NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR–0117
No. 90–3
September 1990

NRC ANNOUNCES BELOW REGULATORY CONCERN POLICY

The U.S. Nuclear Regulatory Commission (NRC) recently issued a new policy to guide its future decisions on small quantities of radioactive materials. The policy establishes the basis for future agency regulations and licensing decisions that would exempt very low-level radioactive material from regulatory controls, where NRC determines that such controls are not necessary to protect the public health and safety. NRC mailed the Below Regulatory Concern (BRC) policy statement to licensees and other *NMSS Licensee Newsletter* recipients on June 27, and published the statement in the *Federal Register* on July 3, 1990 (55 FR 27522-37).

In announcing the policy, NRC's Chairman, Kenneth M. Carr, noted that one of his highest priorities is to establish safe levels of cleanup for contaminated nuclear sites across the country. Chairman Carr said the BRC policy, "...provides the framework for determining these safe levels. The country needs a safe Below Regulatory Concern policy today."

The policy covers a wide scope of NRC licensees, potentially affecting medical, industrial, academic, commercial, and fuel cycle licensees, as well as reactor facilities. However, the policy statement is not a regulation. It does not in itself change current regulations or licenses. The statement provides the Commission's policy on how NRC will decide on future requests for rulemaking or licensing actions that involve very low levels of radioactivity, and the policy defines those BRC levels.

NRC will use the policy in responding to requests for rulemakings or licensing actions to exempt from some or all regulatory controls certain practices involving very low-level radioactive material. The policy covers such activities or products as: (1) cleanup of decommissioned and decontaminated facilities; (2) consumer products containing small amounts of radioactive material; (3) very low-level radioactive waste; and (4) recycled equipment and materials with slight amounts of radiation. For many years, NRC has made exemption decisions on a case-by-case basis. One example is NRC's exemption for smoke detectors.

Now, for the first time, the Commission has a policy to provide consistency, when considering exemption requests.

BRC DOSE CRITERIA

The policy statement provides radiation dose criteria that the Commission will use when making exemption decisions. The levels are set low so that the public and the environment will be protected when NRC approves exemptions under the BRC policy. Two types of criteria are given in the Commission's statement: individual radiation dose levels and collective dose levels.

For individuals, the Commission has decided that the radiation exposure from a single activity or product may be considered for exemption if it will result in an average dose of less than 10 millirem per year. People are exposed to similar levels when they choose to live in a brick rather than a wood frame house (a difference that can exceed 10 millirem per year).

As an added assurance of safety, the Commission has decided to apply an interim individual dose criterion of 1 millirem per year for materials or products involving widespread distribution of radioactive materials in items such as consumer products or recycled material and equipment. This 1 millirem per year interim criterion will protect individuals from receiving a radiation dose from several different activities or products.

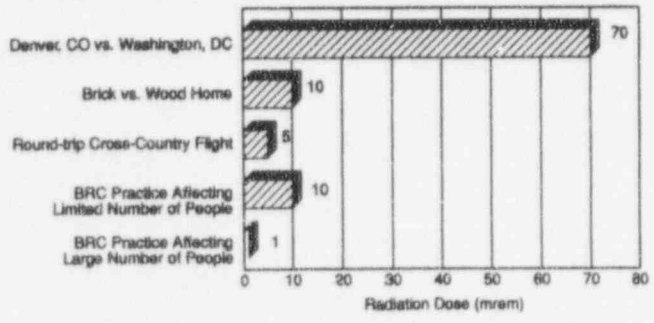
The Commission also has established a criterion that will apply to collective dose—the sum of all the individual doses for the population exposed as a result of an exempted practice. The BRC collective dose level is set in the statement at

1000 person-rem per year, from an exempted practice. The Commission policy statement indicates that, if the collective dose resulting from an exempted practice is less than 1000 person-rem per year, the resources of the Commission and its licensees would be better spent to address more significant health and safety issues.

COMPARABLE RADIATION RISKS

All activities involve some risk. The Commission recognizes the risk involved in using radiation or radioactive materials. The levels of risk associated with exemptions under the BRC policy are small, especially in comparison to risk from our everyday activities. The chart below provides a comparison of the BRC levels to radiation doses from other activities, such as living in Denver, CO, vs. Washington, DC, or flying on a round-trip cross-country flight. These types of common societal choices—deciding where to live or how to travel—can result in low radiation doses from cosmic rays and natural radio nuclides in soils and building materials. The BRC dose criteria are set in the same range as the doses from these other societal activities, and they are only 3 percent, when compared to the 300-millirem dose people receive each year from naturally occurring radiation sources.

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES



CONTINUED NRC OVERSIGHT

Any licensee who produces materials containing very low levels of radioactivity that are exempted from NRC controls would continue to be subject to the full range of NRC regulatory oversight, inspection, and enforcement actions, to ensure compliance with any constraints, requirements, and conditions established by the Commission. For example, the Commission may require labeling, so consumers can make informed decisions about purchasing a product containing exempted material. NRC will also continue to vigorously regulate manufacturers and generators of BRC materials, to ensure that the public and environment are properly protected.

PUBLIC MEETINGS

In August and September 1990, NRC held five public meetings across the nation, to discuss the BRC policy, hear statements from the public, and answer questions about the policy. The meetings were held near NRC regional offices in Philadelphia, Atlanta, Chicago, Dallas, and San Francisco. NRC licensees, as well as Agreement State licensees, government officials, and the public, were encouraged to attend.

BENEFITS OF BRC

The BRC statement establishes the first consistent policy for granting exemption requests concerning small amounts of radioactive material and for setting cleanup levels at contaminated nuclear sites. Chairman Carr noted that, "...this will help ensure every operating facility will complete cleanup in a timely manner and will have adequate levels of funding to complete that cleanup." By limiting regulation of very low levels of radioactive materials, NRC can focus its resources on solving the agency's more important health and safety issues.

> "The country needs a safe Below Regulatory Concern policy today."
>
> - Chairman Carr

OCCUPATIONAL RADIATION DOSES, 1987

The Nuclear Regulatory Commission (NRC) will soon publish NUREG-0713, Vol. 9, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1987." The report summarizes the exposure information, submitted pursuant to 10 CFR Part 20, for employees of NRC licensees who: (1) conduct industrial radiography; (2) fabricate fuel for reactors; (3) manufacture and distribute byproduct material; (4) dispose of low-level waste; (5) operate commercial power reactors; and (6) operate independent spent-fuel storage installations. The average annual measurable whole-body doses calculated from the 455 annual statistical reports that are received from licensees in these groups in 1987 were: (1) 0.41 rem; (2) 0.13 rem; (3) 0.31 rem; (4) 0.14 rem; (5) 0.38 rem; and (6) 0.64 rem, respectively. In each case, these values are about the same or less than the values found for 1986.

The report contains numerous graphical displays of the dose data and tables that provide data for past years. There is also a section that provides information on these six groups of workers who have terminated employment, and a section that summarizes the 13 exposures that exceeded applicable limits during 1987. The report will be sent to those licensees that submit annual reports. It will be made available in public document rooms, or may be purchased from the Government Printing Office:

P.O. Box 37082
Washington, D.C. 20013-7082
(202) 275-2060

SELECTED SIGNIFICANT EVENTS REPORTED TO THE U.S. NUCLEAR REGULATORY COMMISSION

Event 1:	Source Dislodgement—Unintended Dose	A cesium-137 brachytherapy source became dislodged from its applicator while a patient was undergoing treatment. A remote after loading device was being used for irradiation of a pa-
Date Reported:	January 17, 1990	

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Licensee: Monogahela Valley Hospital Monogahela, PA

tient, when the tube used to transfer the sources from the shielded storage unit to the patient became disconnected, resulting in one of the cesium-137 sources being unintentionally located near the upper part of the patient's leg. The unintended dose to a localized area of the patient's leg was estimated to be between 23,000-23,700 rem. The failure appeared to be the use of faulty material in the retaining ring of the connector that attached to the applicator, or inadequate equipment design.

Event 2: Brachytherapy Misadministration

Date Reported: February 7, 1990

Licensee: University of Wisconsin Madison, WI

Two therapy misadministrations, on February 7 and March 15, 1990, resulted from erroneous information being entered into the computer controlling the treatment location.

The treatments used a remote after-loading brachytherapy device. Incorrect data were entered into the treatment planning computer, and the results from the planning computer were entered into the computer controlling the remote afterloading brachytherapy device.

LICENSEE VIOLATIONS INVOLVING ENFORCEMENT ACTION

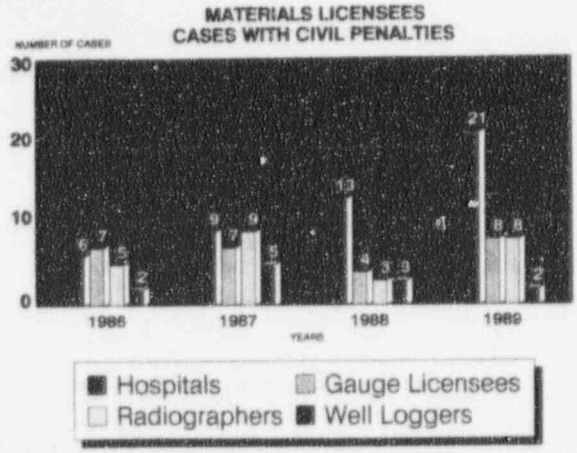
The U.S. Nuclear Regulatory Commission's (NRC's) enforcement program is designed to promote the public health and safety by:

- ensuring compliance with Commission requirements;
- obtaining prompt correction of violations and adverse conditions that may affect safety;
- encouraging the prompt identification and reporting of potential safety problems;
- deterring future violations; and
- encouraging improvement in performance of licensees.

The enforcement program is based on the NRC Enforcement Policy, which is published as Appendix C to 10 CFR Part 2 of the Commission's regulations. The policy provides that licensees who commit significant violations may be assessed civil penalties, or be subject to orders.

MEDICAL LICENSEES

The number of civil penalties assessed from 1986 to 1989 is shown for four classes of licensees in the accompanying chart. The clearest trend is an increase in civil penalties for hospitals.



There may be several reasons for this increase. The Commission has focused attention on the medical area as a result of concerns about misadministrations and violations that frequently indicated a breakdown of oversight by hospital management. Consequently, more NRC staff resources are being devoted to inspection and enforcement for medical licensees, and the frequency of hospital inspections has increased. The new Commission regulation, 10 CFR Part 35, which more clearly lays out responsibilities of medical licensees, became effective April 1, 1987. The new 10 CFR Part 35 consolidates and clarifies requirements and includes some new requirements. Licenses have not completely implemented these new requirements.

NRC regulates medical use of byproduct material in approximately 2200 hospitals and 400 private-practice clinics. Agreement States account for an additional 5000 medical use licensees. Approximately seven million diagnostic procedures and 150,000 therapy procedures are performed nationwide each year.

The following types of hospital violations have been most frequent, according to NRC's most recent experience:

1. Lack of quality control of dose calibrators (accuracy, linearity, constancy).
2. Failure to conduct required annual radiation safety training.
3. Failure to perform ambient radiation and contamination surveys.
4. Incomplete waste disposal records.
5. Failure of the Radiation Safety Committee to meet at quarterly intervals.

In addition, NRC has found a number of instances of falsification of records to indicate that meetings were held or other activities conducted, which did not actually occur as recorded. These have resulted and can result in severe sanctions, including referral to the Department of Justice for possible criminal prosecution.

In addition to ensuring that these specific violations are avoided, licensee senior management should take the following measures to avoid such violations:

1. Ensure that users of radioactive material and the radiation staff are familiar with the requirements of 10 CFR Part 35 and with the hospital's NRC license.
2. Ensure that adequate resources are provided for the radiation safety program; that training is conducted; and that periodic testing, such as daily dose calibrator testing, is done and the results recorded.
3. Ensure that regular audits and reviews, especially the annual radiation safety audit required by 10 CFR Part 35, are performed, reviewed, and that problems are addressed.
4. Ensure that radiation safety meetings are held and that minutes accurately reflect discussions.
5. Ensure that qualified individuals are available to perform radiation safety tasks. If such individuals with special skills are not available on the licensee's staff, the licensee might consider hiring a qualified radiation safety consultant.

RADIOGRAPHY LICENSEES

Although the number of civil penalties for radiography licensees has not increased as has the number for hospitals, NRC has found a number of recurring problems while inspecting radiographers. NRC is now devoting more time to

inspecting field inspection activities of radiographers, because most exposure incidents occur during field radiography, as opposed to fixed facilities. Among the most serious problems is the failure of radiographers to always perform surveys, as required by 10 CFR 34.43. Given the high radiation levels that can result if a radiography source is not retracted completely, it is essential that surveys required by procedures always be performed. Licensees are responsible, under 10 CFR 34.11, for inspecting radiographers' compliance with NRC requirements, including observing performance, at intervals not to exceed 3 months. NRC will issue sanctions, which may include civil penalties and orders, to licensees, for significant errors of their radiographers.

Also, in a number of recent cases, radiographers did not report potential exposures when off-scale dosimeters resulted from inadequate surveys. 10 CFR 20.403 requires reporting, within 24 hours, of potential exposure of greater than 5 rem. Absent conclusive evidence that an exposure did not occur, reporting is expected.

VETERANS ADMINISTRATION/NRC MEDICAL USE WORKSHOPS

On September 24-29, 1990, the U.S. Nuclear Regulatory Commission (NRC) Regions II and IV, Headquarters, and the Veterans Administration (VA) conducted two Radiation Safety Workshops for VA Medical Centers Radiation Safety Officers (RSOs) from around the country. Each workshop lasted 2 1/2 days. The purpose of the workshops was to give the RSOs a working knowledge of the requirements for a quality radiation safety program and ways to implement the program at their facilities. The RSOs were from VA Medical Centers holding specific NRC licenses for medical use of byproduct material. The NRC staff discussed the licensing process, inspection procedures, enforcement policy, and upcoming rulemaking affecting medical users. The VA had about 60 RSOs attend these workshops.

PATHFINDER DECOMMISSIONING

On June 28, 1990, a license amendment was issued to Northern States Power Company (NSP) authorizing decommissioning activities at the Pathfinder Generating Plant, near Sioux Falls, SD. NSP will continue to operate the Pathfinder facility as a fossil-fueled peaking unit, as it has since 1969, while the radiologically controlled areas of the Fuel Handling Building (FHB) and the Reactor Building (RB) are restored to conditions allowing unrestricted use.

The lower levels of the FHB and the entire RB have been maintained in protected isolation since Pathfinder was converted to fossil fuel. After cleanup, the FHB will be used for other purposes. The RB will be demolished, and all the above-grade portions of the RB will be removed and disposed of. After removal of all contaminated equipment, hardware, and concrete, and confirmation that unrestricted-use criteria have been met, the remaining underground portions of the RB concrete cylinder will be buried in place. Void spaces will be backfilled with clean material, and a graded infiltration-resistant soil cover will be installed above the buried concrete.

The unrestricted-use criteria that must be met are: (1) the guidelines in Regulatory Guide 1.86 for surface contamination; and (2) a maximum of 5 micro-R per hour above background at a distance of 1 meter, for gamma radiation.

After completion of decontamination activities, NRC will conduct confirmatory surveys to ensure that the cleanup activities are effective.

In connection with this licensing action, the Nuclear Regulatory Commission staff issued both an Environmental Assessment and a Safety Evaluation Report. These documents may be of interest to licensees who are engaged in or considering decommissioning activities at their facilities. For further information, please contact: John Austin, Branch Chief, Division of Low-Level Waste Management and Decommissioning, at (301) 492-3435.

SITED STATES NOTIFY MICHIGAN OF PROPOSED DENIAL OF ACCESS TO EXISTING LOW-LEVEL RADIOACTIVE WASTE (LLW) FACILITIES

The States of South Carolina, Washington, and Nevada have informed the State of Michigan that, beginning in November 1990, LLW generators in Michigan could be denied access to the three existing LLW disposal facilities.

On July 12, 1990, Governor James J. Blanchard of Michigan was informed by Dr. John B. Patel, Chairman of the Board of Health and Environmental Control for the State of South Carolina, that, commencing 60 days after the post-Labor Day reconvening of the Michigan Legislature, access to the Barnwell, South Carolina, disposal facility could be denied to all LLW generators in the State of Michigan. This letter followed similar letters sent to the Governor by Christine Gregoire, Director of the Washington Department of Ecology, and Jerry Griepentrog, Director of the Nevada Department of Human Resources, on June 28, 1990. These letters were in response to Michigan's elimination of the three candidate areas from consideration for siting as a regional LLW disposal facility.

The letters outline nine actions, in addition to the elimination of the candidate sites, taken by Michigan, that "... make a prima facie case that Michigan will not honor its commitment to host a facility for the Midwest Compact."

The Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPAA) requires States and compacts to develop siting plans, including a schedule, by January 1, 1988, for the establishment of a facility for LLW disposal. The LLRWPAA also requires that by January 1, 1990, non-sited compacts or non-member States file a complete application to operate a LLW facility, or the Governor shall provide written certification to the Nuclear Regulatory Commission (NRC) (or the appropriate agency in an Agreement State) that the State shall provide for the storage, disposal, or management of the waste. If a written certification is provided by the Governor of a non-member State, the LLRWPAA requires, by January 1, 1992, that the State submit a complete application for a license to operate a LLW disposal facility.

Officials from Washington, Nevada, and South Carolina indicated that the denial of access to Michigan LLW generators could be alleviated if:

1) A revised siting criteria bill is signed into law that addresses items outlined in letters by Washington, Nevada, and South Carolina.

2) Candidate sites are designated for characterization, and Michigan provides evidence of good faith action that speak to items outlined in letters by Washington, Nevada, and South Carolina.

James Cleary, Commissioner of the Michigan Low-Level Radioactive Waste Authority attributed the sited States' threatened action against Michigan to the State's "...leadership and candor in regard to the unnecessary proliferation of waste sites, as currently required under Federal law." Cleary added "We are proceeding with a sound and comprehensive plan and, we believe, there is no defensible reason for any of the currently sited facilities to deny access to Michigan." (Excerpt from LLW Forum Notes, July, 1990)

Denial of access to disposal sites could disrupt licensed operations that generate waste by preventing licensees from shipping waste from their facilities. This, in turn, could cause regulatory and safety problems, such as the exceeding of authorized possession limits, due to the accumulation of waste, inadequate waste management capability, or inadequate waste storage facilities. The NRC staff has issued guidance to waste generators on how to manage waste if access to disposal sites is denied. In particular, Information Notice 89-13 outlines actions that licensees should consider if access to disposal sites is denied, such as amending licenses to increase possession limits and using volume reduction techniques and alternative management and disposal techniques.

NRC guidance on the storage of radioactive waste is outlined in the following:

1) Information Notice No. 90-09: "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees"

2) Information Notice No. 89-13: "Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites"

3) Generic Letter 85-14: "Commercial Storage at Power Reactors of Low-Level Radioactive Waste Not Generated by the Utility"

4) Generic Letter 81-38: "Storage of Low-Level Radioactive Wastes at Power Reactors."

Copies of these documents may be obtained by contacting Roland Lickus, at the NRC Region III Office, at (708) 790-5666.

NRC is prepared to address questions that LLW generators may have on the licensing consequences of site-access denial. Questions should be addressed to:

Roland Lickus, Director, State and Government Affairs, Region III, at (708) 790-5666

or

Paul Lohaus, Branch Chief, Division of Low-Level Waste Management and Decommissioning, at (301) 492-0553

or

John Hickey, Branch Chief, Division of Industrial and Medical Nuclear Safety, at (301) 492-3425.

PART 72 AMENDMENT REGARDING SPENT FUEL STORAGE

The U.S. Nuclear Regulatory Commission (NRC) amended its regulations to authorize nuclear power plant licensees to store spent fuel, on reactor sites, in storage casks approved by NRC under a general license, without requiring a specific license for that site. The rule also described criteria and procedures for obtaining NRC approval of a cask.

The reactor licensee must ensure, through written evaluations, that there are no unreviewed safety questions or changes needed to use the casks at its reactor site. The licensee also has to comply with the conditions of the cask's Certificate of Compliance and has to develop operating procedures for use of the casks. On-site spent fuel storage could continue after the reactor shuts down permanently, but the licensee would have to indicate how the spent fuel would be removed from storage and shipped offsite, before decommissioning.

To obtain NRC approval of a storage cask, an applicant has to submit a safety analysis report describing the proposed cask and how it should be used to store spent fuel safely. The applicant would have to make provisions for NRC to inspect the facilities where the casks are fabricated and tested. In addition, the applicant must perform, and allow NRC to perform, tests that NRC decides are necessary.

Design, fabrication, testing, maintenance, and use of a storage cask have to comply with technical criteria in the Commission's regulations and must be conducted under a quality assurance program that meets NRC's requirements. A Certificate of Compliance is valid for 20 years; after that, the cask would have to be reapproved by NRC.

The rule also notes that, to the extent practicable, in designing a cask, consideration should be given to the compatibility of the cask with transportation and other activities related to the removal of the spent fuel from the reactor site, for ultimate disposition by the Department of Energy.

The four storage cask models that have been approved by NRC are: the CASTOR V/21, by General Nuclear Systems, Inc., Columbia, SC; the MC-10, by Westinghouse Electric Corporation, Pittsburgh, PA; and the NAC S/T and the NAC-C28 S/T, by Nuclear Assurance Corporation, Norcross, GA.

Other details of the amendment, which is principally to Part 72 of the regulations, are contained in a *Federal Register* notice published on May 5, 1989.

INFORMATION NOTICES PUBLISHED

April 1, 1990—July 31, 1990

A. Transportation of Model SPEC 2-T Radiographic Exposure Device—IN 90-24, dated April 10, 1990.

This information notice informs licensees of a recent change in the U.S. Nuclear Regulatory Commission (NRC) Certificate of Compliance (COC) No. 9056, which imposes more restrictive requirements for proper transportation of the model SPEC 2-T device. As a result of reevaluation of possible dose rates for the device when loaded with the 100 curies of iridium-192 formerly permitted under the COC, Conditions 8 and 9 of the COC were amended to limit the activity in the device to 45 curies and to reduce the maximum activity of iridium-192 per package from 240 curies to 225 curies.

B. Clarification of the Recent Revisions to the Regulatory Requirements for Packaging of Uranium Hexafluoride (UF6) for Transportation—IN 90-27, dated April 30, 1990.

This notice reviews and clarifies two rulemaking actions by the U.S. Department of Transportation. The new 49 CFR 173.420 in Docket HM-166V formalizes, as regulatory requirements, the use of cylinders, for UF6 transportation, that have already been in use for many years, and adds several other requirements. The rulemaking in Docket HM-190 upgrades the regulatory requirements for the fabrication, maintenance, and use of the DOT Specification 21PF-1 protective overpacks.

C. Update on Waste Form and High Integrity Container Topical Report Review Status, Identification of Problems with Cement Solidification, and Reporting of Waste Mishaps—IN 90-31, dated May 4, 1990.

This notice informs licensees of recent developments concerning the stability of waste forms that contain Classes B or C low-level waste. Attachment 1 lists the status of NRC reviews of topical reports on waste forms and high integrity containers. Licensees are encouraged to obtain a copy of NUREG/ CP-0103, which reports the results of the Workshop on Cement Stabilization of Low-Level Radioactive Waste, which NRC hosted on May 31 - June 2, 1989, to determine if any of the topics discussed will potentially improve their application of waste solidification processes. Licensees should be aware of the possibility of deleterious chemical reaction during waste solidification using cement. Attachment 2 lists waste constituents that could cause problems with campaigns. NRC is increasingly concerned about mishaps that have occurred during the solidification of low-level waste and is evaluating mechanisms for obtaining reports on such mishaps.

D. Transportation of Type A Quantities of Non-Fissile Radioactive Materials—IN 90-35, dated May 24, 1990.

This notice summarizes and clarifies the basic requirements of DOT Hazardous Materials Regulations that are most frequently cited regarding deficiencies or violations, during inspections of transportation activities of NRC licensees. The DOT regulations (49 CFR Parts 170 to 178) have been incorporated into NRC regulations (10 CFR Part 71).

E. Requirements for Processing Financial Assurance Submittals for Decommissioning—IN 90-38, dated May 29, 1990.

This notice reminds licensees of requirements for financial assurance submittals for decommissioning.

F. Dose-Rate Instruments Underresponding to the True Radiation Fields—IN 90-44, dated June 29, 1990.

This notice informs licensees of the potential for underresponse at the two lower ranges for all magnet arm switching dose-rate instruments. Malfunctions may occur for the Bicron Model RSO-5, the Bicron Model RSO-50, the Eberline Model RO-2, and the Eberline Model RO-2A.

RULEMAKINGS PUBLISHED

March 9, 1990—July 31, 1990

FINAL RULES

- "Credit Check—Expanded Personnel Security Investigative Coverage"

  1. Published 3/29/90; correction published 04/17/90

  2. Contact: Jim Dunleavy (301) 492-7343

- "Revision of Fee Schedules: Radioisotope Licenses and Topical Reports"

  1. Published 05/23/90; corrections published 06/12/90, 06/22/90

  2. Contact: C. James Holloway (301) 492-4301

- "Storage of Spent Nuclear Fuel in NRC-Approved Storage Casks at Nuclear Power Sites"

  1. Published 07/18/90

  2. Contact: John Telford (301) 492-3796

PROPOSED RULES

"Willful Misconduct by Unlicensed Persons"

1. Published 04/03/90; correction published 04/11/90

2. Contact: Geoffrey Cant (301) 492-3283

"Notification of Incidents"

1. Published 05/14/90

2 Contact: Joe Mate (301) 492-3795

REGULATORY GUIDES ISSUED

October 6, 1989—July 31, 1989

Guides in Final Form

- 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning under 10 CFR Parts 30, 40, 70, and 72"

  1. Published: 06/90
  2. For information, contact: Keith Steyer (301) 492-3824.

Guides in Draft Form

- 3.58, Revision 1, "Criticality Safety for Handling, Storing, and Transporting LWR Fuel at Fuels and Materials Facilities"

  1. Published: 05/90
  2. For information, contact: Keith Steyer (301) 492-3824.

- "Basic Quality Assurance Program for Medical Use"

  1. Published: 01/90
  2. For information, contact: Anthony Tse (301) 492-2797.

SURVEY EVALUATING GENERAL LICENSE EFFECTIVENESS

The U.S. Nuclear Regulatory Commission's (NRC's) rules governing the licensing of byproduct material provide for the use of a general license for the receipt, possession, use, and transfer of certain devices. NRC is carrying out a survey of general licensees, under 10 CFR Part 31.5, to evaluate the effectiveness of the general license. Three-thousand firms have been chosen to participate in the survey during the next 6 months. The survey, conducted under a contract with ICF Incorporated, is intended to confirm the placements, use, condition, and/or disposition of devices transferred to general licensees between 1980 and 1989. A report will be issued upon completion of the survey.

It is important that general licensees who receive a survey questionnaire fill it out fully and accurately and return it in the postage-paid envelope provided. General licensees who have questions about the survey questionnaire should contact ICF Incorporated at (800) 331-9212. The survey has been approved by the Office of Management and Budget.

MEDICAL USE OF IODINE-131 INCIDENT

The U.S. Nuclear Regulatory Commission (NRC) recently received notification of a medical incident at a large broad-scope licensed facility. The incident involved the administration of iodine-131 to a nursing mother and the resulting radiation exposure to her child.

The incident occurred when a patient, scheduled for a yearly total body scan, was administered 4.8 millicuries of iodine-131, and later found to be nursing a child. This facility's procedures require assessment for pregnancy and determination of whether a patient is nursing a child. In this case, the patient was sent for a pregnancy test, but was not questioned about nursing. The 2-week old infant received an estimated whole-body radiation exposure of 17 rads, and an estimated exposure to the thyroid of 30,000 rads. The mother received an estimated exposure of 8.9 rads to her breasts.

Another similar incident at a smaller facility involved a young woman, scheduled for a thyroid evaluation, who arrived carrying a young baby. The technologist assumed the baby was hers, and that she was not pregnant. Without asking if the patient was pregnant, the technologist administered 15 microcuries of iodine-131. Almost immediately after receiving the dose, the patient told the technologist that she was 4 to 5 weeks pregnant. The total body dose to the fetus was estimated to be 2.7 to 4.6 millirems. Since the fetal thyroid is incapable of concentrating iodine-131 until 10 to 12 weeks, there was estimated to be no additional radiation exposure to the thyroid. There was no requirement at this facility to ask if a patient were pregnant or nursing a child.

NRC is preparing an information notice concerning the aforementioned incidents and several others in an attempt to draw attention to the serious consequences of errors in the administration of iodine-131.

ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES (ACMUI)

The U.S. Nuclear Regulatory Commission (NRC) convened a meeting of the ACMUI on July 10, 1990, at the Holiday Inn, Crown Plaza Hotel. The meeting was open to the public.

The committee was provided with status updates on: The Visiting Fellows Program, Rulemaking for Basic Quality Assurance in Medical Use, and Rulemaking for the Practice of Medicine and Pharmacy.

The following items were discussed: Training and Experience Criteria for Medical Users of Byproduct Material, the desired frequency of meetings of the ACMUI, and how best to expand the membership of the committee.

The next meeting of the ACMUI will be in January 1991, with fall and spring meetings to follow thereafter.

MEDICAL VISITING FELLOWS PROGRAM

The U.S. Nuclear Regulatory Commission (NRC) is seeking to expand its understanding of the regulated community by creating a program for Medical Visiting Fellows. The objectives of this program are to improve NRC's knowledge of the medical community; to keep abreast of new technology and developments in the diagnostic and therapeutic uses of isotopes; to develop an awareness of the socio-economic factors governing health care; to develop and sustain a base of experienced individuals familiar with the regulatory environment; to improve NRC's regulatory process; and to develop medical use regulations that minimally intrude into medical practice.

Individuals participating in the Medical Visiting Fellows Program (MVFP) would join NRC full-time, for approximately 1 year, at Headquarters, in Rockville, MD. The purpose is to undertake activities consistent with the interests and needs of NRC, and with the individual's training and

experience, that will result in a clearly defined assignment useful to NRC's medical regulatory program.

It is anticipated that the Fellows would attend meetings of NRC's Advisory Committee on Medical Use of Isotopes (ACMUI) meetings of Federal, State, and local agencies; meetings of professional organizations; and meetings of other groups, to participate in discussions on issues related to medical affairs and radiation medicine. Former Fellows may be asked to participate, from time to time, in sponsored meetings and seminars, after their appointments end, to provide advice and consultation about the regulated program and the MVFP.

In the *Federal Register* Notice of June 7, 1990, NRC invited nominations of physicians having expert qualifications in the medical specialty fields of Nuclear Medicine or Radiation Oncology. Others having expert qualifications in related fields such as Diagnostic Radiological Physics, Therapeutic Radiological Physics, or Radiopharmacy were also invited to apply. Candidates were nominated by professional groups, medical societies, or were self-nominated. The nomination period closed on August 31, 1990.

An NRC evaluation panel will complete a review of each applicant primarily on the basis of the nomination packet submitted. Each individual's professional experience and interest in terms of the objectives of the Commission will be reviewed. The review and selection process will also include an interview with NRC personnel. One or more individuals will be selected, depending on the availability of qualified applicants and the needs of the Commission at the time of selection. The commencement and duration for each Fellow's appointment will be determined on a case-by-case basis.

NRC intends to periodically publish *Federal Register* Notices announcing a call for nominations of Fellows for the MVFP. If you would like additional information about this program, please contact Janet Schlueter, Medical and Academic Section at (301) 492-0633.

SIGNIFICANT ENFORCEMENT ACTIONS AGAINST MATERIALS LICENSEES

One way to avoid regulatory problems is to be aware of enforcement problems others have faced. Thus, we have included here a discussion of some representative enforcement actions against materials licensees. These enforcement actions include civil penalties, orders of various types, and notices of violations.

A. CIVIL PENALTIES AND ORDERS

1. Atlas Corporation, Grand Junction, Colorado, Supplement IV, EA 89-110

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $6,250 was issued October 5, 1989, to emphasize the licensee's responsibility to conduct its activities in compliance with radioactivity release limits and its responsibility to heed regulatory requirements. The action was based on a violation involving the release of radon-222 concentrations to an unrestricted area in excess of 220 percent of the maximum permissible concentrations permitted by 10 CFR 20.106, when averaged over 1 year. The civil penalty was increased by 25 percent because of prior notice. The licensee responded in letters dated November 3, 1989, and January 12, 1990. After consideration of the licensee's responses, the staff concluded that the licensee provided justification for the civil penalty to be reduced by $2,500. An Order Imposing Civil Penalty for $3,750 was issued March 27, 1990.

2. Basin Testing Laboratory, Inc., Williston, North Dakota, Supplement VI, EA 88-265

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 was issued January 19, 1989, to emphasize the need for increased and improved management attention to activities authorized by the license, so as to ensure that these activities are conducted safely and in accordance with the license. The action was based on violations involving: (1) permitting radiography activities to be independently conducted by an individual who was not qualified to conduct these activities except under direct supervision; (2) failing to notify NRC of licensed activities in Wyoming and Montana; (3) violations of the requirements associated with the transportation of radioactive materials; and (4) providing NRC inaccurate information in response to violations identified during an NRC inspection. The licensee responded on February 22, 1989, requesting mitigation. After considering the licensee's response, an Order Imposing Civil Penalty and an Order to Show Cause Why License Should not be Suspended were issued December 6, 1989. The licensee requested a hearing on December 29, 1989. A settlement was reached on April 9, 1990, with the licensee agreeing to pay the penalty by installment.

3. Bass Memorial Baptist Hospital, Enid, Oklahoma Supplements IV and VI, EA 90-057

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,125 was issued May 2, 1990, to emphasize the importance of compliance with radiation safety requirements and the need for the licensee to establish effective management and audit programs. The action was based on violations relating to the licensee's failures to: comply with NRC's requirements related to ensuring the proper operation of the licensee's dose calibrator; perform surveys and calibrate survey instruments; inventory, label, and maintain surveillance over licensed materials; and keep required and adequate records required by the radiation safety program. The civil penalty was escalated by 25 percent because NRC identified the violations.

4. Bridgestone/Firestone, Inc., Oklahoma City, Oklahoma, Supplements IV and VI, EA 90-004

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $1,000 was issued March 13, 1990, to emphasize the importance NRC places on the effective management of radiation safety programs and compliance with license requirements. The action was based on incidents involving: (1) loss of a measuring gauge containing 25 millicuries of cesium-137; and (2) entries into a vessel equipped with a radioactive gauge, when the shutter on the gauge was not closed or locked.

5. Cintichem, Inc., Tuxedo, New York, EA 90-033

   An Order Modifying License was issued February 13, 1990, based on the identification of an unmonitored release of radioactively contaminated water from the facility's reactor building to an onsite retention pond, as a result of a failure of the concrete wall of the gamma pit and a subsequent failure of the holdup tank. The licensee responded to the Order on March 5, 1990, and it was determined that the response was not adequate. After further communication with the licensee, the licensee notified NRC that it was decommissioning the plant.

6. Divine Providence Hospital, Williamsport, Pennsylvania, Supplements IV and VI, EA 90-038

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued April 11, 1990, to emphasize the need for the medical center management, the Radiation Safety Committee, and the Radiation Safety Officer to aggressively monitor and evaluate licensed activities, to ensure that these activities are conducted safely and in accordance with the terms of the license. The action was based on numerous violations that were considered to represent a breakdown in the control of the licensee's radiation safety program.

7. Milford Memorial Hospital, Milford, Delaware, EA 87-44

   An Order Modifying License, Effective Immediately, was issued June 15, 1987, to remove an individual from the position of Radiation Safety Officer (RSO). The Order also suspended his authority to independently use or supervise the use of licensed material, required independent monthly audits of the radiation safety program, and required the new RSO to review the program, take corrective action for identified deficiencies, and submit a letter to NRC certifying that the program is being operated safely and in accordance with the terms and conditions of the license. On May 31, 1989, a letter was issued indicating that the conditions of the order had all been met.

8. Russell County Medical Center, Lebanon, Virginia Supplements VI and VII, EA 90-006

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,750 was issued March 16, 1990, to emphasize the need for continued and effective management control over activities authorized by the license. The action was based on the deliberate administration of excessive patient doses of licensed radioactive material by the licensee's nuclear medicine technologist for a 4-year period, the deliberate falsification of records to reflect the prescribed doses rather than the actual assayed and subsequently administered doses, and the failure to report the misadministrations caused by this practice, when it became known to the licensee's Director of Radiology.

9. San Juan Cement Company, San Juan, Puerto Rico Supplements IV and VI, EA 90-016

   A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $750 was issued March 28, 1990, to emphasize the importance of radiation safety requirements and adequate preparation and coordination of those requirements with regard to NRC-licensed materials. The action was based on failures to: supervise activities involving licensed material; secure licensed material from unauthorized removal; maintain radiation levels in unrestricted areas below regulatory limits; conduct surveys to evaluate the extent of radiation hazards present; and post NRC regulations.

10. United States Testing Company, Modesto, California, Supplements IV and VI, EA 89-148

    A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $5,000 was issued September 26, 1989, to emphasize the unacceptability of violations that individually or collectively cause a substantial potential for exposure in excess of 10 CFR Part 20 limits and the need for adequate planning and execution of operations, to avoid such violations. The action was based on a number of violations, including the failure to properly establish and provide surveillance of radiation boundaries during radiograhic operations at a hospital. The licensee responded on November 22, 1989, contesting the violations and civil penalty. A settlement was signed May 21, 1990.

11. Veterans Administration Medical Center, Brooklyn, New York, Supplement VI, EA 89-190

    A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $8,750 was issued November 28, 1989, to emphasize the need for the licensee to aggressively monitor and evaluate licensed activities throughout the facility. The action was based on violations involving: (1) failure to follow emergency procedures to remove the patient from the room when a teletherapy treatment timer continued to operate beyond its present time and the source did not return to its shielded position; and (2) 14 violations which in the aggregate demonstrate a lack of management oversight. The licensee responded to the Notice in a letter dated January 3, 1990. After consideration of the licensee's response, the staff concluded the violations occurred as stated. An Order Imposing Civil Penalties was issued April 20, 1990.

B. SEVERITY LEVEL III VIOLATION, NO CIVIL PENALTY

1. Kettering Medical Center, Kettering, Ohio, Supplement VI, EA 90-075

A Notice of Violation was issued June 5, 1990, based on the following: (1) ambient dose rates in the storage area for branchy-therapy sources were not measured on a quarterly basis; (2) records to show the receipt or transfer of byproduct material were not generated before January 1, 1988; (3) the calibration and reference sealed sources in the possession of the licensee were not listed on inventories; (4) the sealed source leak test results were recorded in counts per minute, rather than in microcurie amounts; (5) a patient with a permanent implant of radioactive material was not surveyed before discharge from the hospital; (6) the radiation safety program was not reviewed on an annual basis by the radiation safety committee; (7) bioassays of employees handling liquid iodine-131 were not always conducted within the specified time period; (8) rooms of therapy patients were not always surveyed; and (9) employees did not receive required refresher training on an annual basis. A civil penalty was not proposed because the individual violations were identified by the licensee's employees before the inspection, and the licensee took extensive corrective actions to correct the breakdown in the management of the radiation safety program.

HUMAN FACTORS EVALUATIONS

Misadministrations of nuclear material used for medical purposes and occupational exposures of workers involved in industrial radiography are often blamed, at least in part, on human error. Reduction of human error in medical and industrial use of nuclear material requires detailed knowledge of the tasks people perform, of the requirements those tasks place on the people who perform them, and of the factors that can enhance or degrade performance of those tasks. To obtain this knowledge, the U.S. Nuclear Regulatory Commission (NRC) has selected contractors to perform "human factors evaluations" of brachytherapy using remote afterloaders (Pacific Science and Engineering Group, Inc.), teletherapy (CAE-Link Corporation), and industrial radiography (Battelle Human Affairs Research Centers).

Conduct of the human factors evaluations will require the contractors to contact and visit a number of NRC and State licensees over the next 18 months. Those contacts and visits will not be inspections. NRC encourages participation if you are contacted, but you are under no obligation to participate. Contractors will use a variety of means during contacts and visits to learn how and under what conditions tasks associated with brachytherapy, teletherapy, and industrial radiography are performed. Examples are direct observation of actual or simulated operations, comparison of equipment and procedures against accepted human factors guidelines, interviews, and questionnaires. Means used on a particular contact or visit will depend on the contractor's specific goal for that contact or visit. Contractors will offer participants the greatest degree of confidentiality possible. Information provided by participants will only be used to identify potential root causes for human error in brachytherapy, teletherapy, and industrial radiography.

If you have any questions about the human factors evaluations, the Nuclear Material Safety and Safeguards (NMSS) contact for all three projects is Dennis Serig. He may be reached at (301) 492-3362.

Comments and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:

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