State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Radiation Protection

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
Dayne H. Brown, Director

DEHNR

April 14, 1994 DRP INFORMATION NOTICE 94-01

ALL NORTH CAROLINA BROAD SCOPE LICENSEES

Enclosed you will find three documents that are issued from the Division of Radiation Protection, Radioactive Materials Section.

The first document is a copy of a Presidential Memorandum to the Vice President and the Heads of Executive Departments and Agencies dated February 17, 1994, addressing the Review of Federal Policy for the Protection of Human Subjects. President Clinton directs each department and agency of Government to review present practices to assure compliance with this Federal Policy and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

The next two documents are information notices issued by the United States Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards. These documents address the solubility criteria for liquid effluent released to the sanitary sewerage under the revised 10 CFR Part 20 and the 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.

If any questions arise regarding this information or the North Carolina Rules and Regulations that correspond to 10 CFR Part 20 & 35, please contact this office.

Wendy B Tingle

Wendy B. Tingle, Health Physicist
Division of Radiation Protection
Radioactive Materials Section

Enclosure:
As stated

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THE WHITE HOUSE

WASHINGTON

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT
THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

SUBJECT: Review of Federal Policy for the Protection of Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by departments and agencies. Therefore, I direct each department and agency of Government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

William J. Clinton

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

February 3, 1994

NRC INFORMATION NOTICE NO. 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

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

NRC is issuing this information notice to notify addressees of the Commission's intent for release of patients pursuant to 10 CFR 35.75. It is expected that licensees will review this information for applicability to their operations and distribute it to appropriate staff. The information contained in this notice does not include new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

NRC's current patient release criteria, adopted in 1986, are contained in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants." Specifically, this section states:

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems (mrem) per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries (mCi).

(b) A licensee may not authorize the release from confinement for medical care of any patient administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of one meter.

In the discussion of the proposed 10 CFR 35.75 in 1985, the Commission stated that the proposed limits (30 millicuries (mCi) of activity or 6 milliroentgens per hour dose rate at 1 meter, based on the exposure rate from 30 mCi iodine-131), provided an "... adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable

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considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement." Subsequently, the 1986 Statements of Consideration for the revision to 10 CFR Part 35 discuss that the release criteria, specified in 10 CFR 35.75 (30 mCi of residual activity or 5 millirems per hour (mrem/hr) dose rate at 1 meter) are based, in part, on the considerations addressed in NCRP Report No. 37, "Precautions in the Management of Patients who Have Received Therapeutic Amounts of Radionuclides." Again, the Commission reiterated that the release limit provided an adequate measure of public health and safety.

On May 21, 1991, NRC published a final rule (56 FR 23360) that amended 10 CFR Part 20, "Standards for Protection Against Radiation." Licensees are required to implement the revised Part 20 by January 1, 1994. 10 CFR 20.1301(a) requires, in part, that a licensee conduct operations so that: 1) the total effective dose equivalent to any individual member of the public from licensed activities does not exceed 1 millisievert (mSv) (0.1 rem) in a year; and 2) the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. 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, in releasing, from confinement, a patient containing byproduct material, could be in violation of the revised Part 20, if the dose limits specified in 10 CFR 20.1301(a) are exceeded as a result of radiation emitted from a patient undergoing a medical procedure.

Discussion

The adoption of 10 CFR 35.75 in 1986 was based on an independent NRC public health and safety judgment specific to patient release, and was neither tied to, nor designed to implement, the more general Part 20 dose limits that were later revised in 1990. When Part 20 was revised, there was no discussion in the "Statements of Consideration" on whether or how the provisions of 10 CFR 20.1301 would apply to the release of patients. Since a general and a specific regulation of the Commission both address the same subject, the staff, in consultation with the Commission, has taken an interim position that the more specific regulation prevails in this case, pending action to formally resolve the issue in response to pending rulemaking petitions.

Therefore, licensees should continue past practices regarding radiation exposure to individual members of the public from radioactive materials administered to patients, whether inpatients or outpatients. 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 from confinement in accordance with 10 CFR 35.75 and other applicable requirements in Part 35. Furthermore, if a patient is not required to be confined, pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms or hospital rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

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

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

Technical contacts: Patricia K. Holahan, NMSS
(301) 504-2694

Catherine T. Haney, NMSS
(301) 504-2628

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

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 E-05 mole^2/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 mole^3/liter^3, and the corresponding K_{sp} would be $(1\ E\text{-}05)^{3/2}$ or 3.2 E-08 mole^3/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
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Attachments:
1. List of References
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices