF THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

The U.S. Nuclear Regulatory Commission's Advisory Committee on Medical Uses of Isotopes

(ACMUI) held its regularly scheduled semi-annual meeting on May 11 and 12, 1995, at the NRC Headquarters office in Rockville, Maryland. Agenda items included a discussion of: brachytherapy issues; guidance documents for the final Radiopharmacy Rule, and a petition to review the final Radiopharmacy Rule; prostate implant procedures; training and experience of authorized users to allow exemptions to Subpart J; dose ranges in written directives; information on Sr-90 calibration errors for eye applicators; and revisions to Regulatory Guide 10.8. The staff discussed the status of the implementation of the Quality Management Rule; provided an update of the study of the medical use program by the National Academy of Sciences; and presented a summary of "Business Process Reengineering." In addition, NRC staff provided an update on several rulemakings: "Medical Administration of Radiation and Radioactive Materials"; "Release of Patients Containing Radiopharmaceuticals or Permanent Implants"; and "Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May be Pregnant or Nursing."

Copies of the transcripts and summary minutes for the meeting are available through the Public Document Room, at 202-634-3273. The next meeting of the ACMUI will be held in October 1995, and will be noticed in the *Federal Register.*

(Contact: Torre Taylor, NMSS, 301-415-7900)

REVIEW AND INSPECTION OF IMPLEMENTED QUALITY MANAGEMENT PROGRAMS (QMPs)

Since August 1, 1994, U.S. Nuclear Regulatory Commission inspectors have been reviewing both the written and implemented QMPs as part of the inspection of applicable medical use programs. Based on NRC inspectors' findings, it is apparent that the majority of licensees have implemented programs that meet (or nearly meet) the requirements described in the Quality Management Program and Misadministration Rule (10 CFR 35.32). However, the inspection findings indicate that a few licensees do not have procedures in place to ensure that final plans of treatments and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directive (objective 3 of the rule), and that each administration is in accordance with the written directive (objective 4). Most licensees inspected are reviewing their QMP within each 12-month period. However, the inspectors have identified a number of recordable events that had not been previously identified by the licensees during their reviews.

All the inspection findings have been entered into a database to be used to evaluate the implementation of the Quality Management rule.

(Contact: Sally Merchant, NMSS, 301-415-7874)

NMSS COMPLETES REGULATORY IMPACT SURVEY

The Office of Nuclear Material Safety and Safeguards (NMSS) has completed a mail survey of licensees to determine the impact of NRC regulation on safety and operations. In the first phase of the Regulatory Impact Survey of Materials Licensees, the staff interviewed representatives of nine large licensees and reported to the Commission the results of the interviews and possible changes in the regulations based on those results. The objective of the second phase of the Regulatory Impact Survey is to obtain the views of a broader range of licensees on the impact of NRC regulation on licensee operations. The staff will report to the Commission shortly on the results of this second phase.

With the assistance of a contractor, the staff developed a self-administered, mail-out survey questionnaire based on the interview protocol used in the first phase of the survey. The questionnaire covers five aspects of regulation: (1) Regulations, Policies, and Guidance; (2) Licensing; (3) Inspection; (4) Reporting; and (5) Enforcement. Staff chose a stratified, random sample design for the survey to sample a wide range of licensee categories while giving greater weight to certain categories (i.e., sampling a larger number within the category) based on relative hazard, heterogeneity within categories, and regulatory issues in the various categories. Licensees with recent interactions with NRC (half for inspections and half for licensing actions) were selected at random for the sample.

Almost 600 questionnaires were sent to licensees. A total of 371 licensees returned completed questionnaires for a response rate of 63 percent, distributed across the licensee categories. Licensees were grouped into the following nine categories on the basis of the type of operation:

- Academic
- Medical Institution
- Medical Other
- Well Logging
- Gauges
- Manufacturing/Distribution
- Services

Industrial Radiography
Research and Development

The surveys were confidential; neither NRC nor the survey analysts were able to associate licensees with the responses. The responses were analyzed statistically, using computer software, and responses to open-ended (write-in) questions were also analyzed. The contractor's report summarizes the results of these analyses, using text and supporting graphs, tables, and charts, and suggests a number of areas in which NRC may consider changes. The results were analyzed both in overall terms and by licensee categories.

The survey yielded a number of findings significant for the materials regulatory program, involving usefulness of regulations and guidance, timeliness of licensing actions, performance of license reviewers and inspectors, and open communication with licensees. These findings point to areas for assessment of the program and for future monitoring. Staff expects to address licensee concerns identified in the Regulatory Impact Survey through existing initiatives. The staff is considering the best means, given available resources, for eliciting licensee views of NRC regulation on a regular basis.

The contractor's report of the project is available as NUREG/CR-6330. The staff's report to the Commission is available as SECY-93-130.

(Contact: Paul F. Goldberg, NMSS, 301-415-7842)

AVAILABILITY OF VIDEOTAPES

Nuclear Regulatory Commission and Agreement State licensees may obtain free videotapes that have been sponsored by NRC. The purpose of the videotapes is to illustrate the importance of good practices and the safe use of radioactive material. All requests must be made in writing and addressed to:

Chief, Distribution and Mail Services Section
Mailstop O-P1-37
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

or Faxed to 301-415-2260.

The videotapes are as follows:

1. "Good Practices in Preparing and Administering Radiopharmaceuticals"

2. "Good Practices in Co-60 Teletherapy"

3. "Taking Control: Safety Procedures for Industrial Radiography"

Contact:
Harriett Karagiannis, AEOD, 301-415-6377

FEDERAL REGISTER NOTICES

February 1, 1995 - May 1, 1995

FINAL REGULATORY GUIDES (NOTICE OF AVAILABILITY)

Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," 60 FR 12789, March 8, 1995.

DRAFT POLICY STATEMENTS

"Freedom of Employees in the Nuclear Industry to Raise Safety Concerns without Fear of Retaliation," 60 FR 7592, February 8, 1995.

Contact:
James Lieberman, OE, 301-415-2741

PETITIONS FOR RULEMAKING (All Parts are from 10 CFR.)

Part 20, "Steve Gannis, Denial of Petition" (for 0.01 millisievert (1 millirem)/year public dose limit), 60 FR 13385, March 13, 1995.

Contact:
Charleen T. Raddatz, RES, 301-415-6215

Parts 170 and 171, "American Mining Congress; Denial of Petition" (for reduction of fees), 60 FR 20918, April 28, 1995.

Contact:
Glenda C. Jackson, OC, 301-415-6057

PROPOSED RULES (All Parts are from 10 CFR.)

Parts 170 and 171, "Revision of Fee Schedules; 100% Fee Recovery, FY 1995," 60 FR 14670, March 20, 1995.
Correction, 60 FR 16589, March 31, 1995.
Correction, 60 FR 18882, April 13, 1995.

Contact:
James Holloway, OC, 301-415-6213

Part 2, "Petition for Rulemaking; Procedure for Submission," 60 FR 15878, March 28, 1995.

Contacts:
T. Y. Chang, RES, 301–415–6450, or
Chris Rourk, RES, 301 415–5865

Parts 50 and 70, "Physical Security Plan Format Changes," 60 FR 19170, April 17, 1995.

Contact:
Carrie Brown, NMSS, 301–415–8092

FINAL RULES (All Parts are from 10 CFR.)

Part 20, "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 60 FR 7900, February 10, 1995.

Contact:
Alan K. Roecklein, RES, 301–415–6223

Parts 50, 55, and 73, "Reduction in Reporting Requirements Imposed on NRC Licensees," 60 FR 13615, March 14, 1995.

Contact:
Naiem S. Tanious, RES, 301–415–6103

Parts 20 and 61, "Low-Level Waste Shipment Manifest Information and Reporting," 60 FR 15649, March 27, 1995.

Contacts:
William R. Lahs, NMSS, 301–415–6756, or
Mark Haisfield, RES, 301–415–6196

Part 2, "NRC Size Standards; Revision" (used to qualify a licensee as a "small entity"), 60 FR 18344, April 11, 1995.

Contact:
Michael T. Lesar, ADM, 301–415–7163

Part 20, "Standards for Protection against Radiation; Clarification," 60 FR 20183, April 25, 1995.

Contacts:
Mary L. Thomas, RES, 301–415–6230, or
Jayne M. McCausland, RES, 301–415–6219

Parts 2 and 72, "Interim Storage of Spent Fuel in an Independent Spent Fuel Storage Installation at a Reactor Site; Site-Specific License to a Qualified Applicant," 60 FR 20879, April 28, 1995.

Contact:
C. William Reamer, OGC, 301–415–1640

GENERIC COMMUNICATIONS ISSUED

February 1, 1995 – May 1, 1995

Note that these are only summaries of U.S. Nuclear Regulatory Commission generic communications. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below.

Administrative Letters (ALs)

None.

Information Notices (INs)

IN 94–64, Supplement 1, "Reactivity Insertion Transient and Accident Limits for High Burnup Fuel," April 6, 1995.

This supplement to IN 94–64 provides addressees with additional information on high-burnup fuel-performance data acquired since the original notice, and discusses NRC and industry actions.

Contacts:
L.E. Phillips, NRR, 301–415–3232
S. Wu, NRR, 301–415–3284

Bulletins (BLs)

None.

Generic Letters (GLs)

None.

A SAMPLING OF SIGNIFICANT EVENTS REPORTED TO NRC BY NRC MATERIAL LICENSEES (FIRST QUARTER CY 1995)

Event: Medical Brachytherapy Misadministration

Date Reported: November 22, 1994

Licensee: Welborn Memorial Baptist Hospital, Inc.
Evansville, Indiana

On November 18, 1994, a 73-year-old female patient was prescribed to receive a brachytherapy treatment dose of 600 centigray (cGy) (600 rad) at the vaginal cavity using a GammaMed IIi high-dose-rate (HDR) afterloading unit. However, because of a treatment programming error the patient received a 1250-cGy (1250-rad) dose instead of the prescribed dose. The GammaMed IIi unit contained a nominal 370-gigabecquerel [10-curie] iridium-192 sealed source.

The licensee identified the misadministration during a quality management review on November 21, 1994. The licensee reported the event to the U.S. Nuclear Regulatory Commission on November 22, 1994, and followed up with a written report on December 6, 1994. The referring physician was notified. The patient was notified on November 23, 1994, by the licensee's Radiation Safety Officer and was provided with a written report of the incident.

An NRC medical consultant was retained to evaluate the medical consequences of the misadministration. The medical consultant expressed concern that long-term effects such as fibrosis or loss of blood supply may occur as a result of the 1250-cGy (1250-rad) treatment. The medical consultant also suggested that this case be considered for the U.S. Department of Energy (DOE), Office of Epidemiology and Health Surveillance long-term medical study program. Information regarding the DOE program and a copy of the NRC medical consultant's report were provided to the referring physician.

The licensee concluded that the causes of this misadministration were as follows: (a) the technologist failed to activate a button that automatically corrects for the treatment time based on source decay, manually reentered the treatment time instead, and failed to notice the error message generated; and (b) the treatment software, installed to prevent treatment data entry errors, failed to prevent initiation of the treatment, despite entry of erroneous data.

To prevent recurrence of the incident, the licensee revised its internal procedure for all HDRs" to require both individuals operating the unit to verify the displayed time factor and compare it to the factor supplied by the manufacturer. Before this misadministration, the device operators were required to verify only operator-entered data. Also, the unit was evaluated and the printed circuit board (card) with the read-only-memory integrated circuits containing the defective software program was replaced with a card having the correct software program.

No violations of NRC requirements were identified. As a result of the defective software program, NRC sent a letter to all GammaMed IIi users to inform them of this potential problem and tell them how to test their software for the defect.

Contact:
(Walter C. Leschek, AEOD, 301-415-6365)

A SAMPLING OF SIGNIFICANT ENFORCEMENT ACTIONS AGAINST MATERIALS LICENSEES

1. Forrest L. Roudebush, IA 95-03

   An Order Prohibiting Involvement in U.S. Nuclear Regulatory Commission-Licensed Activities and Requiring Certain Notification to NRC was issued based on deliberate violations of NRC requirements, including providing inaccurate information to NRC inspectors and investigators, and untruthful testimony before the Atomic Safety and Licensing Board. The Order prohibits the individual from becoming involved in licensed activities for a period of 5 years from the date that the NRC staff issued an immediately effective Order suspending the license of the company (October 17, 1991). After the 5-year prohibition, the individual shall provide notice to NRC of acceptance of any employment in an NRC-licensed activity for an additional 5-year period.

2. Babcock and Wilcox Company, Lynchburg, Virginia
   Supplement VI, EA 94-169

   A Notice of Violation and Proposed Imposition of Civil Penalty was issued based on two violations involving: (1) two examples of the failure to conduct activities involving licensed material in accordance with established nuclear criticality safety limits and controls; and (2) two examples of the failure to adequately consider pertinent process conditions and known modes of failure in establishing these safety limits.

3. Material Testing Laboratories, Inc., Norfolk, Virginia
   Supplement VI, EAs 94-244 and 95-003

   An Order Modifying License (Effective Immediately) and Notice of Violation and Proposed Imposition of Civil Penalty was issued based on violations involving: (1) use of NRC-licensed material by an unauthorized and unqualified individual; (2) failure to perform an adequate survey; (3) failure to maintain direct surveillance of radiographic operations; (4) failure to post the high-radiation area; and (5) failure to post a radiography vehicle as a radioactive material storage area. The Order requires the licensee to: (1) retain and maintain the services of a Radiation Safety Officer; (2) retain the services of an independent consultant; (3) have the consultant submit an assessment report and quarterly audit;

(4) submit a response to each audit report; (5) ensure that within 30 days of returning the radiographer, who was involved in the November 15, 1994, violations, to unsupervised work, an audit be conducted by the consultant quarterly for a period of 1 year; and (6) notify the regional office for a period of 1 year—each week—of the location in non-Agreement States where the radiographer will be conducting radiography operations.

4. Veterans Affairs Medical Center, Memphis, Tennessee, Supplement VI, EA 94-245

   A Notice of Violation was issued based on a violation involving a source found taped under the center desk drawer of a physician's desk in the nuclear medicine department. The root cause of the violation was an apparent deliberate failure to adhere to procedures for the control of the source by a licensee employee. A civil penalty was not proposed because the licensee identified the violation, took prompt and extensive corrective actions, and had good past performance.

FORMATION OF INTERAGENCY STEERING COMMITTEE ON RADIATION STANDARDS

The U.S. Nuclear Regulatory Commission and the Environmental Protection Agency (EPA) have formed the Interagency Streering Committee on Radiation Standards (ISCORS) to expedite the resolution and coordination of regulatory issues associated with radiation standards. This committee was formed in response to October 27, 1994, letters from Senator John Glenn to NRC, EPA, and the Office of Science and Technology Policy (OSTP). ISCORS is an expanded version of the Interagency Steering Committee on Radiation Cleanup Standards. It is also one of the committees recommended by OSTP to achieve the goals of the former Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). The objectives of the committee include the following: (1) facilitate a consensus on acceptable levels of radiation risk to the public and workers, (2) promote consistent risk assessment and risk-management approaches in setting and implementing standards for occupational and public protection from ionizing radiation, (3) promote completeness and coherence of Federal Standards for radiation protection, and (4) identify interagency issues and coordinate their resolution.

In addition to NRC and EPA, ISCORS membership also includes senior managers from the Department of Defense (DOD), the Department of Energy (DOE), the Department of Labor's Occupational Safety and Health Administration (OSHA), and the Department of Transportation (DOT). Representatives of the Office of Management and Budget (OMB) and OSTP are observers at meetings. The NRC members are Dr. Carl Paperiello, Nuclear Material Safety and Safeguards (NMSS) Office Director and Dr. Malcolm Knapp, NMSS Deputy Office Director.

Committee meetings involve pre-decisional intragovernmental discussions and, as such, are not open for observation by members of the public or media. However summary meeting notes and agendas will be made available to the public and media after they have been cleared by all agencies. The committee will not act as a decision-making body. Instead, recommendations on specific issues will be provided to the heads of member agencies, OMB, and OTSP. The committee will meet approximately once each calendar quarter, with additional meetings held if needed for addressing specific issues. Subcomittees will meet at a frequency and location determined necessary by the subcommittees.

The first ISCORS meeting was held on April 5, 1995. Representatives from Senator Glen's office, NRC, EPA, DOD, DOE, and OMB attended. The committee discussed a draft charter, and future actions, including the issues that could be addressed by the committee. The committee agreed to increase the membership to include OSHA and DOT.

Among the committee's first actions is finalization of the NRC/EPA "Risk Harmonization White Paper," which outlines the similarities and differences in the agencies' approaches to radiation risk assessment and risk management. NRC and EPA are currently reviewing a draft of this paper with the other Federal agencies who are members of ISCORS. Based on the findings in this white paper, ISCORS plans to develop a specific set of actions that will be submitted to the EPA Administrator and the Commission for their approval by September 30, 1995. Other possible key policy areas for ISCORS review are standards for low-level radioactive waste disposal, radioactive mixed waste, naturally-occurring and accelerator produced radioactive materials (NARM), and recycling criteria.

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