NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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FORMER RADIOGRAPHER IMPRISONED

Gordon Finlay, owner of Finlay Testing Laboratories, was convicted and sentenced, recently, in the U.S. District Court in Honolulu, Hawaii, of criminal charges relating to violations of U.S. Nuclear Regulatory Commission requirements. He was convicted of conspiring to carry radioactive materials on flights between Hawaiian islands and also of making false statements to NRC investigators looking into the matter. The company was convicted of 19 counts arising from the same incidents.

It is illegal to carry radioactive materials on passenger flights. Finlay Testing Labs employees, acting at Mr. Finlay's direction, placed radiography cameras in unmarked luggage that was then checked on flights. Records were falsified to conceal the shipping method actually used, and false information was provided to NRC investigators. Mr. Finlay was sentenced to 21 months in prison for his actions and fined $50,000. The company was given five years probation and fined $380,000.

In addition, the company's manager and Radiation Safety Officer, Timothy Carroll, was convicted and sentenced to 5 years imprisonment and fined $5000. The prison sentence was suspended and he was placed on probation. An explicit condition of his probation is that he not perform any radiographic testing that requires him to travel by other than land transportation.

Previously, NRC had suspended the company's NRC license; subsequently, the license was terminated.

HOW TO MAKE UP RECORDS—LEGALLY

The U.S. Nuclear Regulatory Commission looks on record falsification with a severely jaundiced eye. Since such falsification must be willful, the perpetrator of such an action is subject to *criminal* sanctions under the Atomic Energy Act, as well as civil sanctions under the Wrongdoer Rule (10 CFR 30.10, 40.10, 70.10, and 10 CFR Part 2, Appendix C). If you are a responsible supervisor or manager in a licensee organization and falsify records required by NRC regulations or by license conditions, you could be prohibited from any involvement in NRC licensed activities for several years, or for an indefinite term *at any NRC licensed facility*. This could severely affect your livelihood. I cannot think of any record that might be missing that could cause you this much trouble. Not only that, but there is a legal way of generating a record and properly correcting the problem, when a required record is missing.

The NRC enforcement policy (10 CFR Part 2, Appendix C, Section VII, "Exercise of Discretion") provides for the exercise of enforcement discretion to mitigate sanctions for violations identified by licensees under certain circumstances. If the violation could not have reasonably been prevented by a licensee's action on a previous violation or previous licensee finding that occurred within the past 2 years, or past two inspections, and was or will be corrected within a reasonable time, and comprehensive corrective action is taken to prevent recurrence, NRC may mitigate sanctions. The intent of this policy is to encourage licensee self-identification and correction. Application of the policy can allow a licensee to properly correct a record problem and have NRC recognize the licensee's proactive efforts.

NRC regulations and license conditions generally require licensees to maintain records of radiation surveys, worker training, material receipt and disposition, and internal audits. This list is not meant to be comprehensive, but just to give some examples. Let us assume you find records missing or gaps in records of laboratory contamination surveys, not an uncommon inspection finding. What should you do? Investigate to find out why the survey records are missing. Surveys could have been done and not recorded, or surveys may not have been done. Write a report to your license file on what you found, describe the likelihood of a serious contamination event being undetected, and describe what you plan to do to ensure surveys in the future are properly done and recorded. When you are inspected, show the inspector your file report and describe the results of your corrective actions. If I were the Radiation Safety Officer and I found a log book with missing survey records, I would also probably annotate the log to ensure that no one on the staff would be tempted to fill in blank data.

Other similar violations should be handled in the same fashion. You may be able to find evidence that whatever had to be done was done, but was not recorded, or was just not done. In either case, document that you found and recognized the problem and you took corrective action to prevent recurrence. Even if there is recurrence, continue to document and take corrective action. Even if NRC does not exercise enforcement discretion because of repetition, your efforts could mitigate sanctions in those few cases that rise to monetary penalties.

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

Fundamentally, NRC wants you to run a safe radiation protection program. The NRC's inspection program's purpose is the detection of unsafe programs. Yes, the NRC inspector has to take some kind of official recognition of even minor violations, although not always with a Notice of Violation. However, falsification of a missing record can take a minor violation with low safety significance and make it a career-threatening action. Don't be foolish!

NRC RESPONDS TO FREQUENTLY ASKED QUESTIONS ABOUT LLW STORAGE, PART 2

In the December '93/January '94 edition of the *NMSS Licensee Newsletter*, the U.S. Nuclear Regulatory Commission responded to four frequently asked questions about low-level radioactive waste (LLW) storage. NRC examined the need for amendments to licenses to store LLW, the level of detail required to fulfill criteria in Information Notice 90–09, decay-in-storage of LLW, and issues concerning the consolidation of LLW among licensees. This second installment responds to additional questions about LLW storage, and is meant to assist generators in meeting needs for interim storage of LLW.

The authority to deny access to commercial LLW disposal sites was granted under the Low-Level Radioactive Waste Policy Amendments Act of 1985. As of this date, generators of LLW in the States of Michigan, Rhode Island, and New Hampshire, and the Commonwealth of Puerto Rico, are not eligible for access to either of the two LLW disposal facilities at Barnwell, South Carolina, and Hanford, Washington. On June 30, 1994, the Southeast Compact, which regulates LLW shipments into the Barnwell facility, expects to deny access to all States located outside the

Southeast Compact. Some 28 additional States, and the District of Columbia, will then have no access to any operating LLW disposal site.

Licensees are encouraged to monitor the status of current siting and disposal developments in their LLW compacts or States, and to anticipate potential needs for storage of LLW. NRC recognizes the need for interim storage of LLW while new LLW disposal capacity is developed. However, NRC does not look favorably upon long-term, on-site storage of LLW, and NRC's preference is that LLW be permanently disposed of as soon as possible after it is generated. Information Notices 90-09 and 89-13, and Generic Letters 85-14 and 81-38, previously developed by NRC, provide guidance on storage of LLW. The following additional information answers various technical and licensing questions about LLW storage. If you have other questions about this information, please check with a technical contact listed below.

Region I: Betsy Ullrich (215) 337-5040
Region II: John Potter (404) 331-5571
Region III: Loren Hueter (708) 829-9829
Region IV: Jack Whitten (817) 860-8197
*Region V: Jim Montgomery (510) 975-0249
NMSS Office Contact:
Richard Turtil (301) 415-6721

*Region V licensees likely will need to communicate with the Region IV contact after mid- to late-1994.

- 1. What licensing conditions must be in place to enable one licensee to send LLW to another licensee, for use of the latter licensee's waste compactor, or other waste-processing facilities?

  If licensees wish to share or make available waste-processing services to other licensees, this must be explicitly approved and authorized in the license. License conditions governing this activity will be determined on a case-by-case basis. Licensees interested in obtaining authorization involving these activities should contact the appropriate NRC regional or Headquarters office, to determine the information needed in a license amendment request of this type, since the type of information will vary, depending on the scope of proposed activities. Waste generators shipping waste to other licensees for processing must verify that these licensees are authorized by their license to receive and possess the wastes planned for shipment.

- 2. At the end of the interim storage period, when waste disposal capacity becomes available, what length of time will generators be granted to empty their facilities of stored LLW?

  NRC has not identified a specific length of time for shipment of LLW from interim storage to a LLW disposal facility. This will vary from licensee to licensee, but we expect that wastes would be shipped within a reasonable period of time (i.e., within a few months, up to 1 year). Several factors will affect the time required to ship LLW to final disposal, including:

  - The emptying of storage facilities and loading of transport vehicles with LLW for shipment to disposal facilities.
  - Logistics and operations involving coordination of multiple shipments from individual licensee storage facilities to a limited number of disposal sites.
  - Coordination of legal and financial contracts, agreements, and licenses among the various participants.
  - Review of waste form and waste packaging requirements and inspection of packaged waste against transportation and disposal criteria.

- 3. Why does Commission guidance identify 5 years as the interim storage period?

  The Commission believes that extended on-site storage would be contrary to the national policy, in the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA) of 1985, to accomplish the overall objective of permanent disposal of LLW. As stated in Information Notice 90-09, "In the interest of public health and safety, as well as maintaining exposures as low as is reasonably achievable, the length of time LLW is placed in storage should be kept to a minimum. Accordingly, NRC's approval of requests by materials licensees for interim extended storage will generally be for a period of time no greater than five years." The 5-year storage period is meant to help ensure that storage does not become *de-facto* disposal. Generic Letter 81-38 recommends that a power reactor licensee obtain a Part 30 license when planning additional storage capacity that would accommodate more waste than would be generated during a nominal 5-year period, and for storage periods in excess of 5 years. Additional requirements to ensure safe storage may be necessary if licensees require extended interim storage of LLW.

- 4. What NRC licensing and inspection actions help ensure the safe, interim storage of LLW?

  NRC recognizes that LLW storage will be necessary and needs to be accomplished safely. NRC's current program for ensuring the safe storage of LLW relies on the following three components: (a) guidance for licensees, containing criteria for safe storage of LLW; (b) licensing actions, by NRC, in response to information, submitted by licensees, that describes how waste will be safely stored, and (c) NRC's inspection program, which confirms that licensees are implementing their license conditions, as required. The following four documents, in conjunction with the regulations in Parts 20, 30, 40, 50, and 70, provide the regulatory and licensing framework for LLW storage:

  Generic Letter 81-38
  "Interim Storage of Utility Licensee-

Generated Low-Level Radioactive Waste Reactor Sites"

Generic Letter 85-14
"Commercial Storage at Power Reactor Sites of Low-Level Radioactive Waste Not Generated by the Utility"

Information Notice 89-13
"Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites"

Information Notice 90-09
"Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees"

NRC will continue to monitor and assess the need for additional regulations or guidance, concerning storage, to supplement the existing framework, as experience is gained in licensing LLW storage.

- 5. May centralized storage of LLW at reactors be considered a viable LLW management option for wastes generated offsite?

  As a matter of policy, NRC is opposed to any activity, at a nuclear reactor site, that is not generally supportive of activities authorized by the operating license or construction permit, and that may divert the attention of licensee management from its primary task of safe operation or construction of the power reactor. Accordingly, interim storage of LLW within the exclusion area of a reactor site, as defined in 10 CFR 100.3(a), will be subject to NRC jurisdiction regardless of whether or not the reactor is located in an Agreement State, pursuant to the regulatory policy expressed in 10 CFR 150.15(a)(1).

  As per Generic Letter 85-14, "Commercial Storage at Power Reactor Sites of Low-Level Radioactive Waste Not Generated by the Utility," for NRC to consider any proposal for commercial storage at a reactor site, including commercial storage in existing LLW storage facilities, NRC must be convinced that no significant environmental impact will result and that the commercial storage activities will be consistent with, and not compromise, safe operation of the licensee's activities. A Part 30 license is required for commercial LLW storage and a Part 50 license amendment may also be required. The Office of Nuclear Reactor Regulation (NRR) will conduct an environmental review and review the application to determine whether the low-level waste commercial storage activities on a reactor site impact the safe operation of the reactor.

  Following NRR review, the licensing authority for commercial storage on a reactor site under NRC jurisdiction (all locations in non-Agreement States and locations within reactor exclusion areas in Agreement States) is the Office of Nuclear Material Safety and Safeguards. NRC will assess environmental impact and will issue an environmental impact statement, if appropriate. NRC will provide notice in the *Federal Register* of receipt and availability of any application received for commercial storage activities. The public notice will also indicate the staff's intent regarding preparation of an environmental assessment and its circulation for public review and comment. An environmental impact statement will most likely be needed, based on the environmental assessment.

- 6. What radioactive waste management options are available to licensees that possess greater-than-Class-C (GTCC) waste, or GTCC sealed sources, and that wish to terminate their licenses?

  Waste management options for licensees possessing GTCC waste or sources are limited for the following reasons: 1. Section 61.55 states that GTCC waste is generally not acceptable for near-surface disposal and must be disposed of in a geologic repository, as defined in 10 CFR Part 60, unless another disposal method is approved by NRC pursuant to 10 CFR Part 61. No geologic repository is currently available. 2. The LLRWPAA designates the Federal Government as responsible for disposal of GTCC wastes, and Congress has designated the U.S. Department of Energy (DOE) as the responsible agency for disposal of GTCC waste. DOE currently estimates that an interim storage facility may be available for GTCC wastes by the end of 1997. However, further delays in meeting this schedule may occur.

  Until disposal capacity becomes available for GTCC waste, licensees may consider amending their licenses to restrict activities to possession-only licensed activities. When a storage/disposal facility becomes available, such licensees, upon transfer of their GTCC wastes/sealed sources to the storage/disposal facility, could then request license termination.

  NRC Information Notice 93-50, "Extended Storage of Sealed Sources," published July 8, 1993, addresses what information NRC considers necessary for placing a license into a possession-only status, if extended storage of sealed sources is necessary. Similar general considerations would accompany requests by licensees requiring possession-only licenses to store GTCC waste.

COMMISSION APPROVES WITHDRAWAL OF PROPOSED RULEMAKING CONCERNING ON-SITE STORAGE OF LOW-LEVEL RADIOACTIVE WASTE

In a Staff Requirements Memorandum dated February 1, 1994, the Commission (with all Commissioners agreeing) approved the staff's recommendation to withdraw the proposed rule that would have amended 10 CFR Parts 30, 40, 50, 70, and 72, to establish a regulatory framework containing the procedures and criteria applicable to onsite storage of low-level radioactive waste (LLW) after January 1, 1996. The staff's recommendation was forwarded to the Commission in SECY-93-323, on November 29, 1993.

On February 2, 1993 (58 FR 6730), the U.S. Nuclear Regulatory Commission published, in the *Federal Register*, proposed amendments to 10 CFR Parts 30, 40, 50, 70, and 72 of its regulations. Under the provisions of the proposed rule, onsite storage of LLW would not have been permitted after January 1, 1996 (other than reasonable, short-term storage necessary for decay or for collection or consolidation for shipment offsite, when a licensee has access to an operating LLW disposal facility), unless a licensee documented that it had exhausted other reasonable waste management options. These options included the management of the waste by the State in which a waste generator is located. In addition, a reactor licensee would have had to document that onsite storage activities were consistent with, and did not compromise, the safe operation of the licensee's activities, and did not decrease the level of safety provided by applicable regulatory requirements. The proposed rule would have required applicable licensees to retain all relevant documentation for at least 3 years and to make the documentation available for NRC inspection. The 60-day comment period for the proposed rule expired on April 5, 1993.

Fifty-five comment letters were received addressing the proposed rule. The commenters' principal concerns, impacting NRC's decision to withdraw the proposed rule, are: (1) the need to define "reasonable waste management options"; (2) the burden imposed on licensees; (3) the effect on the protection of the public health and safety and the environment; and (4) the impact on the States. SECY–93–323 includes a discussion of each of these concerns. In addition, this commission paper includes a summary of all the comments received in response to the proposed rule and NRC responses to these comments.

After considering the comments submitted on the proposed rule, NRC does not now believe that there is a sufficient connection between the requirements in the proposed rule for documenting that a licensee has exhausted reasonable disposal options and the objectives of reducing onsite storage of LLW, or encouraging the development of new LLW disposal capacity. The few comments received in support of the proposed rule were based on the general desirability of encouraging disposal over storage. However, these commenters did not address the issue of whether the documentation procedures in the proposed rule would prove to be an effective method for achieving this goal. After further analysis of the rationale for the rule prompted by the public comments, it is not clear that this proposed rule would provide licensees a substantially greater incentive over existing requirements to dispose of their LLW at available locations in a timely manner. Therefore, the proposed rule would neither be a necessary nor significant addition to the protection of the public health and safety. In view of these considerations, the Commission has determined that the proposed rule should be withdrawn.

The withdrawal of this proposed rule does not alter the Commission position concerning long-term onsite storage of LLW. The Commission considers the long-term onsite storage of LLW to be a last-resort measure. NRC's preference is that LLW be permanently disposed of as soon as possible after it is generated. The protection of public health and safety and the environment is enhanced by disposal rather than long-term storage of wastes. In addition, the Commission continues to support the goals that have been established in the Low-Level Radioactive Waste Policy Amendments Act of 1985. The Commission expects LLW disposal facilities to be sited and developed in a timely manner and that waste generators and States will continue to take all reasonable steps to ensure that LLW disposal capacity is available soon.

TWFN NRC OPERATIONS CENTER TELEPHONE NUMBER (301–816–5100)

With the move of the NRC Operations Center to the Two White Flint North (TWFN) building, the primary 24-hour telephone number for the NRC Operations Center will change from 301–951–0550 to 301–816–5100. The backup numbers will change from 301–427–4056, 427–4259, 492–8893, 951–6000, and 951–1212, to a single number, 301–951–0550 (which is the previous primary telephone number). The facsimile number will change from 301–492–8187 to 301–816–5151. This change will occur on or about May 31, 1994. After this date, both numbers will reach the new center for no less than 90 days. After this time, only the new phone number will reach the Operations Center.

NEW REGIONAL PHONE NUMBERS AND FUNCTIONS

Recently, there have been a number of changes in regional office functions and in phone numbers. For the convenience of licensees, the new primary phone numbers are listed here:

Region I—New area code 610– replaces 215; otherwise, numbers remain the same; primary number is 610–337–5000.

Region II—No change: primary number remains 404–331–4503.

Region III—New primary number 708–829–9500; new address:

U.S. Nuclear Regulatory Commission
Region III
801 Warrensville Rd.
Lisle, IL 60532–4351.

Region IV—Now includes all Region V functions. It will be assuming Uranium Recovery Field Office (URFO) inspection functions over the next several months. Primary number is 817–860–8100.

Walnut Creek Field Office—Formerly Region V, now part of RIV; licensees formerly covered by RV should address correspondence and phone calls to RIV, unless they have business with the Walnut Creek Office or have been instructed otherwise. Primary phone number is 510–975–0200.

Uranium Recovery Field Office—Primary number is 303–231–5800. Licensing is being transferred to NRC Headquarters. In future, call High-Level Waste and Uranium Recovery Projects Branch on 301–504–3391. Inspection is being transferred to RIV. In future, call RIV number. Individual licensees will be notified in the next several months when responsibilities are transferred and will be told whom to call and where to address correspondence.

OSP DIRECTOR BANGART PRESENTS GOALS

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U.S. Nuclear Regulatory Commission Director of the Office of State Programs Richard L. Bangart recently provided thoughtful and pertinent responses to questions put forth by isoTOPICS.

As the new Agreement State Program's Director what are your major goals and objectives?

In keeping with NRC' s primary statutory responsibility, the most fundamental of goals is to ensure that Agreement State programs are adequate to provide the public protection from the hazards associated with the use of radioactive materials. Another broad objective is to achieve a materials radiation safety program of regulation, among the Agreement States and NRC, that is more consistent and coherent in approach than now exists. From a specific Agreement States program standpoint, however, developing and implementing the program restructuring activities called for by the Commission is my highest priority. These initiatives include the development of a new compatibility policy (between NRC and Agreement State programs); the use of common performance indicators to assess both NRC regional office and Agreement State performance in licensing and inspection of materials licensees; and the development of a number of other new policies and procedures, such as definitive criteria for Agreement State program suspension, probation, and reassertion of authority by the NRC.

What would you like to see different from the current situation in the Agreement State programs five years from now?

Achieving stability in the program, hopefully well in advance of the 5-year mark, is a difference that of necessity we must achieve. The current program initiatives and restructuring activities are placing unprecedented demands on Agreement State and NRC personnel and creating uncertainty, and in some cases apprehension, for many people both within and outside NRC. Once the program modifications are developed and implemented, I believe the Agreement States will find the NRC program focusing on those program elements that relate to our collective health and safety mission, will find that their needed flexibility will not be impaired, and will find the NRC management of the Agreement State program predictable. A stable, consistent, coherent national materials radiation safety regulatory program, that because of its recognized quality is free from the same degree of criticism that exists today, will hopefully be the situation that we (Agreement States and NRC) will find 5 years into the future.

What impact do you foresee the increased Congressional/media attention on medical programs having on the Agreement States?

The impact on both NRC and Agreement State programs is similar, as one would expect. Both NRC and the Agreement States are confident that their existing regulatory programs provide an adequate level of safety for the public. However, some believe that we cannot definitively defend that position to the satisfaction of those who have reviewed our programs. Agreement States and NRC are being impacted by the need to revise our programs to the extent necessary to establish the increased credibility that will address some of the current skepticism. For example, as Agreement States promulgate their equivalent of NRC's 10 CFR Part 35 Quality Management rule, by January 1995, they may find an increase in enforcement actions resulting from failure of some licensees to implement the rule's quality assurance provisions effectively, just as NRC has experienced. The need to have an accurate database to establish the rate of medical misadministration currently exists, but "event" reporting accuracy has been subject to question. Accordingly, NRC is planning to establish an "events" database that will include both NRC and Agreement States events, and a training workshop, to promote a better understanding of the need for accurate and complete event reporting, will be conducted. Reporting of misadministration will be a key topic in that workshop. Of course, major changes to both NRC and Agreement State programs could occur if legislation results from the National Academy of Sciences review of the regulation of the use of radioactive materials and radiation in the practice of medicine in the U.S.

Do you see increasing oversight and/or greater consistency of the State programs as a goal/necessity?

Oversight will likely be somewhat different in the future, but not necessarily increased in the sense that more effort will be expended in oversight. The oversight NRC will exercise in the future will be at least a more effective, and hopefully a more efficient, use of NRC resources. The use of common performance indicators, a team of evaluators, and a management review board to arrive at a final finding of adequacy and compatibility will, if implemented, be a major change in the way NRC provides oversight. Having established more comprehensive procedures for addressing significant weaknesses in Agreement State programs will also be a major change. The overall long-term goal of establishing a coherent national materials regulatory program among NRC and the Agreement States has consistency as a key element. This will better assure the public that the level of protection they are afforded is as good in one State as in another.

What advice would you give to the State radiation control program directors?

NRC usually limits our comments to those provided through the formal process of Agreement State program evaluation and to those conclusions drawn in the process of developing policy or program changes. Each of the program directors is dedicated to our common mission of ensuring effective regulation of the use of radioactive materials. Most, if not all, of the State program directors also face the broader responsibility of managing the regulation of the use of machine-produced radiation and naturally occurring radioactive materials, and in some cases other health-related programs. Because of this broader responsibility, they often are able to provide a perspective that is valuable to NRC as we provide oversight of their programs and work cooperatively to establish radiation protection standards and regulations. While not advice, I would hope that Agreement State program directors will

continue to work cooperatively with NRC to develop and implement what I think are positive improvements to the Agreement States program.

What are your thoughts about the apparent inequity in the licensing and inspection fees that the NRC licensees must pay versus those institutions in Agreement States?

The Energy Policy Act of 1992 requires NRC to review its policy for assessment of annual fees, solicit public comment on the need for changes to this policy, and recommend, to the Congress, changes, in existing law, that NRC finds are needed to prevent the placement of an unfair burden on certain NRC licensees. On April 19, 1993, NRC requested comments on the NRC fee policies and received 566 comments. One of the concerns raised by the commenters and addressed in the policy review involved fees paid by NRC licensees for regulatory activities that support both NRC and Agreement State licensees. The results of the fee policy review (SECY-93-342) are under consideration by the Commission. After the Commission completes its review, the required report will be sent to the Congress.

Do you have a statement you would like to make to our readership?

The public's expectations are demanding even greater accountability from the NRC and the Agreement States in terms of assurance that adequate levels of protection are being provided. Because of this, licensees should also realize that their own standards for conduct of licensed programs must remain high. If problems in licensee programs develop, and especially if "events" or "accidents" occur, both the regulator and the licensee may receive intensive scrutiny and possible criticism.

For the foreseeable future, this spotlight of attention will likely continue. There are demanding challenges that must be addressed by the NRC, the Agreement States, and licensees, to improve the degree of public confidence in our programs. Although these challenges will be difficult, I am confident the necessary program revisions will result in improvements that will prove beneficial to NRC, the Agreement States, the licensed community, and the public. I have mentioned that in the future I envision a more consistent, coherent, national program for the regulation of the use of Atomic Energy Act materials. That program should be well-documented, predictable, and developed with input from all interested parties, including the public. It should focus on those areas that are directly related to safety and lead to a more effective and efficient use of NRC and Agreement State resources. I look forward to working with Agreement States, licensees, and the public to achieve this goal.

(From May 1989 to August 1993, when he assumed the position of NRC Director of the Office of State Programs, Richard L. Bangart was the Director of the NRC Division of Low-Level Waste Management and Decommissioning. In that position, he was responsible for NRC programs that ensure that commercial low-level radioactive waste is safely managed, treated, and disposed of. In both regional offices and Headquarters, Mr. Bangart has held progressively more responsible positions throughout his 25-year career with the NRC and its predecessor agency, the Atomic Energy Commission. His most recent prior assignment was in NRC's Region IV office, where he served as Director of the Division of Radiation Safety and Safeguards. He graduated from Willamette University in Salem, Oregon, with a Bachelor of Arts degree in mathematics and physics. He then received Master of Science and Master of Public Health degrees from the University of Michigan in environmental science and radiological health, respectively.)

REORGANIZATION OF HLWM AND LLW DIVISIONS INTO DIVISION OF WASTE MANAGEMENT

The Commission has recently approved a reorganization of waste management activities that combines the Division of High-Level Waste Management and the Division of Low-Level Waste Management and Decommissioning into a single Division of Waste Management. It is led by Malcolm Knapp as Director and John Greeves as Deputy Director. It consists of four branches, as shown on the top of the next page (p. 8).

PROPOSED REVISION TO 10 CFR PART 34 PUBLISHED IN *FEDERAL REGISTER*, FOR COMMENT

On February 28, 1994, a proposed revision to 10 CFR Part 34 was published in the *Federal Register* (59 FR 9429) for comment. The comment period ends May 31, 1994. These revisions to the NRC regulations have been under development for several years and are intended to improve radiography safety and include a number of updated radiography regulations that have been adopted by the Agreement States.

The major changes of the proposed rule include requirements for: 1) two qualified individuals to be present any time radiographic operations occur outside at a temporary jobsite; 2) mandatory certification of all radiographers; 3) permanent radiographic installations; and 4) a radiation safety officer.

Regulatory Guide 10.6 is also being revised to reflect the changes in the proposed rule. It should be published for public comment before the end of the comment period for the proposed rule.

PART 36 DRAFT GUIDE PUBLISHED: APPLICABILITY TO TELETHERAPY UNITS USED FOR NON-HUMAN USE

Draft Guide: The June 1993 issue of the *NMSS Newsletter* discussed the publication, in the *Federal Register*, of the final rule addressing licensing and radiation safety requirements for large irradiators (10 CFR Part 36). The final rule became effective on July 1, 1993. In January 1994, NRC published, for comment, a licensing guide to support Part 36. The guide is identified as Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators." Copies of the guide were sent to licensees subject to Part 36 requirements. Write to the USNRC, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail

DIVISION OF WASTE MANAGEMENT

Malcolm Knapp, Director
John Greeves, Deputy Director
John Surmeier, Assistant to the Director
Betty Lynn, Secretary
Eileen D. Schultz, Secretary

	Low-Level Waste and Decommissioning Projects	High-Level Waste (HLW) and Uranium (UR) Recovery Projects	Performance Assessment and Hydrology	Engineering and Geosciences
BR CH	John Austin	Joseph Holonich	Margaret Federline	Michael Bell
SEC LDRS	Larry Bell Tim Johnson	Dan Gillen Robert Johnson	Norm Eisenberg Dave Brooks	Keith McConnell John Thoma
DETAIL	Division lead for Decommissioning, LLW, Site Decommissioning Management Plan (SDMP) & EPA Interface	Division lead for HLW & UR Disposal Waste Systems Engineering and Integration (WSE&I), QA	Division lead for PA, Hydrology, Geochemistry, & Health Physics	Division lead for Geosciences, Geotechnical Engineering, including Geologic Setting, Repository Design, Construction and Operations (RDCO), and Engineered Barrier System (EBS)

Services Section, to request single copies of the draft guide (which may be reproduced) or placement on an automatic distribution list for single copies of future draft guides. Send written comments on the draft guide (with supporting data) to the Regulatory Publications Branch, DFIPS, Office of Administration, USNRC, Washington, DC 20555. Comments will be most helpful if received by October 1, 1994.

Applicability to Teletherapy Units: Based on contacts with licensees and results of some inspections, it appears that some academic and medical organizations do not recognize that the requirements of Part 36 apply to their activities. Specifically, a licensee with a teletherapy-type unit is subject to the requirements of Part 36 if: the unit's source is capable of delivering 5 grays (500 rads) per hour at 1 meter from the radioactive sealed source in air AND the licensee uses the teletherapy-type unit either solely or partially for non-human use (e.g., to irradiate animals, materials, or objects such as blood, tissue, cells, or electronic equipment, and to calibrate radiation detection instruments); see 10 CFR 36.1, "Purpose and scope." Licensees authorized to use their teletherapy units to treat patients must also comply with the applicable provisions of 10 CFR Part 35.

Section 36.17 of 10 CFR Part 36 covers "Applications for exemptions," and 10 CFR 36.17(b) provides that, if an applicant or licensee (applicant) wants to use a teletherapy-type unit to irradiate materials or objects, the applicant may propose alternatives for the requirements of Part 36. NRC will approve proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that it is likely to provide an adequate level of safety for workers and the public. To obtain an exemption, existing licensees must submit an amendment request with the information described in 10 CFR 36.17(b). In the absence of an approved amendment, the licensee is expected to comply with the requirements of Part 36.

QM (QUALITY MANAGEMENT) NOTES

NRC has recently issued an Information Notice (No. 94–17), that reminds licensees that are authorized for and using a strontium-90 eye applicator, of the need to submit and implement a quality management program (QMP) that meets the requirements in 10 CFR 35.32. The submitted QMP should provide high confidence that radiation from the Sr–90 eye applicator will be administered as directed by the authorized user.

NRC is aware of problems associated with assaying beta-emitting radiopharmaceutical dosages in dose calibrators. The staff intends to publish an information notice to clarify this issue, soon. Licensees that have submitted QMPs for radionuclide therapy are reminded of the need to revise their QMPs if the procedure for measuring patient dosages is changed. Your QMP should reflect your current procedures.

Questions about quality management programs should be directed to Sally L. Merchant at (301) 504–2637.

SECTION 2.206 PETITION ON NATIONAL INSTITUTES OF HEALTH INCINERATOR

On December 2, 1993, a citizen's group known as the North Bethesda Congress of Citizen's Associations filed a 10 CFR Part 2.206 petition to suspend a condition in the National Institutes of Health (NIH) license (Condition 24) that permits NIH to incinerate radioactive waste in its three incinerators on the Bethesda, Maryland, campus. Two reasons were given by the citizen's group to support

their request: (1) they believed that there should have been an environmental assessment completed before issuance of an NRC license condition, and (2) NIH does not appear to have sufficiently good control of the quantities of radioactive materials that are incinerated. The first reason was based on the petitioner's interpretation of 10 CFR Part 51, which the group believed required completion of an environmental assessment by the U.S Nuclear Regulatory Commission before granting a license to incinerate radioactive materials. The second reason was based on the contents of a 1988 NRC inspection report, which found NIH to be deficient in many aspects of control and quantification of the flow of radioactive waste to the incinerators. The petitioners also requested information on some other issues, including the basis for granting NIH exemption from the sewer release limits in 10 CFR 20.303(d), which limits total annual release of activity other than H-3 and C-14 to the sewer to 37 gigabecquerels (1 curie) (Ci). Licensee Condition 21 in the NIH license raises this limit to 296 gigabecquerels (8 Ci) per year.

For those who may not be familiar with 2.206 petitions, 10 CFR 2.206 provides that any person may file a request with NRC to modify, suspend, or revoke a license, or for any other appropriate action. The request must be sent to the Executive Director for Operations (EDO) and must specify the actions requested and the reasons for requesting these actions. The EDO assigns the request to the office with responsibility for the subject area. The office director will, within a reasonable time period, either take the requested action or notify the petitioner that the action was denied in part or in whole, and the reasons for the decision. The director's decision is filed with the Office of the Secretary, and the Commission may, within 25 days, review the decision.

After review by NRC staff, the petition was denied, in part, on the basis that a 1992 NRC inspection report found the incineration operation to be in compliance with 10 CFR Part 20 limits, as required by the license condition, and therefore not a safety concern. Specifically, the inspection report found that the airborne effluents were calculated to be well below 10 CFR Part 20, Appendix B, concentrations, as were the water and ash effluents. The matter of whether an environmental assessment was required was left open, pending a director's decision. In the meantime, NIH took two of its three incinerators permanently out of service because of obsolescence, and decided to upgrade the third unit during a prolonged maintenance shutdown, scheduled to start in April 1994. It also agreed to conduct a study of the chemical composition of the effluents from the incinerator stacks (already underway), and to conduct an environmental study of the incinerator operation. None of these actions was prompted by or taken in response to any action by NRC.

A search of NIH's records by a Region I inspector unearthed some interesting historical facts related to this petition. It turned out that both the incineration operation and the 296-gigabecquerel/yr (8-Ci/yr) limit on sewer releases were apparently incorporated into NIH's license long before creation of NRC by the Energy Reorganization Act of 1974. The earliest license found on record in Region I dates from November 1973, and was already in amendment 31. That license amendment contained the incineration and release limit conditions, and references documents dated as far back as January of 1966. It is also interesting to note that these license conditions predate the National Environmental Policy Act (NEPA) (1969) and promulgation of 10 CFR Part 51 (1973). (NIH, on May 12th, shut down its last incinerator.)

FEDERAL AGENCIES' REVIEW OF ACTIVITIES RELATED TO RESEARCH INVOLVING HUMAN SUBJECTS

On January 15, 1994, President Clinton signed an Executive Order entitled "Advisory Committee on Human Radiation Experiments," which, among other things, established the advisory committee, instructed the committee to provide advice and recommendations to the government's newly established "Human Radiation Interagency Working Group" and to review human experiments conducted from 1944 to May 30, 1974, and defined as "human radiation experiments." The U.S. Department of Energy (DOE), a member of the Human Radiation Interagency Working Group, initiated a comprehensive review of DOE files retained from its predecessor, the Atomic Energy Commission (AEC). The U.S. Nuclear Regulatory Commission, which retained the civilian licensing aspects of the AEC, is in possession of some AEC licensing files and records.

NRC staff, in a memorandum to the Commissioners dated February 4, 1994, summarized: (1) the results of the staff's survey to determine whether readily available Commission and Agreement State files have information about licensees that may have conducted research studies using AEC licensed radioactive materials, or the radiation therefrom, on human subjects; (2) a description of the types of human research currently authorized by NRC materials licenses and the review criteria for those authorizations; and (3) a summary of future actions. This document is available in the public document room.

Currently, some NRC medical licenses participate in human research studies performed to obtain information about metabolism and biodistribution of compounds, monitor patient treatments, or develop screening studies. The licensing criteria for issuing human research authorizations include a commitment that the licensee has, and uses, an Institutional Review Board, or other appropriate review committees, to approve studies based on ethical considerations, scientific merit, and radiation safety considerations. The staff requires confirmation that the committees, as constituted, have been approved by the Food and Drug Administration (FDA).

When requested, NRC is assisting DOE and other government agencies (e.g., the Department of Veterans Affairs, Department of Navy, and the Department of the Air Force) with specific requests to locate information in active or retired AEC, NRC, or Agreement States license

files. NRC also continues to respond to specific requests by the press, licensees, and members of the general public for information on research involving human subjects. When responding to these specific requests, NRC retrieves the files, reviews them following the provisions of the Freedom of Information Act procedures, and places them in the Public Document Room.

"RECORDABLE EVENT" IN BRACHYTHERAPY

"Recordable event" is defined in 10 CFR 35.2, "Definitions," and contains six criteria. Item (2) identifies a recordable event as the administration of "A radiopharmaceutical or radiation where a written directive is required without *daily recording* of each administered radiopharmaceutical dosage or radiation dose in the appropriate record." The term "daily recording" is not defined in 10 CFR Part 35 nor discussed in Part 35 Statements of Consideration; therefore, clarification is provided. Specifically, for brachytherapy procedures, the failure to provide the total source strength and exposure time or the total dose in the written directive, before completion of the procedure, constitutes a recordable event. This clarification is based on the following.

While formulating the "Quality Management Program and Misadministration" final rule, U.S. Nuclear Regulatory Commission staff intended the daily recording of the administration of a single radiopharmaceutical dosage, daily teletherapy fraction, or an administration of a radiation dose delivered within a single day for brachytherapy or gamma stereotactic surgery procedures. NRC staff did not intend to apply the term "daily recording" to manual and low-dose rate (LDR) remote afterloading brachytherapy procedures, in that daily recording is not relevant since the prescribed dose is not fractionated, and frequently extends over more than a single day. Rather, the prescribed dose is delivered continuously over a calculated period of time and is recorded as the total dose, or equivalently, total source strength and exposure time. Thus, for manual and LDR procedures, there is no recording of the "daily administered dose," but, rather, there is only the recording of the total dose or its equivalent.

NRC recognizes that the total prescribed dose may not be determined until treatment plans are finalized, based on the source strength, and anatomical location of implanted sources. In addition, since the total source strength is fixed when the sources are implanted, delivering the prescribed dose is a matter of using the correct sources, source strength, and exposure time. The definition of written directives for brachytherapy requires licensees to record the radioisotope, treatment site, source strength, and exposure time (or equivalently, the total dose) before removal of the implanted sources. Therefore, in accordance with the definition of "Recordable event," item (2), the failure to provide the total source strength and exposure time, or the total dose in the written directive, before completion of the procedure, would constitute a recordable event.

A SAMPLING OF SIGNIFICANT EVENTS REPORTED TO NRC BY NRC NUCLEAR MATERIAL LICENSEES

A. NRC LICENSEES

Event 1: Medical Brachytherapy Misadministration at Mountainside Hospital in Montclair, New Jersey

Date Reported: December 3, 1993

Licensee: Mountainside Hospital, Montclair, New Jersey

On December 1, 1993, during a routine inspection, the U.S. Nuclear Regulatory Commission identified a therapeutic misadministration involving a high-dose-rate (HDR) remote afterloader, which occurred at Mountainside Hospital in Montclair, New Jersey, on July 1, 1993. NRC identified the misadministration while reviewing the licensee's Radiation Safety Committee (RSC) meeting minutes for 1993.

On July 1, 1993, a patient was scheduled to receive the last of three brachytherapy treatments to the right mainstem bronchus. Each fraction was to deliver 750 centigray (cGy) (750 rad) to the target using a Nucletron Micro-Selectron HDR remote afterloader and a intrabronchial catheter. During the July 1, 1993, treatment, the radiation oncologist mistakenly connected the catheter to the HDR afterloader with a 750-mm (29.5-inch) transfer tube, instead of a short connector. This prevented the source from entering the intrabronchial catheter, and while delivering a negligible dose to the tumor, the face, the lenses of the eyes, the thyroid, and the whole body of the patient received unscheduled exposures.

The source strength at the time of the incident was 161,000 megabecquerel (4.35 curie) of iridium-192 and the exposure time was 445.5 seconds. Following the reconstruction of the incident by the licensee, the surface dose to the lens of the left eye was determined by the licensee to be 1.97 cGy (1.97 rad); the dose to the chin (the closest surface of the body) was 4.56 cGy (4.56 rad); and the dose to the thyroid was 3.07 cGy (3.07 rad). The authorized user identified the error on termination of the treatment and wrote a memorandum about the incident to the hospital's physicist and radiation safety officer (RSO).

The authorized user mistakenly determined that the incident was not a misadministration, and so advised the RSO. The RSO, relying on the authorized user's judgment, did not notify NRC and filed the report in the RSC minutes folder. The radiation oncologist decided against making up the missed third fraction of therapy.

On December 3, 1993, NRC notified the licensee, by telephone, that the event constituted a misadministration and the licensee notified the NRC Operations Center on the same day. The licensee's written report of the misadministration, dated December 13, 1993, was received in the NRC Region I office on December 17, 1993.

An error by the attending physician in connecting the catheter to the HDR remote afterloader, and the failure

of the console operator to recognize the faulty connection, were the direct causes of the event. Both individuals relied on the treatment computer to indicate any problems with the therapy setup. The computer on a Nucletron HDR is not designed to alert the user to an incorrect connection of a longer transfer tube.

NRC retained a medical consultant to determine the significance of the misadministration to the patient. The consultant's calculations of doses to the lens of the left eye, the chin, and the thyroid of the patient agreed with the licensee's estimates, based on the strength of the source, the time of exposure, and the distances of the source from the patient. The consultant concluded that the patient would not suffer any adverse effects from the misadministration. The medical consultant also determined that the oncologist failed to notify the patient of the misadministration because he did not fully understand the requirements of 10 CFR 35.33(a)(3). After discussions with the consultant, the referring physician agreed to inform the patient of the misadministration.

The licensee arranged for additional training by Nucletron on July 30, 1993. The training was attended by both HDR remote afterloader unit authorized users and by three technologist-console operators.

The medical consultant's report, dated February 1, 1994, was received by the NRC Region I office on February 3, 1994; the report indicates that the second individual observing the transfer tube connection during each treatment setup was a different console operator. Since the console operator in attendance during the third treatment had not been present during the prior treatments, he/she was unaware of the intended setup. The consultant indicated that if the licensee had required a medical physicist to be present during every setup and treatment, as recommended in NRC Bulletin 93-01, it is likely that this misadministration would not have occurred. In the consultant's opinion, a medical physicist would have been more likely to have noticed the human error in the setup of the third HDR treatment.

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Event 2: Exposure to a Nursing Infant at Queen's Hospital in Honolulu, Hawaii

Date Reported: Unreported; discovered during routine U.S. Nuclear Regulatory Safety inspection about 2 years later

Licensee: Queen's Medical Center, Honolulu, Hawaii

On October 25, 1993, during a routine safety inspection, a Region V inspector discovered an unreported unscheduled exposure of a 9-month-old nursing infant. On December 2, 1991, a patient was administered 0.56 megabecquerel (15 microcuries) of iodine-131 for a diagnostic scan. Although the patient noted on a hospital form that she was breastfeeding, the technologist failed to notice this notation until the patient returned for a scan the following day. The patient was informed of the oversight by the licensee and instructed to stop breastfeeding. The authorized user and the referring physician were also notified, on December 3, 1991.

The licensee's Radiation Safety Officer calculated the infant's absorbed dose to the thyroid to be approximately 250 millisievert (mSv) (25 rem), based on information obtained during an uptake scan of the mother 6 hours after the administration.

NRC retained a medical consultant to evaluate the circumstances of this incident. The consultant estimated the dose to the infant's thyroid to be between 160 to 650 mSv (16 to 65 rem). The medical consultant concluded that the infant was not likely to experience any adverse effects as a result of this incident.

A contributing factor to this event was that a supervised technologist did not adequately review the hospital form used to inform the hospital staff that a patient is pregnant or breastfeeding, as he/she was instructed by the authorized user.

The licensee's corrective actions include incorporating, into the clinical procedures manual, a screening procedure used to inform the hospital staff that a patient is pregnant or breastfeeding. It was reviewed by each of the present technologists, and it will be reviewed by all newly hired technologists. It will also be reviewed annually, during a radiation safety training course.

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Event 3: Medical Brachytherapy Misadministration at Good Samaritan Medical Center in Zanesville, Ohio

Date Reported: (Not in provided data)

Licensee: Good Samaritan Hospital, Zanesville, Ohio

A patient was being treated for lung cancer. The treatment included performing an iridium-192 therapeutic implant. The prescribed treatment dose was 6000 centrigray (cGy) (6000 rad) to the patient's lung. On November 10, 1993, a catheter was surgically implanted in the patient. Iridium-192 seeds, contained in a ribbon, were inserted into the catheter.

Following normal licensee procedure, the physicist requested that the attending nurse order a "stat" chest x-ray, to verify source position. The "stat" radiograph was completed, and 2 hours later, on review of the film, the seed positions could not be visualized. Two additional radiographs using different techniques were done. In the second radiograph, completed 1 hour later, the seeds were located in the patient's throat. The ribbon was removed and the physician successfully reinserted the ribbon to the proper location. Another radiograph was done to verify the source location. The treatment time was recalculated to deliver the total original intended dose, and the treatment was completed without further difficulty.

The sources were in the improper location for about 3 hours, delivering an estimated dose to the larynx area of about 282 cGy (282 rad). An NRC medical consultant evaluated the medical aspects of the brachytherapy misadministration and concluded that the dose to the larynx and surrounding area was not clinically significant.

The physician verbally notified the patient of the misadministration after the successful reinsertion of the source ribbon, with a follow-up written report.

The immediate cause of the misadministration was an apparent crimp in the catheter, which resulted in the seeds not being placed correctly. The seeds were blocked by the crimp at the level of the patient's larynx.

A contributing factor to this incident was that an inexperienced radiation therapy technician implanted the source under inadequate supervision. During an interview, the physician stated that it would be difficult for an inexperienced person to know the difference between a properly seated ribbon and when ribbon insertion was impeded by a crimp in the catheter.

The licensee's plan for preventing recurrence of the misadministration included: (1) formalizing the dosimetrist's "rule of practice" regarding comparison of the ribbon and catheter lengths before source implantation, to ensure that the ribbon is properly seated; (2) providing training to all radiation therapy technologists and each medical physicist in the new procedure; (3) requiring that the authorized user physically implant source ribbons; (4) requiring that each radiation therapy technologist receive hands-on training and instruction in source implantation; and (5) requiring that the "stat" post-insertion radiograph be hand-carried to the prescribing physician for evaluation as soon as possible, to determine proper source placement.

Event 4: Medical Brachytherapy Misadministration at Marquette General Hospital in Marquette, Michigan

Date Reported: (Not in provided data)

Licensee: Marquette General Hospital, Marquette, Michigan

On November 17, 1993, a patient was undergoing a brachytherapy procedure using cesium-137 sealed sources placed in a treatment device (catheter) inserted into the patient's uterus. When the catneter was removed on November 19, it was observed that it was too short to have been fully inserted into the uterine cavity. The three sources in the catheter had actually been in the patient's vagina instead of the uterus.

The case was evaluated by an NRC medical consultant who concluded that the lower vagina received a radiation dose of 2700 centigray (2700 rad), when it would not have received a significant dose if the treatment had been performed as planned. The medical consultant concluded that the radiation doses to the vagina would not be expected to cause any acute or long-term effects because the vaginal tissue is extraordinarily tolerant of radiation. This placement error did not result in additional exposure to other organs.

The intended treatment area received about 50 percent of the intended dose. Subsequently, the patient received an additional dose to the uterus to complete the prescribed treatment. The licensee informed the patient of the treatment error.

The hospital routinely uses two lengths of catheters for brachytherapy treatments, a shorter catheter for vaginal procedures and a longer one for uterine procedures. The medical physicist inadvertently placed the cesium-137 sources in the shorter (vaginal) catheter, instead of the required long catheter, for the uterine procedure prescribed.

The hospital has revised its QM procedures to include added precautions for ensuring that the correct length catheter is used in each brachytherapy procedure.

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B. AGREEMENT STATE LICENSEES

Event 1: Medical Teletherapy Misadministration at Rocky Mountain Gamma Knife Center, Denver, Colorado

Date Reported: (Not in provided data)

Licensee: Rocky Mountain Gamma Knife Limited Liability Company; Denver, Colorado

A patient was admitted on July 8, 1993, for treatment of a longstanding arteriovenous malformation (AVM) in the left posterior dura of the brain. The patient underwent a series of diagnostic procedures to identify the AVM targets to be used. The films were given to the physicist, who optically scanned them into the computer planning system.

The physicist and neurosurgeon worked to complete the dose planning function; however, several anomalous events were noted during the process: (1) during the "definition process," the screen showed a sudden "floating point error" message. This was described as serious, but the cause of the message was not known; (2) the definition program in the Leksell Gamma Plan (LGP) refused to accept, on at least two occasions, the "correct" orientation of the image, as viewed by the physicist and neurosurgeon. Eventually, the neurosurgeon and physicist had to instruct the LGP to accept the image they knew to be intuitively correct, but which the computer had failed to recognize. At this point, the screen images appeared correct as to orientation for diagnosis; however, the planning team did not realize that the P/A image was reversed, in regard to the LGP dose-planning system.

The team then generated two separate treatment plans for the two separate targets. The radiation oncologist was consulted and concurred with the dose prescription. It was noted that the "X" coordinates for the targets indicated a right-of-midline stereotactic position, but the patient's head was tilted inside the frame, placing the midline of the brain to the left of the midline of the stereotactic system. Therefore, the coordinates were accepted as plausible. After initiating the treatment sequence for the next exposure, the physician reviewed the target points and noticed that the X coordinates indicated a definite right-side target. The physicist immediately terminated the exposure and notified the physician of a possible treatment error. It was determined that the Y and Z coordinates were accurate, but the X offset resulted in a target miss by 16 millimeters (0.63 inches).

The brainstem was stated to be the only critical structure within the 10 percent isodose contour. Reconstruction of the dose profile indicated that less than 10 cubic millimeters received no more than 2.5 gray (Gy) (250 rad). The tolerance dose for the brainstem was stated to be 10 Gy (1000 rad). The neurosurgeon believed that the dose delivered was well below the dose-volume threshold for inducing any neurological damage.

Although the images were "intuitively correct" to the neurosurgeon and physicist, they were perceived as incorrect by the computer software. The physicist was apparently able to override the computer rejection of the data, to continue with the procedure.

The floating point error is described as an error resident in the calculation code of the software platform, and is not a part of the LGP program. The licensee was assured by the software developers that, in the future, this error message would either cause the program to crash on the next command, or it would self-correct before the next command. None of the participants has been able to recreate this floating point error.

The licensee has implemented a policy that any computer error message, regardless of origin or seriousness, will require termination of the preparation for treatment. The software will not be overridden under any circumstances. A Quality Assurance (QA) Program has been instituted for angiographic images, including the use of proximal and distal markers. The physicist will personally observe the acquisition of the angiographic images. A policy has been implemented that no treatment will be based on angiographic images, alone. All treatment plans are sent to and verified by the Director of the Hospital of the Good Samaritan in Los Angeles, California.

Event 2: Medical Brachytherapy Misadministration at Mt. Sinai Medical Center in Miami Beach, Florida

Date Reported: December 3, 1993

Licensee: Mt. Sinai Medical Center, Miami Beach, Florida

On December 3, 1993, the State of Florida, Office of Radiation Control (ORC), was notified by phone that eight patients, with a total of 22 treatments, had received therapeutic exposure to parts of the body not scheduled to receive radiation. These exposures were delivered by a Nucletron Micro-Selectron high-dose-rate (HDR) remote afterloader brachytherapy treatment unit. The device used an iridium-192 (Ir-192) sealed source of approximately 300 gigabecquerel (8.1 curie), as of December 1, 1993. All the patients were receiving gynecological booster treatments after external beam radiotherapy.

The licensee reported that the misadministration was caused by the use of a 1.5-meter (4.9-foot) Obstetrical/Gynecological (OB/Gyn) transfer tube/applicator combination length instead of a 1.0-meter (3.3-foot) length, as intended. Seven of the eight patients were treated with a single transfer tube with an average exposure per treatment of 3.6 centigray (cGy) (3.6 rad). The exposures were given at approximately 51 centimeters (cm) (20 inches) from the intended site and outside of the patients' bodies, with the source being approximately 30 to 34 cm (12 to 13 in.) from the patients' knee areas. The licensee reported that no physical effects were observed or expected in these patients. One patient was treated with four catheters and one transfer tube per treatment. The transfer tube was used to treat the vaginal vault and the four shorter catheters were used to treat the interstitial tissues. Since the transfer tube was longer than the four interstitial catheters, it was looped over the patient's knee, for comfort. This patient developed skin erythema in this area, and a conservative estimated dose of 4000 to 6000 cGy (4000 to 6000 rad) to the knee area was calculated.

On the same day as the telephone report of the misadministration, an ORC inspector went to the licensee's facility to investigate the cause and ensure that immediate corrective actions were taken. The ORC inspector confirmed the two different size OB/Gyn transfer tubes, and ensured that immediate action was taken to segregate the tubes, and ensured that all transfer tubes were properly measured and marked. Since adequate actions were taken and the authorized user physician stated that it would be difficult and not advisable to switch from the HDR to other treatments for patients already undergoing HDR treatments, the licensee was allowed to complete the therapy on patients who were currently undergoing HDR treatments. These treatments have now been completed and the license has been temporarily amended to a "storage-only" status.

The investigation will continue with emphasis on determining the causes of the use of incorrect-length transfer tubes, and ensuring that the necessary corrective actions are in place before initiating any new HDR treatments.

The licensee's immediate corrective actions consisted of the following: (1) removed long transfer tubes from treatment room and made inaccessible; (2) requested Nucletron to place some type of identification on transfer tubes; (3) marked all existing transfer tubes in HDR room; (4) revised the procedure and checklist used to verify equipment set-up; (5) obtained an outside consultant to help review and modify the Quality Assurance Program, as needed; (6) scheduled retraining by Nucletron of all individuals involved in the use of the HDR; and (7) disallowed any new patient treatments on the unit.

INFORMATION NOTICES AND BULLETINS ISSUED

December 1993 - March 17, 1994

Note that these are only summaries of information notices and bulletins. If one of these publications appears relevant to your licensed operation and you have not received it, we recommend that you obtain the notices from the U.S. Regulatory Commission contact listed here, or speak with the contact about its provisions.

A. "Reporting Requirements for Bankruptcy," IN 93-100, December 22, 1993

Technical Contact: Kevin Ramsey, NMSS (301) 504-2534

This notice alerts licensees to the failure of some licensees to notify NRC when they filed for bankruptcy. Such failures have resulted in uncertainty as to the disposition of licensed material and have resulted also in cases of unlicensed trustees and creditors taking possession of radioactive material. Regulations in 10 CFR 30.34 (h), 50.54 (cc), 70.32 (a) (9), and 72.44 (b) (6) require each licensee to notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or of an involuntary petition for bankruptcy.

B. "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20," IN 94-07, January 28, 1994.

Technical Contacts: Rateb (Boby) Abu-Eid, NMSS (301) 504-3446
Cynthia G. Jones, NMSS (301) 504-2629

This notice emphasizes the changes in 10 CFR Part 20 (the new 10 CFR 20.2203 (a) (1)), with respect to liquid effluent releases to sanitary sewerage; discusses possible approaches to determining solubility; and recommends that any approach used be documented to demonstrate compliance with the regulations.

C. "Release of Patients with Residual Radioactivity from Medical Treatment, and Control of Areas due to Presence of Patients containing Radioactivity, Following Implementation of Revised 10 CFR Part 20," IN 94-09, February 3, 1994

Technical Contacts: Patricia K. Holahan, NMSS 301-504-2694
Catherine T. Haney, NMSS 301-504-2628

This information notice informs addressees of the Commission's intent for release of patients administered radioactive materials for diagnostic and therapeutic procedures. This applies to patients who have been confined pursuant to 10 CFR 35.75, or released following a diagnostic or therapeutic procedure that does not require the patient to be confined. There has been some concern, in the medical community, that a licensee, assuming compliance with 10 CFR 35.75 and other applicable Part 35 requirements, could be in violation of the revised Part 20. Specifically, release of a patient undergoing a medical procedure involving byproduct material could result in a member of the general public being exposed to radiation exceeding the dose limits specified in 10 CFR 20.1301(a). Since both a general regulation and a specific regulation of the Commission address the same subject (i.e., dose limits), the staff, in consultation with the Commission, has taken an interim position that the more specific regulation (10 CFR 35.75) prevails in this case.

Licensees should continue past practices regarding radiation exposure to individual members of the public from radioactive materials administered to patients, whether in-patients or out-patients. The provisions of 10 CFR 20.1301(a) should not be applied to radiation received by a member of the general public from patients released in accordance with 10 CFR 35.75 and other applicable requirements in Part 35. Furthermore, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a released patient containing byproduct material to 0.02 mSv (2 mrem) in any 1 hour. Patient waiting rooms or hospital rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75. Licensees are reminded that they must continue to comply with the dose limits to members of the general public in unrestricted areas adjacent to a restricted area (e.g., nuclear medicine imaging room, hot lab, posted patient room).

D. "Radiation Exposures during An Event Involving a Fixed Nuclear Gauge," IN 94-15, March 2, 1994

Technical Contacts: Judith A. Joustra, RI (215) 337-5257
Joseph E. DeCicco, NMSS (301) 504-2067

This notice alerts licensees to events, involving industrial gauges, that resulted, or may have resulted, in unnecessary radiation exposure to members of the public and licensee personnel. A level gauge at a glass factory containing approximately 5 curies of cesium-137 was subjected to severe heat that resulted in the loss of its lead shielding, producing a high radiation dose rate near the source housing. The source, mounted on an external surface of a furnace, was apparently damaged during an electrical outage, when the licensee operated the furnace with natural gas, creating a high operating temperature. In addition, an opening in the furnace wall adjacent to the source housing was covered by refractory board. The licensee did not consider the effect of extreme heat on the source housing before removing fire brick to make the opening and failed to follow its emergency procedures by not immediately notifying the RSO when leaking lead was first discovered. Individuals working near a gauge should be aware of the hazard, and any changes in the gauge surroundings, or the gauge itself, need to be reviewed by radiation safety personnel.

E. "Recent Incidents Resulting in Offsite Contamination," IN 94-16, March 3, 1994.

Technical Contacts: Roy Caniano, RIII (708) 829-9804
Joseph E. DeCicco, NMSS (301) 504-2067

This notice alerts licensees to three recent contamination incidents and their root causes. In each case, a laboratory was contaminated, individuals and personal property, both on and off the licensees' property, were contaminated, and access to the contaminated areas was restricted for more than 24 hours. In all three cases, the licensee initially stated that contamination was confined to the site and NRC special inspection teams and others, including the licensees, subsequently found widespread contamination offsite. The root cause of the cases described was one or a combination of the following: (1) inadequate training of the employee in the handling and use of radioactive material; (2) inadequate monitoring of persons and facilities where material was used; and (3) inadequate management oversight of licensed activities.

RULES PUBLISHED

December 1, 1993 - March 30, 1994

PROPOSED RULES

Radiation Protection Requirements; Amended Definitions and Criteria (Parts 19, 20)

1. Published: February 3, 1994, 59 FR 5132
2. Contact: Allan Roecklein, 301-492-3740

Standard for Certification of DOE Uranium Enrichment Gaseous Diffusion Facilities (Part 76)

1. Published February 1, 1994, 59 FR 6792
2. Contact: Charles Nilsen, 301-492-3834

Radiography and Radiation Safety Requirements for Radiography Operations (Part 34)

1. Published: February 28, 1994, 59 FR 9429
2. Contact: Donald Nellis, 301-492-3628

ADVANCE NOTICE OF PROPOSED RULEMAKING

Disposal by Release into Sanitary Sewerage (Part 20)

1. Published: February 25, 1994, 59 FR 9429
2. Contact: George Powers, 301-492-3747

REGULATORY GUIDES ISSUED

December 1, 1993 - March 30, 1994

FINAL GUIDE

Material Control and Accounting for Uranium Enrichment Facilities Authorized to Produce Special Nuclear Material of Low Strategic Significance, RG 5.67.

1. Issued: December 1993
2. Contact: Harry Tovmasssian, 301-492-3634

DRAFT GUIDE

Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators, DG-0003

1. Issued:. January 1994
2. Contact: Stephen McGuire, 301-4492-3757

A SAMPLING OF SIGNIFICANT ENFORCEMENT ACTIONS AGAINST MATERIAL LICENSEES

One way to avoid regulatory problems is to be aware of enforcement problems others have faced.

A. Individual Actions

George D. Shepherd IA 93-002

An Order Prohibiting Involvement in Certain U.S. Nuclear Regulatory Commission-Licensed Activities was issued October 27, 1993, to the above individual. The Order was based on the individual deliberately failing to: wear an alarm ratemeter, post boundaries, and perform radiation surveys of the exposure device and guide tube during the performance of radiographic operations on July 1, 1992. The Order prohibits the individual, for a period of 2 years, from performing, supervising, or engaging in any way in licensed activities under an NRC license, or an Agreement State license, when activities under that license are conducted in areas of NRC jurisdiction. For a period of 2 years after the prohibition, the individual shall be required to notify NRC of his employment by any person engaged in licensed activities under an NRC or Agreement State license, so that appropriate inspections can be performed. During that same period, the individual shall also be required to provide a copy of the Order to any person employing him and who holds an NRC license or an Agreement State license and performs licensed activities in an NRC jurisdiction.

B. Civil Penalties and Orders

1. City of Columbus, Columbus, Ohio
Supplement VI, EA 92-132

A Notice of Violation and Proposed Imposition of Civil Penalty was issued April 6, 1993, to emphasize the significance that NRC attaches to deliberate violations of Commission regulations and license requirements, and to emphasize that senior managers and supervisors must involve themselves in the radiation safety program. This action is based on the present Radiation Safety Officer's (RSO's) and two former RSOs' removal of source rods in moisture density gauges for cleaning, when the individuals were not authorized.

2. Edwards Pipeline Testing, Inc.,
Supplement VI, EA 93-015

A Notice of Violation and Proposed Imposition of Civil Penalty was issued September 1, 1993, to emphasize the unacceptability of the licensee's electing to remain in noncompliance with a requirement that is important to safety, and to ensure that the licensee's corrective actions are lasting. The action was based on repetitive willful failures to perform quarterly audits on radiography personnel. The licensee responded on September 28, 1993, requesting mitigation of the civil penalty. After consideration of the licensee's response, an Order Imposing Civil Monetary Penalty in the amount of $12,000 was issued December 6, 1993. The licensee paid the civil penalty on December 31, 1993.

3. Glendive Medical Center, Glendive, Montana
Supplement VI, EA 93-231

A Notice of Violation and Proposed Imposition of Civil Penalty was issued October 21, 1993, to emphasize the importance of ensuring that licensed activities are supervised and monitored in accordance with

NRC regulations and in the interest of ensuring safety. The action was based on the hospital conducting nuclear medicine activities without either an authorized user or radiation safety officer. The licensee responded and paid the civil penalty on November 16, 1993.

4. Hahnemann University,
Philadelphia, Pennsylvania
Supplement IV and VI, EA 93-249

A Notice of Violation and Proposed Imposition of Civil Penalty was issued November 17, 1993, to emphasize the importance of: (1) adequate implementation of the licensee's medical quality management program, and (2) aggressive management oversight of the radiation safety program. The actions were based on two violations that involved (1) a substantial failure to implement the Quality Management Program, and (2) the failure of the Radiation Safety Officer to ensure that certain specific requirements were met, thus representing a breakdown in the control of licensed activities at the facility.

5. N.V. Enterprises, Casper, Wyoming
Supplement IV, 93-033

A Notice of Violation and Proposed Imposition of Civil Penalty was issued May 7, 1993, to emphasize the importance of taking immediate action, on discovering a violation, to restore compliance with NRC requirements, and the importance of maintaining an awareness of all NRC requirements, particularly those that are designed to ensure the safety of radiography personnel and the public. The action was based on a Severity Level II violation involving the deliberate failure of the licensee to comply with the requirement that radiography personnel wear alarm ratemeters at all times during radiographic operations.

6. Tulsa Gamma Ray, Inc., Tulsa, Oklahoma
Supplement IV, EA 93-172

A Notice of Violation and Proposed Imposition of Civil Penalty was issued July 28, 1993, to emphasize the importance of maintaining control of radioactive material and the importance of effecting lasting corrective actions to prevent incidents of this type. The action was based on the loss of a radiography camera from a licensee vehicle. The camera was recovered by a member of the public and returned to the licensee within an hour of the incident.

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