



DEPARTMENT OF THE NAVY

NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

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Ser 31/ 02290
13 JUN '94

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM
INFORMATION NOTICE 94-04

- Encl:
- (1) U.S. Nuclear Regulatory Commission (NRC) Information Notice No. 94-07: Solubility criteria for liquid effluent releases to sanitary sewerage under the revised 10CFR Part 20
 - (2) U. S. Nuclear Regulatory Commission (NRC) Information Notice No. 94-16: Recent incidents resulting in offsite contamination
 - (3) U.S. Nuclear Regulatory Commission (NRC) Information Notice No. 94-17: Strontium-90 eye applicators: Submission of Quality Management Plan (QMP), calibration, and use operations are being performed.
 - (4) U.S. Nuclear Regulatory Commission (NRC) Information Notice No. 94-21: Regulatory requirements when no operations are being performed.

1. I am forwarding U.S. Nuclear Regulatory Commission Information Notices No. 94-07, 94-16, 94-17, and 94-21, enclosures (1) through (4) respectively, for your use.

2. Please review this information for applicability to your operations and distribute it to appropriate staff.

3. Further questions concerning this notice should be directed to Mr. P. D. Tveten, Radiation Health Department (NEHC-312), DSN 564-4657 or (804) 444-4657, Ext 227.

J. D. Campbell
J. D. CAMPBELL
By direction

Distribution:

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Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM
INFORMATION NOTICE 94-04

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A.T.

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

January 28, 1994

NRC INFORMATION NOTICE 94-07: SOLUBILITY CRITERIA FOR LIQUID EFFLUENT
RELEASES TO SANITARY SEWERAGE UNDER THE
REVISED 10 CFR PART 20

Addressees

All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to emphasize the changes in 10 CFR Part 20 with respect to liquid effluent releases to sanitary sewerage and to encourage you to prepare for these revisions.* It is expected that licensees will review this information for applicability to their operations, distribute it to appropriate staff, and consider actions to prepare for, and incorporate, these changes. Suggestions contained in this information notice are only recommendations; therefore, no specific action nor written response is required.

Background

On December 21, 1984, NRC released an information notice documenting several instances of reconcentration of radionuclides released to sanitary sewerage (IN No. 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303"). Several other instances have since occurred in Portland, Oregon; Ann Arbor, Michigan; Erwin, Tennessee; and Cleveland, Ohio. The primary contributors, in some of these cases, appear to have been insoluble materials released as dispersible particulates or flakes. This issue was addressed again on May 21, 1991, by NRC, when it published its revision of Part 20 in the Federal Register (56 FR 23360), which removed insoluble non-biological material from the types of material that may be released to sanitary sewerage. Relative to this issue, the NRC Office of Nuclear Regulatory Research is conducting a study to clarify the mechanisms underlying reconcentration in sanitary sewerage and sewage treatment facilities.

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* Sanitary sewerage is defined by 10 CFR 20.1003 as "a system of *public sewers* for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee [emphasis added]."

Description of Circumstances

To help prevent further reconcentration incidents at public sewage treatment facilities, 10 CFR 20.2003(a)(1), effective January 1, 1994, was written as follows:

§20.2003 Disposal by release into sanitary sewerage

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and...

However, this revision to Part 20 did not contain an operational definition of solubility, and this precipitated many questions, from licensees, concerning how the solubility of a material may be demonstrated. Without the ability to demonstrate compliance, these licensees were unable to determine whether new procedures should be developed, new treatment systems installed, or whether they should apply for an exemption, based on the principle of maintaining all doses as low as is reasonably achievable (ALARA).

Discussion

In some of the known reconcentration incidents, the greatest reconcentrations appear to have been due to compounds released to sanitary sewerage that were not soluble. There are many approaches that may be used to determine a chemical compound's solubility in water. The following discusses two of the more common approaches:

1. Direct Determination of Compound Solubility Class, Formal Solubility, or Solubility Product (K_{sp})

This approach would be applicable whenever there is sufficient knowledge of the chemical form of all materials contained in the liquid effluent at the point of release. With this knowledge, it would be possible to use one (or more) of the following methods:

(a) Solubility Class Determination:

The solubility class of the compound to be released could be determined directly from common literature data (e.g., *Handbook of Chemistry and Physics* - CRC Press, and *Lange's Handbook of Chemistry* - McGraw-Hill Book Company). If a compound is classified as "v s" (very soluble) or "s" (soluble), this would indicate the compound is "readily soluble." On the other hand, if it is classified as "i" (insoluble), "sl s" (slightly soluble), or "v sl s" (very slightly soluble), this would indicate materials that are "not readily soluble." Certain compounds are designated as class "d" (decompose). If the decomposed species of these compounds are classified as either "v s" or "s," this would indicate that the parent compound is "readily soluble." If these decomposed species are simple ions, such compounds (class "d") should be considered "readily soluble."

(b) Solubility Product (K_{sp}) Determination:

The solubility product constant of the compound could also be used to determine if a compound is readily soluble in water. The solubility product constant, K_{sp} , for a strong electrolyte M_mA_a , is expressed as:

$$K_{sp} = [M]^m [A]^a$$

where $[M]$ and "m" are the ionic concentration (mole/liter) and the number of moles, respectively, of the dissolved cation; and $[A]$ and "a" are the ionic concentration and the number of moles, respectively, of the dissolved anion.

For a simple electrolytic compound, with one mole of a dissolved cation species and one mole of a dissolved anion species, a K_{sp} greater than $1.00 \text{ E-}05 \text{ mole}^2/\text{liter}^2$ would indicate that a compound is "readily soluble." For other compounds with more complex dissolution reactions (i.e., more than one mole dissolved for each species and/or more anionic or cationic species present in the dissolved products), the K_{sp} constant would increase exponentially, based on the number of moles and/or the number of dissociated species. For example, if three moles are present (two for the anion and one for the cation), the unit of K_{sp} would be $\text{mole}^3/\text{liter}^3$, and the corresponding K_{sp} would be $(1 \text{ E-}05)^{3/2}$ or $3.2 \text{ E-}08 \text{ mole}^3/\text{liter}^3$; the same principle could be applied for more complex dissolution reactions.

(c) Formal Solubility Determination:

Compound solubilities (g/100 ml or mole fraction per 100 ml) are also listed in the chemical literature. From a review of general scientific literature, "formal solubilities"*** greater than 0.003 mole/liter would indicate that a compound is "readily soluble."

** The general relation between the formal solubility, S_f , and the solubility product, K_{sp} , of a strong electrolyte M_mA_a in water is given by:

$$S_f = \sqrt[m+a]{\frac{K_{sp}}{m^m a^a}}$$

where K_{sp} is the solubility product, $[M]$ is the molar concentration of the metal ion (cation), $[A]$ is the molar concentration of the anion, "m" is the number of moles of dissolved cation per mole of dissolved substance, and "a" is the number of moles of the dissolved anion per mole of dissolved substance.

For further discussion on the determination of solubility products and formal solubility, refer to Chapter 6, "Precipitation and Dilution," from Water Chemistry, by Vernon L. Snoeyink and David Jenkins (John Wiley and Sons: 1983) or texts relating to physical and/or analytical chemistry.

Formal solubilities less than 0.003 mole/liter would indicate compounds that are "not readily soluble."

It should be pointed out that all values mentioned above (e.g., solubility class, formal solubility, and solubility product) correspond to measurements taken under standard conditions (e.g., 25°C, 101.3 kPa, pH of 7, and E_h of 0).

2. Filtration and Radiometric Analysis of Suspended Solids

This approach may be used if knowledge of the chemical form of all materials contained in the liquid effluent at the point of release is incomplete. It is most applicable when releases are made in a batch mode. This approach involves the use of standard laboratory procedures to test representative samples of the waste stream for the presence of suspended radioactive material.

The following two laboratory procedures were developed specifically to determine the suspended solids content of water: ASTM Method D 1888-78, "Standard Test Methods for Particulate and Dissolved Matter, Solids, or Residue in Water," and the American Public Health Association's Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)" from Standard Methods for the Examination of Water and Wastewater. It should be noted that ASTM Method D 1888-78 was developed to measure the total suspended solids content of water, not just the radioactive portion. In either case, activity in the suspended solids portion of effluent greater than that found in similarly processed background water samples would indicate the presence of insoluble radioactive material.

Whether one of the above approaches or a self-developed alternative is used, it is a good health physics practice to document this approach in the form of a procedure. Procedures such as these usually include provisions for the documentation of any models, calculations, analytical measurements, and/or quality control measures used. This information is usually maintained with the applicable release records, to demonstrate that the developed procedure will ensure compliance with the regulations.

If material to be released would not qualify as being "readily soluble," 10 CFR 20.2003(a)(1) would prohibit release to sanitary sewerage unless an exemption has been granted. Exemptions will be judged on a case-by-case basis, when it is demonstrated that release to sanitary sewerage is in accordance with the ALARA principle, consistent with applicable regulations, and in the public interest.

It is expected that licensees will review this information for applicability to their operations, and consider actions, as appropriate to their licensed activities. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

If you have any questions about the information in this information notice, please contact one of the technical contacts listed below or the appropriate regional office.



Robert F. Burnett, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material
Safety and Safeguards



Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

Technical contacts: Rateb (Boby) Abu-Eid, NMSS
(301) 504-3446

Cynthia G. Jones, NMSS
(301) 504-2629

Attachments:

1. List of References
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

REFERENCES

Annual Book of ASTM Standards. Volume 11.01, "Water (I)." American Society for Testing and Materials, Easton, MD, 1989.

CRC Handbook of Chemistry and Physics. CRC Press, Inc., Boca Raton, FL, 65th ed, 1984.

Lange's Handbook of Chemistry. McGraw-Hill, Inc., New York, NY, 13th ed, 1985.

Snoeyink, Vernon L. and David Jenkins, Water Chemistry. John Wiley & Sons, Inc., New York, NY, 1980.

Standard Methods for the Examination of Water and Wastewater. American Public Health Association, Washington, DC, 17th ed, 1989.

LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.
93-80	Implementation of the Revised 10 CFR Part 20	10/08/93	All byproduct, source, and special nuclear material licensees.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.
93-69	Radiography Events at Operating Power Reactors	09/02/93	All holders of OLs or CPs for nuclear power reactors and all radiography licensees.
93-60	Reporting Fuel Cycle and Materials Events to the NRC Operations Center	08/04/93	All fuel cycle and materials licensees.
93-50	Extended Storage of Sealed Sources	07/08/93	All licensees authorized to possess sealed sources.
93-36	Notifications, Reports, and Records of Misadministrations	05/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-31	Training of Nurses Responsible for the Care of Patients with Brachytherapy Implants	04/13/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-30	NRC Requirements for Evaluation of Wipe Test Results; Calibration of Count Rate Survey Instruments	04/12/93	All U.S. Nuclear Regulatory Commission medical licensees.

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-06	Potential Failure of Long-Term Emergency Nitrogen Supply for the Automatic Depressurization System Valves	01/28/94	All holders of OLs or CPs for boiling water reactors.
93-85, Rev. 1	Problems with X-Relays in DB- and DHP-Type Circuit Breakers Manufactured by Westinghouse	01/20/94	All holders of OLs or CPs for nuclear power reactors.
94-05	Potential Failure of Steam Generator Tubes with Kinetically Welded Sleeves	01/19/94	All holders of OLs or CPs for pressurized water reactors (PWRs).
94-04	Digital Integrated Circuit Sockets with Intermittent Contact	01/14/94	All NRC licensees except licensed operators.
94-03	Deficiencies Identified during Service Water System Operational Performance Inspections	01/11/94	All holders of OLs or CPs for nuclear power reactors.
94-02	Inoperability of General Electric Magne-Blast Breaker Because of Misalignment of Close-Latch Spring	01/07/94	All holders of OLs or CPs for nuclear power reactors.
94-01	Turbine Blade Failures Caused by Torsional Excitation from Electrical System Disturbance	01/07/94	All holders of OLs or CPs for nuclear power reactors.
93-101	Jet Pump Hold-Down Beam Failure	12/17/93	All holders of OLs or CPs for boiling-water reactors.
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.

OL = Operating License
 CP = Construction Permit

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

March 3, 1994

NRC INFORMATION NOTICE 94-16: RECENT INCIDENTS RESULTING IN OFFSITE
CONTAMINATION

Addressees

All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.

Purpose

NRC is issuing this information notice to alert licensees of recent contamination incidents and their root causes. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, information contained in this notice does not constitute a new requirement, and no specific action nor written response is required.

Description of Circumstances

Recently, NRC responded to three radioactive material contamination incidents, which resulted in contamination of both individuals and personal property, both on and off the licensees' property, and which required access to the contaminated areas to be restricted for more than 24 hours. Two of the cases summarized below occurred at large universities and one occurred at a large medical facility. All have resulted in escalated enforcement actions involving fines.

Case 1: The licensee notified NRC that a contamination event involving phosphorus-32 (P-32) had occurred at the facility, contaminating several floors of a research building. A graduate student, working on the weekend, using P-32, accidentally and unknowingly contaminated the floor of the laboratory with 3.7 to 18.5 megabecquerels (100 to 500 microcuries) of the material. He failed to survey himself or the laboratory before leaving, as required by the licensee's procedures. His actions resulted in the widespread contamination of the laboratory building and of private residences, clothing, and vehicles. The licensee reported the event after it was clear that the research building decontamination work was going to extend beyond 24 hours, and that the facility would have to remain restricted. In the licensee's verbal report, it assured NRC that the contamination was confined to the research building. NRC dispatched a special inspection team to the site, and in the process of conducting confirmatory surveys, off-site contamination was identified. The licensee focused its efforts on the decontamination of the laboratory, and failed to perform an adequate assessment of possible offsite contamination. Contributing causes of this

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contamination event were: 1) failure of a student researcher to exercise appropriate precautions in the handling of licensed materials; 2) failure to conduct personnel surveys; 3) inadequate training or supervision by the authorized user; 4) failure to conduct performance-oriented audits of the licensee's authorized users; and 5) failure of the Radiation Safety Staff to properly analyze and respond to the event.

Case 2: NRC became aware of a potential contamination problem and called the licensee to determine if a problem did exist. The licensee confirmed that a contamination event had occurred involving carbon-14 (C-14) in a research building, but that it was confident that no contamination had left the building. NRC dispatched a special inspection team to the site. While the team was traveling to the site, the licensee discovered that the contamination occurred because a researcher, looking for materials for an experiment, unknowingly contaminated himself and some personal effects with C-14. The individual was not aware that he had handled radioactive material because the material was improperly stored in an unrestricted area, in an unmarked container. Surveys conducted by the licensee, NRC, three States, other universities, and a U.S. Department of Energy laboratory, identified that the individual unknowingly spread the contamination throughout the facility, to residences he visited, to automobiles, and to his private residence. In addition, other personnel who had entered the facility contaminated their shoes. Contributing causes of this contamination event were: 1) the improper storage of the material which was caused, in part, by 2) an inadequate inventory system that did not identify the presence of long-lived licensed material in an unrestricted area; 3) improper labelling; and 4) inadequate training for staff responsible for storage.

Case 3: A contamination event occurred when a post-graduate student came into a laboratory to do some work involving P-32, on the weekend. He failed to survey, because of an inoperative survey meter, and left the laboratory, having contaminated himself with P-32. When the contamination was discovered, the licensee focused on the contaminated individual and the laboratory. The licensee called to inform NRC that it was sending a report documenting a P-32 contamination event that had occurred at the facility approximately 10 days earlier. The licensee indicated that there had been personnel contamination, but that no offsite contamination had occurred. NRC dispatched a special inspection team to the facility. Confirmatory surveys conducted by the licensee and this team identified offsite contamination in a church, several residences, and in automobiles. Contributing causes of this event were: 1) the licensee failed to respond properly to a recognized spill; 2) the licensee failed to perform an adequate survey of all the possible locations where the individual had been during the interim period

after the contamination event; 3) the licensee failed to follow proper, established survey procedures; 4) there was inoperative equipment; and 5) inadequate training of staff.

Discussion

In the cases described above, the root cause 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.

Training had been provided to the user of the material, in most cases, but it was either inadequate or ignored. Site-specific training should include proper survey techniques and correct response to contamination events, and should be strongly emphasized through retraining programs.

General requirements for monitoring are contained in 10 CFR 20.1501. In specific cases, licensees have not discovered the spread of contamination, because of inadequate surveys, until days, or sometimes weeks, after the original incident occurred. The person using the material did not check for personal contamination before leaving the laboratory, and routine surveys of the area were not conducted in time to prevent widespread contamination.

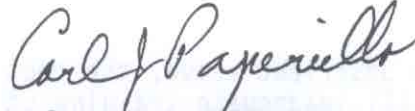
Regulations also require licensed materials to be properly stored and labeled; proper labeling could have prevented some of the above, by alerting personnel to the existence of radioactive material and to the necessity of following radiation safety procedures and survey requirements.

When a spill does occur, it is important that the licensee respond properly to the event. A rush to resume normal activities should be avoided. The lack of sufficient technical personnel for proper offsite assessment may complicate an already undesirable situation. The possibility of offsite contamination should be considered in the evaluation of a spill or contamination, and in a subsequent decontamination plan.

In two of the cases detailed above, licensees failed to notify the NRC Operations Center within 24 hours, as required by 10 CFR 30.50, after the discovery of an unplanned contamination event that required access to the contaminated area to be restricted for more than 24 hours. The notification requirements of 10 CFR 30.50, 40.60, and 70.50, are in addition to 10 CFR 20.2202, involving personnel exposure and releases of radioactive material. The NRC Operations Center telephone number is (301) 951-0550; it is available 24 hours a day.

Each licensee is responsible for protecting the public health and safety by ensuring that all NRC requirements are met, and any potential hazards are promptly identified, corrected, and, if necessary, reported. This responsibility can only be fulfilled if there is persistent and adequate management oversight of licensed activities.

This information notice requires no specific action nor written response. If you have questions about the information in this notice, please contact the technical contact listed below, or the appropriate regional office.



Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
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Technical contacts: Roy Caniano, RIII
(708) 829-9804

Joseph E. DeCicco, NMSS
(301) 504-2067

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-09	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	02/03/94	All U.S. Nuclear Regulatory Commission medical licensees.
94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20	01/28/94	All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.
93-80	Implementation of the Revised 10 CFR Part 20	10/08/93	All byproduct, source, and special nuclear material licensees.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.
93-69	Radiography Events at Operating Power Reactors	09/02/93	All holders of OLs or CPs for nuclear power reactors and all radiography licensees.

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-14	Failure to Implement Requirements for Biennial Medical Examinations and Notification to the NRC of Changes in Licensed Operator Medical Conditions	02/24/94	All holders of OLs or CPs for nuclear power and non-power reactors and all licensed reactor operators and senior reactor operators.
92-36, Supp. 1	Intersystem LOCA Outside Containment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-13	Unanticipated and Unintended Movement of Fuel Assemblies and Other Components due to Improper Operation of Refueling Equipment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-12	Insights Gained from Resolving Generic Issue 57: Effects of Fire Protection System Actuation on Safety-Related Equipment	02/09/94	All holders of OLs or CPs for nuclear power reactors.
94-11	Turbine Overspeed and Reactor Cooldown during Shutdown Evolution	02/08/94	All holders of OLs or CPs for nuclear power reactors.
94-10	Failure of Motor-Operated Valve Electric Power Train due to Sheared or Dislodged Motor Pinion Gear Key	02/04/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
 CP = Construction Permit

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

March 11, 1994

NRC INFORMATION NOTICE 94-17: STRONTIUM-90 EYE APPLICATORS:
SUBMISSION OF QUALITY MANAGEMENT
PLAN (QMP), CALIBRATION, AND USE

Addressees

All U.S. Nuclear Regulatory Commission Medical Use Licensees.

Purpose

The NRC is issuing this Information Notice to remind licensees authorized to possess Sr-90 for authorized uses described in 10 CFR 35.400(e) of the need to: (1) implement and submit a quality management plan (QMP) that includes policies and procedures to meet the requirements described in 10 CFR 35.32; and (2) inform all licensees of recent information regarding the use and calibration of Sr-90 eye applicators.

Description of Circumstances

There has been confusion as to the need for a QMP for Sr-90 eye applicators used for patient treatment procedures. The NRC's Office of the General Counsel advised the technical staff that because the QM program requirements in 10 CFR 35.32 apply to "any brachytherapy dose," the use of Sr-90 eye applicators, as described in 10 CFR 35.400(e), requires submission of a QMP. This Information Notice reminds Sr-90 eye applicator licensees of the requirement to submit and implement a QMP that meets the requirements of 10 CFR 35.32.

Additionally, this letter alerts licensees to possible discrepancies associated with the calibration of Sr-90 eye applicators and reminds licensees of the regulatory requirements associated with their calibration and use.

Discussion

Submission of a Quality Management Plan

If you are licensed for and using a Sr-90 eye applicator, the NRC's regulations require you to submit a QMP that meets the requirements of 10 CFR 35.32. The QMP should provide high confidence that radiation from the Sr-90 eye applicator will be administered as directed by the authorized user. The submitted QMP should include written policies and procedures that meet the five objectives, as described in 10 CFR 35.32(a):

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1. That prior to administration, a written directive, signed and dated by an authorized user, is prepared for each applicable administration.

(A written directive for Sr-90 eye-applicators means an order, in writing, for a specific patient, dated and signed by an authorized user prior to administration of radiation. It must include the radioisotope, the treatment site, source strength (corrected for decay), and exposure time (or equivalently, the total dose).

2. That prior to each administration, the patient is identified by more than one method as the individual named in the written directive.
3. That final plans of treatment and related calculations are in accordance with the respective written directive.
4. That each administration is in accordance with the written directive.
5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action taken.

Additionally, to meet the requirements of 10 CFR 35.32(b), you need policies and procedures for conducting a review of the QMP to verify compliance of all aspects of the program at intervals no greater than 12 months. The review is to include a representative sample of patient administrations, all recordable events and all misadministrations, and any corrective actions taken.

Licensees may make modifications to their QMPs to increase the program's efficiency provided the program's effectiveness is not decreased. 10 CFR 35.32(e) requires licensees to submit modifications to their QMP to the appropriate NRC regional office within 30 days after the modification has been made.

If you are licensed for a Sr-90 eye applicator, but are not, or do not intend to use it, you may submit a "negative declaration" in lieu of a QMP. This written declaration must commit to your submission of a QMP to NRC prior to use of the Sr-90 eye applicator for patient treatment procedures.

Calibration and Use of Strontium-90 Eye applicators

The NRC staff has had discussions with and received correspondence from researchers at the National Institute of Standards and Technology (NIST) about large discrepancies among calibrated outputs assigned to Sr-90 eye applicators. The manufacturer's original calibrations may have been in units that are no longer used or have little relationship to System Internationale units in use today. Further, comparisons between units from different manufacturers may be meaningless and misleading. Finally, discrepancies larger than 10 percent still exist when comparing output measurements between competent measurement labs using state-of-the-art techniques.

The above information was provided to NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) at its November 1 and 2, 1993, meeting. The ACMUI members advised the staff that calibration was not a critical factor in the use of Sr-90 eye applicators for treating pterygium because licensees treat for response rather than to tolerance. The ACMUI recommended that NRC inform licensees of the potential problems associated with calibration of Sr-90 eye applicators. The Committee also recommended cautioning licensees that if they use an applicator, other than the one currently in their possession or buy a new one, their current technique may not be applicable to another device because of variances in stated and actual exposure rates for the different applicators.

NIST offers a service for the calibration of Sr-90 eye applicators that provides: (1) the calculation of the emission rate, and (2) a mapping of the Sr-90 distribution across the face of the applicator in order to ascertain uniformity of dose. For further information on the NIST calibration service, contact either Dr. Christopher Soares at (301) 975-5589 or Dr. Bert Coursey at (301) 975-5584. Although NIST is, to the best of the staff's knowledge, the only provider of such a service, there may be others. NRC is not requiring that licensees participate in the NIST program, and accepts calculations of exposure time based on the original vendor's calibration, corrected for radioactive decay.

Since 10 CFR 35.400(e) identifies the Sr-90 eye applicator as a brachytherapy device, licensees are reminded that 10 CFR 35.59, "Requirements for possession of sealed sources and brachytherapy sources," does apply to Sr-90 eye applicators. Specifically, licensees must perform applicable leak tests and surveys described in 10 CFR 35.59. Additionally, 10 CFR 35.400(e) limits the use of Sr-90 eye applicators to "treatment of superficial eye conditions." Licensees are reminded that NRC authorization for use of a Sr-90 eye applicator for patient procedures does not authorize its use on treatment sites other than the eye.

This Information Notice requires no specific action or written response. If you have questions about the information in this notice, please contact the appropriate technical contact listed below.



Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Jim Dwyer, RI (215) 337-5309
Jacqueline Burks, RIV (817) 860-8132
John Pelchat, RII (404) 331-5083
James Montgomery, RV (510) 975-0249
Cassandra Frazier, RIII (708) 790-5704
Sally L. Merchant, NMSS (301) 504-2637

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-09	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	02/03/94	All U.S. Nuclear Regulatory Commission medical licensees.
94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20	01/28/94	All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.
93-80	Implementation of the Revised 10 CFR Part 20	10/08/93	All byproduct, source, and special nuclear material licensees.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.

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NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-14	Failure to Implement Requirements for Biennial Medical Examinations and Notification to the NRC of Changes in Licensed Operator Medical Conditions	02/24/94	All holders of OLs or CPs for nuclear power and non-power reactors and all licensed reactor operators and senior reactor operators.
92-36, Supp. 1	Intersystem LOCA Outside Containment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-13	Unanticipated and Unintended Movement of Fuel Assemblies and Other Components due to Improper Operation of Refueling Equipment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-12	Insights Gained from Resolving Generic Issue 57: Effects of Fire Protection System Actuation on Safety-Related Equipment	02/09/94	All holders of OLs or CPs for nuclear power reactors.
94-11	Turbine Overspeed and Reactor Cooldown during Shutdown Evolution	02/08/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

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

March 18, 1994

NRC INFORMATION NOTICE 94-21: REGULATORY REQUIREMENTS WHEN NO OPERATIONS ARE BEING PERFORMED

Addressees

All fuel cycle and materials licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to remind addressees that all regulatory requirements must be satisfied even when no operations are being performed. It is expected that recipients will review this information for applicability to their operations and consider actions, as appropriate, to avoid violations of regulatory requirements.

Description of Circumstances

On June 26, 1990, NRC received allegations of safety violations concerning a service company that was licensed to handle and transport radioactive material for its customers. During a followup NRC investigation, the licensee claimed that it was working under the license of its customers, and not under its own license. The licensee viewed its license as "inactive" because activities were not being performed under that authorization. After an extensive investigation, the licensee was cited for seven violations including failure to have an NRC-approved radiation safety officer (RSO) for a period of time, and failure of the radiation safety committee to review all licensed activities.

Discussion

NRC issues licenses for many types of operations, including service companies that may only perform licensed activities for short periods of time at temporary job sites. Many licensees experience slow periods where their workers are inactive, but there is no such thing as an inactive license. Most licenses have a condition similar to the following:

"Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The NRC's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(Application and correspondence listed chronologically.)"

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The radiation safety programs required by NRC regulations and license conditions must be maintained in an active state while the license is in effect. Without a license amendment, a licensee may not suspend required radiation safety programs and then attempt to re-establish these programs at a later date. The license must be amended to authorize such program changes. Licensees should remain competent to undertake activities authorized by their license if they want to maintain their authorization to perform those activities.

Actions to maintain an active radiation safety program include the following:

- A. Maintaining qualified personnel in key positions (i.e., RSO, radiation safety committee members, etc.).
- B. Holding required safety committee meetings.
- C. Performing required maintenance and calibration of safety equipment.
- D. Completing required training (including periodic retraining).
- E. Maintaining required signs, labels, and postings.
- F. Completing required monitoring and surveillance.
- G. Maintaining required records.

This information notice requires no specific action or written response. It is expected that recipients will consider actions, as appropriate, to avoid violations of regulatory requirements. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.



Robert F. Burnett, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards



Carl J. Paperie, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Kevin M. Ramsey, NMSS
(301) 504-2534

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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-17	Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use	03/11/94	All U.S. Nuclear Regulatory Commission Medical Use Licensees.
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-09	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	02/03/94	All U.S. Nuclear Regulatory Commission medical licensees.
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NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-20	Common-Cause Failures due to Inadequate Design Control and Dedication	03/17/94	All holders of OIs or CPs for nuclear power reactors.
94-19	Emergency Diesel Generator Vulnerability to Failure from Cold Fuel Oil	03/16/94	All holders of OIs or CPs for nuclear power reactors.
94-18	Accuracy of Motor-Operated Valve Diagnostic Equipment (Responses to Supplement 5 to Generic Letter 89-10)	03/16/94	All holders of OIs or CPs for nuclear power reactors.
94-17	Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use	03/11/94	All U.S. Nuclear Regulatory Commission Medical Use Licensees.
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-14	Failure to Implement Requirements for Biennial Medical Examinations and Notification to the NRC of Changes in Licensed Operator Medical Conditions	02/24/94	All holders of OIs or CPs for nuclear power and non-power reactors and all licensed reactor operators and senior reactor operators.

OL - Operating License
CP - Construction Permit

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