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Rev. 1

Health Physics Positions Data Base

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Prepared for
U.S. Nuclear Regulatory Commission

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ABSTRACT

The Health Physics Positions (HPPOS) Data Base of the Nuclear Regulatory Commission (NRC) is a collection of NRC staff positions on a wide range of topics involving radiation protection (health physics). It consists of 328 documents in the form of letters, memoranda, and excerpts from technical reports. The HPPOS Data Base was developed by the NRC Headquarters and Regional Offices to help ensure uniformity in inspections, enforcement, and licensing actions.

Staff members of the Oak Ridge National Laboratory (ORNL) have assisted the NRC staff in summarizing the documents during the preparation of this NUREG report. These summaries are also being made available as a "stand alone" software package for IBM and IBM-compatible personal computers. The software package for this report is called HPPOS Version 2.0. A variety of indexing schemes were used to increase the usefulness of the NUREG report and its associated software. The software package and the summaries in the report are written in the context of the "new" 10 CFR Part 20 (§§20.1001 - 20.2401).

The purpose of this NUREG report is to allow interested individuals to familiarize themselves with the contents of the HPPOS Data Base and with the basis of many NRC decisions and regulations. The HPPOS summaries and original documents are intended to serve as a source of information for radiation protection programs at nuclear research and power reactors, nuclear medicine, and other industries that either process or use nuclear materials.

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FOREWORD

Health physics positions are Nuclear Regulatory Commission (NRC) staff positions on NRC regulatory requirements and guidance for radiation protection (health physics). Documents that contain health physics positions include NRC memoranda, letters, information notices and generic letters. The Health Physics Positions Data Base (HPPOS) is a compilation of summaries of the health physics positions and a categorization of those positions. This data base was developed and is being maintained primarily for use by regional inspectors in an effort to maintain consistency in the NRC inspection program in the area of radiation protection (health physics).

Health physics positions originated within the headquarters group responsible for the inspection program in the area of radiation protection in the NRC's predecessor agency, the Atomic Energy Commission (AEC). Inevitably, inspectors in the field raised questions concerning the applicability of AEC regulatory requirements to specific situations found at AEC-licensed facilities and the AEC headquarters group was asked to answer these questions. An early prototype of today's Health Physics Positions Data Base appears in the form of "discussions" of pertinent parts of the regulations in a December 1, 1959 Draft AEC Manual Appendix 0705 "Guide for Inspection of Materials Licensees."

With the formation of the Nuclear Regulatory Commission in 1975, programmatic responsibility for the inspection program resided in the Office of Inspection and Enforcement (IE) until it was abolished and its functions divided between the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Material Safety and Safeguards (NMSS) in 1987. During the late 1970s and early 1980s, IE initiated efforts to ensure more consistency in the inspection program. At that time, there was no central repository of health physics positions, although some of these positions had been placed in Chapter 9900 of the Inspection Manual as "Interpretive Guides."

In the early 1980s, an NRC contractor contacted cognizant NRC radiation protection staff members in all regional offices and IE to obtain copies of documents those individuals believed contained health physics positions. These documents were screened for current relevance, summarized, and categorized by the radiation protection staff of IE. The initial consolidation of these positions was completed in about 1984. During this time period, personal computer software was developed to provide a computerized data base of the summaries of the health physics positions. This computerized data base can be searched by subject, regulatory reference and author. Personal computer diskettes containing this data base were first sent to NRC Regional Offices in February, 1986.

On April 3, 1987, Inspection Procedure 9910, "Health Physics Positions" was added to the Inspection Manual. (The last revision of this document was issued on 2/19/91.) This procedure describes the HPPOS Data Base computer program and provides instructions for using that program. The procedure also includes the following standards for inclusion of documents in the data base:

(a) The document contains unique (not otherwise available) guidance which inspectors can use in the NRC inspection program (for reactors, fuel facilities, and materials licensees) or contains a position on a regulatory requirement applicable to matters encountered by NRC inspectors who specialize in radiation protection or by NRC materials licensing reviewers.

(b) The document is a final version that has been signed, dated and issued.

(c) The document has been signed by, or has the concurrence of, an appropriate level of NRC management or by a representative of the NRC Office of the General Council (OGC).

(d) If the document raises an issue that is subject to the NRC backfit rule (10 CFR 50.109), then the matter has been properly addressed through the applicable NRC backfit procedures.

A few exceptions to the above standards have been made on a case-by-case basis. For example, the data base contains an interpretation of the American National Standard (ANS-3) by the committee that prepared the standard.

Although maintained by the Radiation Protection Branch in NRR, the HPPOS Data Base also is used by NMSS and includes positions provided by NMSS. Copies of the positions, including the summaries on personal computer diskette and copies of the original documents, are available at all five NRC Regional Offices and the NRC Technical Training Center in Chattanooga, as well as at the NRC Headquarter Offices of NRR, NMSS, Nuclear Regulatory Research (RES), Office of State Programs, and Office of Enforcement (OE). After the positions were released to a reactor licensee in response to a Freedom of Information Act (FOIA) request in early 1989, all of the positions were placed in the NRC Public Document Room.

Health physics positions continue to be developed by the radiation protection staffs in NRR and NMSS in the course of fulfilling their responsibilities to provide NRC Headquarters direction and guidance to the Regional Offices in their implementation of the NRC inspection program (and the materials licensing program in the case of NMSS). Usually, a health physics position originates as a specific question or issue concerning regulatory requirements that is referred by a region to NRR or NMSS for resolution. If the issue is determined to be applicable to other licensees and is likely to be questioned by other inspectors, the issue is considered generic and is considered for incorporation into HPPOS. Under current practice, the cognizant headquarters office (NRR or NMSS) drafts a response for resolution of the issue and sends a copy of the draft to all NRC Regional Offices and to other NRC Headquarter Offices, as appropriate, for review and comment before the final position document is prepared. When the issue concerns a requirement applicable to all licensees (e.g., the implementation of a provision of 10 CFR Part 20), the draft is reviewed by NMSS (when the draft is prepared by NRR), NRR (when the draft is prepared by NMSS) and RES, as well as all Regional Offices. When the draft position has potential applicability to enforcement actions, it is sent to OE for review. When the draft position may be considered to be an interpretation of the regulations, it is sent to OGC for review. When there is a change or a perceived change to a previous position, the draft is sent to the Chairman of the Committee to Review Generic Requirements (CRGR) to determine whether formal CRGR review is needed.

Before being included in the HPPOS Data Base, a position document must meet the standards given in the inspection manual as outlined above. The summary of each position is reviewed by two or more senior health physicists before being added to the data base.

Upon implementation of the new major revision of 10 CFR Part 20, many of the existing positions that referred to Part 20 will no longer be applicable and need to be deleted. Other positions must be revised to refer to sections of the "new" Part 20 that corresponded to the sections of the "old" Part 20 referred to in the positions. These changes have been made to the summaries included in this revision; however, the original documents have not been, and will not be, revised. The NRC radiation protection staff welcomes public comments on these positions. It should be noted that the summaries contained in this NUREG are only meant to provide an overview of the contents of the original document and the positions reflected are not binding on the NRC or any NRC licensee. Any questions, statements or points of order concerning a position must be addressed from the standpoint of the original document. Furthermore, the original documents do not constitute official legal interpretations, which can only be provided by the General Council, and they do not reflect official NRC policy as approved by the Commission. The positions do reflect NRC staff decisions and technical opinions on specific aspects of regulatory requirements.

LeMoine J. Cunningham, Chief
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Division of Radiation Safety and Safeguards
Office of Nuclear Reactor Regulation

ABBREVIATIONS AND ACRONYMS

AAPM	-	American Association of Physicists in Medicine
ABHP	-	American Board of Health Physics
ABR	-	American Board of Radiology
ACMUI	-	Advisory Committee on Medical Use of Isotopes
ACNW	-	Advisory Committee on Nuclear Waste
AD	-	Alarm Dosimeter
AEA	-	Atomic Energy Act
AEC	-	Atomic Energy Commission
AEOD	-	Office for Analysis and Evaluation of Operational Data, NRC
AITS	-	Action Item Tracking System
ALAB	-	Alabama Administrative Board
ALARA	-	As Low As Reasonably Achievable
ANI	-	American Nuclear Insurers
ANPR	-	Advanced Notice of Proposed Rulemaking
ANO	-	Arkansas Nuclear One
ANS	-	American Nuclear Society
ANSI	-	American Nuclear Standards Institute
APA	-	Administrative Procedure Act
AP&L	-	Arkansas Power and Light Company
ASNL	-	American Society of Nuclear Technicians
ASTM	-	American Society for Testing and Materials
BRC	-	Below Regulatory Concern
BTP	-	Branch Technical Position
BWR	-	Boiling Water Reactor
C&D	-	Cross-check and Document
CDC	-	Centers for Disease Control
CFM	-	Cubic Feet Per Minute (also, cfm)
CFR	-	Code of Federal Regulations
CNSRB	-	Corporate Nuclear Safety Review Board
CTP	-	Continuous Training Program
CTR	-	Cathode Ray Tube
DAC	-	Derived Air Concentration
DBER	-	Division of Biological and Environmental Research, NRC
DE	-	Department of Energy, U.S.
DFP	-	Decommissioning Funding Plan
DOE	-	Department of Energy, U.S.
DOL	-	Department of Labor, U.S.
DOP	-	Dioctyl Phthalate
DOR	-	Division of Operating Reactors, NRC
DOT	-	Department of Transportation, U.S.
DPM	-	Disintegrations Per Minute (also, dpm)
DRD	-	Direct Reading Dosimeter
DU	-	Depleted Uranium
EDO	-	Executive Director for Operations, NRC
EEI	-	Edison Electric Institute
EGM	-	Enforcement Guidance Memorandum
EI	-	Enforcement and Investigations, NRC
ELD	-	Executive Legal Director, NRC
EPA	-	Environmental Protection Agency
EPRI	-	Electric Power Research Institute
ESTSC	-	Energy Science and Technology Software Center, DOE
FAA	-	Federal Aviation Administration
FDA	-	Food and Drug Administration
FEMA	-	Federal Emergency Management Administration
FES	-	Final Environmental Statement
FOB	-	Free On Board
FOIA	-	Freedom of Information Act
FR	-	Federal Register
FSAR	-	Final Safety Analysis Report
FTC	-	Federal Trade Commission
GAO	-	Government Accounting Office, U.S.
GC	-	General Counsel, NRC
GM	-	Gieger-Müller (tube or detector)
GMR	-	Gas Mask Respirator
GPA	-	Office of Government and Public Affairs, NRC
HEPA	-	High Efficiency Particulate (filters)
HMR	-	Hazardous Material Regulation
HP	-	Health Physics or Health Physicist
HPO	-	Health Physics Office
HPPOS	-	Health Physics Position
HPS	-	Health Physics Society
HPT	-	Health Physics Technician or HP Tech
HRA	-	High Radiation Area
HRNG	-	High Range Noble Gas (monitor)
HQ	-	Headquarters, NRC
IAEA	-	International Atomic Energy Agency
IAL	-	Immediate Action Letter
ICAO	-	International Civil Aviation Organization

ICRP	-	International Commission on Radiological Protection
IDLH	-	Immediately Dangerous to Life and Health
IE	-	Office of Inspection and Enforcement, NRC
IEC	-	IE Circular
IEIN	-	IE Information Notice
IN	-	Information Notice
INEL	-	Idaho National Engineering Laboratory
INPO	-	Institute of Nuclear Power Operations
LANL	-	Los Alamos National Laboratory
LCD	-	Liquid Crystal Display
LCO	-	Limiting Conditions for Operation
LED	-	Light Emitting Diode
LLD	-	Lower Limit of Detection
LLNL	-	Lawrence Livermore National Laboratory
LLW	-	Low Level Waste
LLWM	-	Division of Low-Level Waste Management and Decommissioning, NRC
LOCA	-	Loss of Coolant Accident
LSA	-	Low Specific Activity
LWR	-	Light Water Reactor
MAELU	-	Mutual Atomic Energy Liability Underwriters
MC	-	Manual Chapter
MPC	-	Maximum Permissible Concentration
MSA	-	Mine Safety Administration
MSHA	-	Mine Safety and Health Administration
NAT	-	Natural (also, nat)
NBS	-	National Bureau of Standards
NCRP	-	National Council on Radiation Protection and Measurements
NEPA	-	National Environmental Policy Act
NIH	-	National Institutes of Health
NIOSH	-	National Institute for Occupational Safety and Health
NJDEP	-	New Jersey Department of Environmental Protection
NMSS	-	Office of Nuclear Material Safety and Safeguards, NRC
NORM	-	Normally Occurring Radioactive Materials
NOV	-	Notice of Violation
NPDES	-	National Pollutant Discharge Elimination System
NRC	-	Nuclear Regulatory Commission, U.S.
NRDC	-	National Resource Defense Council
NRR	-	Office of Nuclear Reactor Regulation, NRC
NUREG	-	Nuclear Regulatory Commission Document
NVLAP	-	National Voluntary Laboratory Accreditation Program
ODCM	-	Offsite Dose Calculation Manual
OE	-	Office of Enforcement, NRC
OELD	-	Office of the Executive Legal Director, NRC
OGC	-	Office of the General Counsel, NRC
OIE	-	Office of Inspection and Enforcement, NRC
OJT	-	On-the-Job Training
ORNL	-	Oak Ridge National Laboratory
OL	-	Operating Licensee
OSHA	-	Occupational Safety and Health Administration
PASS	-	Post Accident Sampling System
PC	-	Protective Clothing
PCP	-	Process Control Program
PDR	-	Public Document Record
PF	-	Protection Factor
PM	-	Photomultiplier (tube)
POC	-	Plant Operations Committee
PPAM	-	Preplanned Alternative Method
PPM	-	Parts Per Million (also, ppm)
PRA	-	Probability Risk Assessment
PRM	-	Petition for Rulemaking
PVNGS	-	Palo Verde Nuclear Generating Station
PWR	-	Pressurized Water Reactor
QA	-	Quality Assurance
QC	-	Quality Control
RDRC	-	Radiation Drug Research Committee
REP	-	Radiation Emergency Plan
RES	-	Office of Nuclear Regulatory Research, NRC
RETS	-	Radiological Effluent Technical Specifications
RG	-	Regulatory Guide
ROS	-	Radiological Operations Supervisor
RPB	-	Radiological Protection Branch, NRC
RPI	-	Rensselaer Polytechnic Institute
RPM	-	Radiation Protection Manager
RSC	-	Radiation Safety Committee
RSIC	-	Radiation Shielding and Information Center, ORNL
RSO	-	Radiological Safety Officer
RWP	-	Radiation Work Permit
SAR	-	Safety Analysis Report
SAT	-	Systems Approach to Training
SCBA	-	Self Contained Breathing Apparatus
SEC	-	Securities and Exchange Commission

SECY	-	Office of the Secretary of the Commission, NRC
SEP	-	Systematic Evaluation Program
SER	-	Safety Evaluation Report
SFS	-	Spent Fuel Storage (pool)
SGTS	-	Standby Gas Treatment System
SOC	-	Statement of Consideration
SOP	-	Step-Off Pad
SRP	-	Standard Review Plan
STS	-	Standard Technical Specifications
TAR	-	Technical Assistance Request
TIC	-	Technical Information Center, DOE
TLD	-	Thermoluminescence Dosimeter
TMI	-	Three Mile Island
TP	-	Technical Position
TS	-	Technical Specifications
TSC	-	Technical Support Center
UCRL	-	University of California Radiation Laboratory
UFSAR	-	Updated Final Safety Analysis Report
UMTRCA	-	Uranium Mill Tailings Radiation Control Act
USAF	-	U.S. Air Force
USNRC	-	U.S. Nuclear Regulatory Commission
WGDT	-	Waste Gas Decay Tank
WMG	-	Waste Management Group, Inc.
WNP	-	Washington Nuclear Plant

1. INTRODUCTION

The Health Physics Positions (HPPOS) Data Base is a collection of memoranda, letters, and excerpts from various technical reports that pertain to NRC inspection, enforcement, and licensing issues. These documents are used by NRC Headquarters and Regional Offices to help ensure uniformity in inspections, enforcement, and licensing actions.

This NUREG report provides summaries of documents contained in the HPPOS data base that are relevant to the "new" 10 CFR Part 20 (§§20.1001 - 20.2401). In the preparation of the report, the 247 original documents contained in the HPPOS data base that were reviewed and summarized in NUREG/CR-5569 were reexamined. Alterations to the summaries throughout this document are highlighted to show the area of change.

Eighty one new summaries have been added to HPPOS since the publication of NUREG/CR-5569. Of this total of 328 summaries, fifty six were deleted because they were duplicates or because they were no longer relevant due to recent revisions in federal regulations. The 272 remaining summaries contained in this NUREG report are meant to provide the pertinent details of the original documents and are composed of six elements. These are:

1. HPPOS Number. The HPPOS document number, assigned by the NRC, is used throughout this document for HPPOS identification. Summarized health positions that refer to or contain similar or related topics in other documents are referenced by this number when applicable. A list of HPPOS document numbers and titles is found in Appendix A.

2. PDR Number. The PDR (Public Document Record) number is provided for users to obtain copies of the original document of interest from the NRC Public Document Room. This number must be used when documents are ordered. A list of PDR numbers relative to the HPPOS Document Number is found in Appendix A.

3. Title and Summary. The title and document summary follow the identification numbers. The title of each summary is descriptive to aid the reader in identifying the contents of the summary that follows. The first paragraph of each summary contains specific information about the document. This includes the type of document (memorandum, letter, Information Notice, etc.), the author, and the date the document was released. Memoranda, letters, or other types of documents included as attachments with the original document are also noted. At the end of the first paragraph of each summary, the more relevant points of the original document are stated. The document summary follows the first paragraph.

Any changes to HPPOS summaries 001 through 247 originally prepared for NUREG/CR-5569 are highlighted. It is important to realize that the one-page summaries are just what they are stated to be — summaries. Therefore, the summaries contained in this NUREG are not binding nor should they be construed to be binding on the NRC or any NRC licensee. They are only meant to provide a brief overview of the contents of the original HPPOS document and to provide information to the interested public on the contents of documents contained in HPPOS. Any licensee questions, statements, or points of order concerning a document contained in HPPOS must be addressed from the standpoint of the original document and not the summary contained in this NUREG.

4. Regulatory Reference. This section provides the most relevant references for the HPPOS summary. The references are typically to the Code of Federal Regulations, Regulatory Guides, Technical Specifications, or other NRC-associated regulatory sources. In the preparation of this NUREG, the regulatory references to "old" 10 CFR Part 20 of HPPOS summaries 001 through 247 were left unchanged, but the relevant section of the "new" 10 CFR Part 20 was added and highlighted. Appendix D provides a list of applicable Regulatory References included in this NUREG while Appendix E provides a list of HPPOS summaries associated with each Regulatory Reference.

5. Subject Code. Each HPPOS summary is coded for its most relevant subject content. A list of these subject codes is found in Appendix B. Appendix C provides a list of HPPOS summaries associated with each Subject Code.

6. Applicability. Each summary was coded to aid the reader in identifying the target audience, the type

of licensee, or the particular situation for which the HPPOS document was intended (All, Reactors, Byproduct Material, Source Material, Radiography, etc.). Appendix F provides a list of Applicability codes while Appendix G provides a list of HPPOS summaries associated with each.

After each document summary was written and coded, it was arbitrarily assigned to one of eighteen categories. The categories (such as Management, Authorized User, etc.) are similar to book chapters in that individual document summaries are in sections with others of similar topics. It must be realized, however, that assigning HPPOS documents to a single topic is difficult, if not impossible in most cases. For this reason, each HPPOS document was cross-referenced with the Regulatory, Subject, and Applicability codes. Through the combination of these four categorization schemes, we have attempted to aid the reader in locating information on topics of interest as quickly as possible.

Copies of any of the HPPOS documents contained in this report can be obtained from the NRC Public Document Room for a nominal charge per page plus a shipping and handling fee. In the preparation of this report, many shorter HPPOS documents were quoted essentially verbatim, while only a brief critique of larger HPPOS documents was possible. Therefore, the summaries contained in this report must not be construed to provide or impose NRC regulatory requirements. If a topic of interest is identified, contact the NRC Public document room at the address or phone numbers listed below to obtain copies of the original HPPOS documents.

- Telephone: (202) 634-3273
- Write: U.S. Nuclear Regulatory Commission
  Public Document Room
  2120 L Street, N.W.
  Room LL6
  Washington, DC 20013-7082

A software version of this NUREG report for IBM or IBM-compatible systems can be obtained from the Energy Science and Technology Software Center (ESTSC), the Department of Energy's (DOE) centralized scientific and technical software center that serves as the agent for NRC software. The HPPOS software may be searched by Regulatory Reference, Subject Code, or by Document Author and is provided to speed summary document access. The software package for this report is called HPPOS Version 2.0.

ESTSC will respond promptly to all requests for information about the HPPOS software and its costs and may be contacted as follows:

- Telephone: (615) 576-2606
- Write: Energy Science and Technology Software Center
  P.O. Box 1020
  Oak Ridge, TN 37831-1020, USA
- FAX Number: (615) 576-2865

The HPPOS software can also be obtained under agreement with ESTSC through ORNL's Radiation and Shielding Information Center (RSIC). RSIC will also respond promptly to requests for information about the HPPOS software and its costs and may be contacted as follows:

- Telephone: (615) 576-6176
- Write: Radiation Shielding Information Center
  Oak Ridge National Laboratory
  P.O. Box 2008
  Oak Ridge, TN 37831-6362, USA
- FAX Number: (615) 574-6182

Availability of future software revisions to the HPPOS Data Base will be announced on the "Energy Science and Technology Database" (available through DIALOG, 3460 Hillview Avenue, Palo Alto, CA 94304), the "Energy" data base (available through STN International, c/o Chemical Abstracts Service, 2540 Olentangy River Road, P.O. Box 3012, Columbus, OH 43210), and by DOE's Integrated Technical Information System. In addition, ESTSC publishes a list of software processed by the center quarterly and a semi-annual newsletter containing notifications of corrections, revisions, and replacement releases of software. RSIC publishes a monthly newsletter that is a timely vehicle for keeping abreast of corrections, revisions, and replacement releases of software having application to radiation shielding and health physics. Persons or organizations wanting to be added to these mailing lists should contact ESTSC and RSIC.

2. HPPOS SUMMARIES

2.1 MANAGEMENT

HPPOS-020 **PDR-9111210132**

Title: Clarification of Regulatory Guide 1.8 on Qualification of Radiation Protection Manager

See the letter from A. Schwencer to W. O. Parker, Jr., dated October 11, 1977, and the incoming request from W. O. Parker, Jr. (Duke Power Company) dated May 13, 1977. The NRC position is that ANSI N18.1-1971 does not provide appropriate qualifications needed for the Radiation Protection Manager whose responsibility is to manage an onsite radiation protection program. A clarification is provided for the equivalent of a bachelor's degree as used in Regulatory Guide 1.8. HPPOS-018 and HPPOS-217 contain related topics.

ANSI N18.1-1971 states that "the responsible person shall have a minimum of five years experience in radiation protection at a nuclear reactor facility. A minimum of two years of this five years experience should be related technical training. A maximum of four years of this five years experience may be fulfilled by related technical training or academic training."

Regulatory Guide (RG) 1.8 requires the RPM to have nine years of training and experience (e.g., a bachelor's degree plus an additional five years of experience, three of which must be in radiation protection). The requirements for Station Manager and Technical Services Superintendent, established by ANSI N18.1-1971 and deemed acceptable by RG 1.8, are ten years and eight years of experience, respectively, with a degree not being a requirement.

The requirement of a bachelor's degree is not considered to be germane to the specific functions of the Radiation Protection Manager (RPM). The only position at the station that presently requires a degree is that of the Reactor Engineer. The attributes of a good RPM are considered to be gained almost exclusively by specialized on-the-job, practical and supervisory experience rather than through the broad generalized academic training received by a person with a bachelor's degree.

RG 1.8 states that the RPM shall have a bachelor's degree or equivalent in a science or engineering subject. To provide clarification on this point, "equivalent" in the content of RG 1.8 is defined as follows:

1. Four years of formal schooling in science or engineering.

2. Four years of applied radiation protection experience at a nuclear facility.

3. Four years of operation or technical experience/ training in nuclear power.

4. Any combination of the above totaling four years.

It should be noted that the above requirement is in addition to the requirement for five years of professional experience in applied radiation protection as specified in RG 1.8.

Regulatory references: ANSI N18.1-1971, Regulatory Guide 1.8, Technical Specifications

Subject codes: 1.1

Applicability: Reactors

HPPOS-018 **PDR-9111210120**

Title: Qualification of Radiation Protection Manager - Regulatory Guide 1.8, Revision 1

See the memorandum from L. J. Cunningham to E. Greenman dated August 5, 1982. Technician experience is not equivalent to professional experience when evaluating the qualifications of a Radiation Protection Manager (RPM).

The RPM experience factors mentioned in Regulatory Guide 1.8, Rev. 1, were reviewed by IE. A licensee proposed to allow a one-for-one substitution of an incumbent technician's experience for the Regulatory Guide's stated "... at least 5 years of professional experience ...."

Consistent with the position of NRR's Radiological Assessment Branch, IE agreed that technician experience was not equivalent to professional experience. NRR also agreed that exceptions may be granted under certain circumstances but such cases must be examined on a case-by-case basis.

Regulatory references: Regulatory Guide 1.8, Technical Specifications

Subject codes: 1.1

Applicability: Reactors

HPPOS-217 PDR-9111220020

Title: Qualification of Radiation Protection Manager - Regulatory Guide 1.8, Revision 2

See the memorandum from L. J. Cunningham to R. R. Bellamy (and others) dated August 24, 1989. The minimum qualifications of the Radiation Protection Manager (RPM) at nuclear power plants should include four years of professional experience. At least three years of this professional experience should be in applied radiation protection work similar to that encountered at nuclear power stations, preferably at an actual nuclear power station.

Regulatory Guide 1.8, Revision 2, "Qualification and Training of Personnel for Nuclear Power Plants," includes Regulatory Position C.1.k: "The radiation protection manager should have the qualifications described in Section 4.44 of ANSI/ANS 3.1-1981 with the clarification that three of the four years experience in applied radiation protection should be professional-level experience."

ANSI/ANS 3.1-1981 includes the requirement that at least three of the four years experience in applied radiation protection "... shall be in applied radiation protection work on a nuclear facility dealing with radiological problems similar to those encountered in nuclear power plants, preferably in a nuclear power plant."

To clarify the intent of Regulatory Position C.1.k in Regulatory Guide 1.8, Revision 2, the three years experience "... in applied radiation protection work in a nuclear facility ..." should all be professional level experience. This is consistent with the earlier position of Revision 1 in Regulatory Guide 1.8 that "at least three years of this professional experience should be in applied radiation protection work in a nuclear facility dealing with radiological problems similar to those encountered in nuclear power stations, preferably in an actual nuclear power station." In preparing Revision 2, there was no intention to change the position of Revision 1.

Regulatory references: ANSI/ANS 3.1-1981, Regulatory Guide 1.8

Subject codes: 1.1, 1.2

Applicability: Reactors

HPPOS-172 PDR-9111210259

Title: Qualification Requirements of Line Health Physics Supervisors

See the memorandum from L. J. Cunningham to R. R. Bellamy dated March 14, 1988, and the incoming request from R. R. Bellamy dated March 2, 1988. A line Health Physics (HP) supervisor according to ANSI N18.1-1971 must have four years of craft or discipline experience. A line supervisor with first line foremen/supervisors reporting to him and having broad scope responsibilities falls under Section 4.3.2.

On November 30, 1987, Region I issued a licensee a Notice of Violation (NOV) for assigning an individual to the position of Radiological Operations Supervisor who did not meet applicable TS qualification requirements for supervisors. The individual possessed only eight months of the required four years of directly applicable radiological controls experience. The licensee responded to the violation in a January 8, 1988 letter. The violation and licensee responses are included as Attachment 1 and Attachment 2 of this memorandum and provide other pertinent information including applicable Technical Specifications (TS), Radiation Protection Organization charts, and applicable FSAR sections.

In his response, the licensee contended that the individual assigned to this position need not be qualified as a "supervisor" as defined in Section 4.3.2 of ANSI N18.1-1971, and therefore, need not possess four years of experience "in the craft or discipline he supervises" as specified in Section 4.3.2. The licensee believed it appropriate to qualify this individual as a "technical manager" as defined in Section 4.2.4 of ANSI N18.1-

1971. Section 4.2.4 specifies that an individual should possess a minimum of eight years in responsible positions of which one year of this experience shall be nuclear power experience. This section does not specify any experience requirement in a particular craft or discipline.

The Radiological Operations Supervisor has program responsibilities for infield radiological controls, ALARA, and radwaste shipping. Because of the scope of responsibilities of this individual, and the impact his direction has on the health and safety of personnel, NRC believes it appropriate that this individual be qualified with the four year experience provision of Section 4.3.2 of ANSI N18.1-1971. The licensee elected not to place an individual in this position who was qualified to Section 4.3.2.

NRR believes an HP line supervisor should meet the Section 4.3.2 supervisor's experience requirement. Specifically, in this case, the Radiological Operations Supervisor (ROS) had two HP foremen and one HP reporting to him, and he was also directly responsible for the infield implementation of the site radwaste, classical HP job coverage/RWP program, ALARA program, and job scheduling. Given this broad spectrum and scope of operating activities and their direct worker safety implications, the ROS (a line supervisor with first line foreman/supervisors reporting to him) unquestionably fell under Section 4.3.2. The ROS, thereby, needs to have four years of "craft or discipline" experience to be in full compliance with Technical Specifications 6.3.

A word of caution is needed in the generic application of this guidance. With the expansion of the HP staff in the post-TMI period, many HP organizations have added staff HP specialists who are assigned narrow, specific areas of responsibility. For example, individuals may be assigned as Respiratory Supervisor, Dosimetry Supervisor, etc. NRR does not believe individuals filling these types of narrow specialty positions with small support staffs should be expected to meet the requirements specified for Section 4.3.2 supervisors.

NRR believes that the stated guidance is generally consistent with past HQ and Regional actions in the plant staff qualification area.

Regulatory references: ANSI N18.1-1971, Technical Specifications

Subject codes: 1.1, 1.4, 1.5

Applicability: Reactors

HPPOS-021 **PDR-9111210121**

Title: Enforceability of NRR Letter Regarding "Individuals Qualified in Radiation Protection Procedures."

See the memorandum from L. J. Cunningham to W. L. Fisher dated December 20, 1977. This memo provides a list of criteria for "Individuals Qualified in Radiation Protection Procedures." The criteria are to be used as part of a determination of compliance with Technical Specifications that require one member of each operating shift crew to be so qualified. Citations for non-compliance should be against Technical Specifications and not the list of criteria.

Region III expressed doubts about the enforceability of the criteria contained in an NRR letter sent to all operating power reactor facilities and asked whether a citation could be issued for failure to comply with any or all of the criteria for certifying an individual as qualified in radiation protection procedures.

The criteria for "Individuals Qualified in Radiation Protection Procedures" are as follows:

1. Conduct special and routine radiation, contamination and airborne radioactivity surveys and evaluate the results.

2. Establish protective barriers and post appropriate radiological signs.

3. Establish means of limiting exposure rates and accumulated radiation doses, including the use of protective clothing and respiratory protection equipment.

4. Perform operability checks of radiation monitors and survey meters.

5. Recommend appropriate immediate actions in the event of a radiological problem and perform necessary activities until the arrival of health physics personnel.

6. Conduct other routine radiological duties (e.g., TS surveillance items) as may be required on backshifts or weekends.

NRR stated that the "Criteria" are to be used as part of the determination of compliance with the Technical Specifications requiring "at least one member of each operating shift crew be qualified to implement radiation protection procedures." Therefore, any citation must be against the Technical Specifications and not the list of criteria. However, the list of criteria may be referenced to detail the basis for the citation.

Regulatory references: ANSI N18.1-1971, Regulatory Guide 1.8, Technical Specifications

Subject codes: 1.1, 12.7

Applicability: Reactors

HPPOS-023 PDR-9111210130

Title: Significant Finding, Big Rock Point Health Physics Appraisal

See the memorandum from J. H. Sniezek to J. G. Keppler dated September 11, 1980. Technical Specifications (TS) require that an individual qualified in radiation protection procedures be onsite when fuel is in the reactor. HPPOS-021 contains a related topic.

Guidance was requested on how to proceed with a contested item of noncompliance issued to a licensee. The item of noncompliance was the failure to provide an individual qualified in radiation protection procedures on back shift in accordance with TS requirements. The licensee contended that the "criteria for individuals qualified in radiation protection procedures" contained in DOR's letter of 1977, were not made a part of the license either by license amendment or licensee commitment; therefore, the citation was not valid.

The NRC provides information for the purpose of clarifying the specific meaning and intent of regulatory requirements by numerous means; some examples are Statements of Consideration, Regulatory Guides, NUREG Reports, Bulletins, Circulars, Branch Technical Positions, and Generic Letters. These documents do not establish regulatory requirements, but simply clarify the meaning and intent of existing requirements or denote acceptable methods of implementing the regulatory requirements. The licensee acknowledged receipt of this clarifying information and did not propose or receive approval for implementing an alternative means of complying with the subject TS. Based on these facts, the citation in question was valid and proper.

Regulatory references: Technical Specifications

Subject codes: 1.1, 1.4, 1.5

Applicability: Reactors

HPPOS-022 PDR-9111210126

Title: Qualification of Reactor HP Technician

See the letter from R. C. DeYoung to J. A. Jones (Carolina Power and Light Company) dated December 1, 1981. Sufficient time and breadth of experience are important for an HP Technician placed in a responsible position. The licensee used an HP Technician with only eleven months experience, most of which was observing personnel monitoring themselves for contamination, to control radiation exposures to workers during steam generator maintenance.

A radiation exposure to the head in excess of NRC limits was received by a worker during steam generator maintenance at a licensee facility. The exposure of the worker was controlled by chest-worn, self-reading pocket dosimeters, despite the fact that evaluation of working conditions had previously revealed the head would receive a higher exposure than the chest. Additionally, the use of an HP Technician (or so-called HP Tech) who did not meet the minimum experience level required by TS, appeared to be among the causes of the radiation exposure in excess of NRC limits.

Technical Specification 6.3.1 requires that each member of the facility staff shall meet or exceed ANSI N18.1-1971 with regard to the minimum qualifications for comparable positions. Paragraph 4.5.2 of this ANSI standard states, in part, that technicians in responsible positions shall have a minimum of two years of working experience.

Contrary to the above, the Reactor HP Tech only had eleven months of experience consisting primarily of observing other workers surveying themselves for contamination. This level of experience was far below that required for performing survey work during steam

generator maintenance. The overexposed worker was marking steam generator tubes, a high radiation exposure task requiring vigilance on the part of the HP Tech to carefully monitor and control radiation dose rates and total worker doses. If the HP Tech had been more vigilant and experienced, he most likely would have been aware of the need for monitoring the exposure to the worker's head and to control the four entries into the steam generator by the overexposed worker.

While the magnitude of the radiation dose received by the worker only slightly exceeded the regulatory limit in this instance, NRC was concerned that, notwithstanding the previous civil penalty for a similar problem, the licensee did not adequately evaluate radiological conditions, establish effective protection measures, and implement applicable plant procedures. These concerns were expressed in an enforcement conference held on September 16, 1981, at the Region II office. One of the issues discussed was the requirement for continuous HP coverage of steam generator maintenance work. During the enforcement conference, the Manager, Environmental and Radiation Control, denied the allegation of failure to provide continuous HP coverage of the steam generator tube marking operation. NRC acknowledged the presence of an HP Tech, but more than mere presence was required during a high exposure task. Civil penalties in the cumulative sum of $85,000 were imposed for the three items in the Notice of Violation.

Regulatory references: ANSI N18.1-1971, Technical Specifications

Subject codes: 1.1, 1.2, 12.7

Applicability: Reactors

HPPOS-238 **PDR-9111210362**

Title: Health Physics Position on Task Qualification of HP Technicians

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated September 20, 1991. Health Physics Technicians (HPTs) may independently perform specific tasks or job assignments if they meet the required prerequisites and complete the required task qualifications of their plant training programs. There are certain tasks and job assignments, however, that require in-depth knowledge and can only be performed by fully qualified ANSI technicians.

ANSI/ANS 3.1-1987, "Selection, Qualification and Training of Personnel for Nuclear Power Plants," states that while in an initial training program an HPT may not make decisions (give authorization) or take actions affecting plant safety until they meet the performance requirements of the job position assigned. However, they may independently perform specific tasks or job assignments for which they are qualified.

HPTs are allowed to perform (without supervision) specific tasks or job assignments (i.e., radiation surveys, swipe surveys, air samples, and survey meter calibrations) if they meet the required prerequisites and complete the required task qualifications of their plant training program. However, there are certain tasks that require in-depth knowledge and can only be performed by fully qualified and experienced personnel.

The following general items are examples of areas which a non-fully qualified HPT should not be authorized to perform (without supervision):

- The free release of radioactive materials from the restricted area.
- Approval of effluent release permits.
- Approval of radiation work permits.
- Receipt and shipping of radioactive material.

Also, as examples in the area of Emergency Preparedness, a non-fully qualified HPT should not be authorized to:

- Lead emergency search and rescue teams.
- Lead environmental monitoring teams.
- Perform offsite dose assessment.

Each Institute of Nuclear Power Operations (INPO) accredited licensee training program will vary somewhat in its approach on qualifying its HPTs. However, each program should be based on a systems approach to training (SAT). The SAT should include the following key areas: how were criteria derived to select tasks to be done without supervision and how were

HPTs evaluated against these criteria to permit or authorize them to work unsupervised.

Regulatory references: ANSI/ANS 3.1-1987

Subject codes: 1.1, 1.2

Applicability: Reactors

HPPOS-067 **PDR-9111210253**

Title: Chemistry and Radiation Protection Technician Training and Qualifications

See the memorandum from D. P. Allison to F. A. Wenslawski dated March 28, 1984. If a technician fills a dual role as a responsible HP/Chem Tech, then 2 years experience in each area is necessary. Common areas may exist so that an experience period of less than 4 years could be acceptable. Preoperational, design, construction, and startup experience can be counted as well as operational experience. HPPOS-020, HPPOS-062, and HPPOS-096 contain related topics.

Technicians filling responsible positions in a specialty are required to have two years experience in that specialty. Therefore, if a technician is fulfilling a dual role (as a responsible HP/Chem Tech), then a total of four years experience (two in each area) is required by ANSI N18.1-1971. IE understands that common areas of chemistry and radiation protection may exist, so that some experience period less than four years could be acceptable for full, dual-specialty qualification. The overall goal of the TS requirement is to ensure that technicians filling responsible positions have the necessary experience, education, and skill to perform their assigned functions during normal and abnormal conditions.

Nuclear power plant preoperational experience, as well as design, construction, startup, and operations, can count on a one-for-one basis toward the two-year experience requirement defined in Section 4.1 of the ANSI standard. The licensee must make definitive applicability assessments of any type of experience as it relates to the technicians current or projected job responsibilities. Well documented training programs, structured to specific job functions, should form the basis for licensee qualification assessments.

Regulatory references: ANSI N18.1-1971, Technical Specifications

Subject codes: 1.1, 1.2

Applicability: Reactors

HPPOS-019 **PDR-9111210125**

Title: Qualification (Experience) of Contractor Health Physics Technicians

See the letter from W. M. Morrison to B. E. Leonard (President, Institute for Resource Management, Inc.) dated August 26, 1980. For contractor health physics technicians, two-thousand or more working hours in a period of not less than 40 weeks is acceptable as representing one year of experience. HPPOS-021 and HPPOS-022 contain related topics.

The NRC staff recognizes that contractor health physics technicians are utilized at many of the power reactor facilities and that considerable overtime is frequently associated with this work. In consideration of this situation, members of the staff of NRR and IE developed guidance for the application of man-hours to years of experience for use only in determining the qualification of contractor health physics technicians. This guidance recommends that 2,000 or more working hours accumulated during a total period of not less than 40 weeks is acceptable as representing one year of experience.

The type of work performed by the individuals, however, is important in determining whether the hours worked meet the requirements for work experience. In addition, work experience is only one of several criteria for qualification. Experience, education, training, and demonstrated proficiency are also required for qualification (see HPPOS-021 and HPPOS-022).

Regulatory references: Regulatory Guide 1.8

Subject codes: 1.1

Applicability: Reactors

HPPOS-216 PDR-9111220013

Title: Fitness For Duty Rule

See the memorandum from L. J. Cunningham to R. R. Bellamy (and others) dated December 7, 1989. The intent of 10 CFR 26.24(a)(3), which requires drug testing "immediately ... after accidents in individual performance resulting ... in a radiation exposure or release ....," is not for minor releases. NRC will use reasonable interpretation of regulation to judge license action.

In November of 1988, the NRC published a proposed rule concerning the issue of Fitness for Duty (10 CFR Part 26). Paragraph 26.24(a)(3) of this proposed rule lists instances that require drug testing "for cause." In part, this paragraph requires drug testing "immediately ... after accidents involving a failure in individual performance resulting ... in a radiation exposure or release of radioactivity in excess of regulatory limits." A strict reading of this criteria provides a very low threshold since even a minute amount or activity in a solid form, inadvertently released from site would be in excess of regulatory limits. NRC received several questions from the regions about the impact of Part 26 on the inspection program.

NUREG-1385 was issued to respond to several industry questions regarding the implementation of Part 26. Response No. 4.4 in the NUREG report, addressed testing for cause, and states that "the NRC will use reasonable interpretation of 10 CFR Part 26 to determine if the licensee acted prudently." During a seminar on Part 26 implementation, one of the rules authors verified that the reference to release of radioactivity refers to plant effluents and was not intended to apply to inadvertent releases of minor amounts of solid waste. It was also stated that once Part 26 is finalized, a Temporary Instruction will be issued and Team Inspections will be conducted to ensure proper licensee compliance. As part of this effort, inspection teams will be given appropriate training to ensure consistency of review.

Regulatory references: 10 CFR 26.24

Subject codes: 1.1, 12.14

Applicability: Reactors

HPPOS-247 PDR-9111220100

Title: Required Continuing Training Program for HP Professionals

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated November 13, 1990. This memo provides guidance on what constitutes a reasonable continuing training program for HP professionals. HPPOS-247 contains a related topic.

Standard Technical Specifications require licensees to be committed to some ANSI standard that establishes a retraining or continuing training program that includes HP professionals. The following guidance should be considered when judging the adequacy of a continuous training program (CTP) for HP professionals.

1. Purpose of CTP

    a. To keep up with state-of-the-art technology
    b. To keep abreast of current industry issues
    c. To maintain awareness of industry performance
    d. To refresh initial technical training

2. Guidance for CTP

    a. Professional programs need to be flexible
    b. Licensees need to formally document commitment for CTP
    c. Time requirements for accomplishing CTPgoals should be specified but can be flexible, with large degrees of freedom

3. What Counts as Technical/Supervisory Training

    a. Includes, but not limited to, related formal course work
    b. Progress toward ABHP certification (and continuing credits toward maintenance or certification)
    c. Professional technical meetings (e.g., HPS, EEI, EPRI, ANS, Westinghouse REM seminar, etc.)
    d. Trips or temporary assignments to other plants
    e. Structured self-education
    f. Others

NRC is currently planning to issue a proposed rule and attendant regulatory guide concerning training. In

addition, the Human Factors Assessment Branch has reviewed and supports this guidance. However, as a result of the rulemaking, the guidance provided here may require modification. [Note: The Training and Qualification Rule 10 CFR 50.120 has been issued without a regulatory guide. No further guidance is necessary.]

Regulatory references: Technical Specifications

Subject codes: 1.2, 12.19

Applicability: Reactors

HPPOS-325 PDR-9308260260

Title: New Training Rule for Nuclear Power Plant Personnel

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated August 9, 1993. The NRC has published a final rule, "Training and Qualification of Nuclear Power Plant Personnel," on April 26, 1993 (58 FR 21904) and also published a correction of a date on July 21, 1993 (58 FR 39092). A review of the final rule and supporting supplementary information by NRR's Radiological Protection Branch (PRPB) and earlier Regional feed back on the new rule has resulted in several questions. After discussions with NRR's Human Factors Assessment Branch, PRPB developed the following health physics position that summarizes the questions and answers. HPPOS-247 contains a related topic.

Question: Regarding the "Engineering Support Personnel" category listed as requiring training and qualification under the rule, are health physics (radiation protection) professionals such as radiation protection managers, ALARA engineers, and professional support technical staff (including foremen) included in this category?

Answer: No. The only radiation protection job category covered under 10 CFR 50.120 is the "Radiation Protection Technician" (or HP technician). The training and retraining requirements for the HP professionals are contained in the plant technical specifications - administrative controls section.

Question: Does the training rule cover contract HP or chemistry technicians?

Answer: Contract Health Physics/Chemistry technicians providing short-term support (e.g., outage work) and not filling a regular position in the permanent plant staff are not required to take part in the training program required by the rule [systems approach to training (SAT)]. However, all contractors assigned to work independently must be qualified to do the assigned tasks. As an example, the ongoing training and qualification programs, which are not part of the facility SAT program, are focused to task-qualify incoming outage workers.

On the other hand, contractors filling permanent plant staff positions that require them to work independently are covered by the rule. They should be included in the next scheduled session of the staff SAT training for that position.

Regulatory references: 10 CFR 50.120, Technical Specifications

Subject codes: 1.2

Applicability: Reactors

HPPOS-276 PDR-9306140075

Title: Technical Assistance Request, Continental Airlines, On-the-Job Training of Radiographers

See the memorandum from J. E. Glenn to R. R. Bellamy dated August 1, 1991 in response to a TAR from Region I. Continental Airlines proposed to designate individuals as radiographers who had completed only 360 hours of on-the-job training (OJT) verses the 520 hours normally expected of NRC licensees. The licensee based their request on the fact that they will be using only one type of radiography exposure device and performing one type of exposure.

Continental maintained that because it would use only one type of radiography device and because of the repetitive nature of its radiography operations, 360 hours would be sufficient to qualify an individual. Continental also pointed out that only 45 days (or 360 hours) was the amount of OJT "agreed" to with the state of Texas under Continental's Texas license (in fact, Texas' regulations specifically require two months OJT), and that Continental was also conducting similar radiography operations under California and Colorado licenses in those states. Colorado's regulations imposed a one month period for OJT that was

based on a revision of the Conference of Radiation Control Program Director's "Suggested State Regulations." The State of California as determined by NRC required Continental to provide for 520 hours OJT.

The NRC normally requires 520 hours to qualify an individual as a radiographer and felt it inappropriate to waive this "requirement" based only on current job restrictions. Therefore, the burden is on Continental Airlines (the applicant) to show that 360 hours will be adequate to fully qualify an individual as radiographer. Factors such as hardship (where an individual is only infrequently involved in radiographic operations and to obtain the 520 hours will entail a period significantly greater than three months), number of procedures, and the quality of supervision and testing should be considered by the applicant.

Regulatory references: 10 CFR 34.11, 10 CFR 34.31

Subject codes: 1.2, 11.1, 11.3

Applicability: Byproduct Materials

HPPOS-173 PDR-9111210261

Title: Applicability of Generic Letter 82-12 to Radiation Protection Staff

See the memorandum from L. J. Cunningham to W. D. Shafer dated April 1, 1988. Generic Letter 82-12 (overtime) applies to Radiation Protection personnel assigned to emergency response duties as part of their job description or assigned to perform safety-related work (e.g., maintenance and calibration of monitors, etc.) and does not apply to simple survey support. HPPOS-024 and HPPOS-253 contain related topics.

A licensee had interpreted Generic Letter 82-12 and the Technical Specifications reflecting Generic Letter 82-12 to be applicable to radiation protection/chemistry technicians who were performing "safety-related" functions. Their definition of "safety-related" was similar to that referenced in Generic Letter 83-14 for maintenance workers. The licensee had concluded that only one radiation protection/chemistry technician per shift was needed to perform the sole identified safety-related function and therefore applied the overtime restrictions of Generic Letter 82-12 to only one designated radiation protection/chemistry technician per shift.

As stated in the Commission's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (see HPPOS-024), licensees must "establish controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition." Health physics (and chemistry) personnel can be called upon to perform "safety-related" functions during routine and emergency conditions. It is vital that when personnel are called upon to perform these tasks, they are capable of performing the tasks in a safe, competent manner. The guidance of Generic Letter 82-12 applies to all health physics/chemistry personnel who meet the following criteria:

1. Personnel who are assigned certain emergency response duties including assignment to in-plant rescue teams, environmental monitoring and dose calculations, or who handle, process or provide data and input to emergency response decision makers.

2. Personnel who are assigned to perform, or who could reasonably be expected to perform, safety-related work related to normal plant operations. Such work includes maintenance and calibration of effluent monitors, area radiation monitors, engineered safety feature systems, or any that are "safety-related" as this term is defined in 10 CFR 50.49(b)(1), which is the definition provided in Generic Letter 83-14 clarification of Generic Letter 82-12.

A broader interpretation of safety-related work for purposes of Generic Letter 82-12 can not be supported. It is the NRR position that performing radiological surveys in support of maintenance work on a safety system does not meet the intent of the Commission Policy statement. Providing adequate HP job coverage is an important worker safety issue; however, such coverage does not stand the test of Generic Letter 83-14's narrow definition of "safety-related."

Regulatory references: Technical Specifications

Subject codes: 1.4, 1.5, 12.19

Applicability: Reactors

HPPOS-024 **PDR-9111210135**

Title: Nuclear Power Plant Staff Working Hours

See the letter from D. G. Eisenhut to All Power Reactor Licenses dated June 15, 1982. The letter provides a revised policy statement on working hours for reactor power plant staffs, including HP's. Individual staff members should not work more than 16 hours straight, more than 16 hours in a 24-hour period, more than 24 hours in a 48-hour period, or more than 72 hours in a 7-day period. HPPOS-173 and HPPOS-253 contain related topics.

Licenses of operating plants and applicants for operating licenses shall establish controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition. The controls should focus on shift staffing and the use of overtime as key job-related factors that influence fatigue.

The objective of the controls would be to assure that, to the extent practicable, personnel are not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or their decision making capability. The controls shall apply to the plant staff who perform safety-related functions (e.g., senior reactor operators, reactor operators, health physicists, auxiliary operators, and key maintenance personnel).

Enough plant operating personnel should be employed to maintain adequate shift coverage without heavy routine use of overtime. The objective is to have operating personnel work a normal 8-hour day, 40-hour week while the plant is operating routinely. However, in the event that unforeseen problems require substantial amount of overtime to be used on a temporary basis, or during extended periods of shutdown for refueling, major maintenance or major plant modifications, the following guidelines shall be followed:

1. An individual should not be permitted to work more than 16 hours straight (excluding shift turnover time).

2. An individual should not be permitted to work more than 16 hours in any 24-hour period, more than 24 hours in any 48-hour period, or more than 72 hours in any 7-day period (all excluding shift turnover time).

3. A break of at least eight hours should be allowed between work periods (including shift turnover time).

4. Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift.

Recognizing that very unusual circumstances may arise requiring deviation from the above guidelines, such deviations shall be authorized by the plant manager or his deputy, or higher levels of management. The paramount consideration in such authorization shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely.

In addition, procedures are encouraged that would allow licensed operators at the controls to be periodically relieved and assigned to other duties away from the control board during their tour of duty.

Regulatory references: Technical Specifications

Subject codes: 1.4, 1.5, 1.7

Applicability: Reactors

HPPOS-253 **PDR-9209210083**

Title: Clarification of Nuclear Power Plant Staff Working Hours

See memorandum from L. J. Cunningham to J. H. Joyner (and others) dated September 17, 1992. The memo provides a clarification of the Technical Specifications (TS's) concerning working hours for nuclear power plant staffs, including HP's. Individual staff members should not work more than 16 straight hours, more than 16 hours in a 24-hour period, more than 24 hours in a 48-hour period, or more than 72 hours in a 7-day period. The 7-day period specified in TS's should be treated as any rolling 7-day period. HPPOS-024 and HPPOS-173 contain related topics.

Standard TS's state that for personnel performing safety related functions "... in the event overtime is to be used, on a temporary basis, the following guidelines shall be followed:

1. An individual should not be permitted to work more than 16 hours straight, excluding shift turnover time.

2. An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any 7-day period, all excluding shift turnover time.

3. A break of at least 8 hours should be allowed between work periods, including shift turnover time.

Any deviation from the above guidelines shall be authorized in advance by the Plant Superintendent or his deputy or higher levels of management."

A review of a Regional inspection report and resulting Notice of Violation has suggested that clarification is needed concerning TS's on working hours for nuclear power plant staffs, including HP's. In the reported violation, the 7-day week period was treated by the licensee as a fixed, one-week period, Sunday through Saturday. This allowed the 7-day window to be reset at the end of the week. The 7-day week period specified in TS's should be treated as any rolling 7-day period.

Another concern in the inspection report was what the licensee interpreted as "shift turnover." Shift turnover consists of non-working activities such as casual conversation with fellow employees concerning watch relief, review of shift logs and the changing of clothing (modesty garments into street clothes and vice versa). The Radiation Protection and Operations supervisors misinterpreted this TS and permitted off-going technicians to complete radiological survey maps after shift relief. This time was incorrectly left off the time applied toward the 72-hour TS requirement, which added to the violation.

In addition, other activities, such as individual decontamination, whole-body counting, and decay (e.g., to permit the decay of gaseous radon daughter products), should not normally be considered part of shift turnover time. The time associated with these activities (as well as other related activities to be considered on a case-by-case basis) should be considered working time towards TS limits. This added time should not cause the individual to have less than 8 hours off between shifts. However, the licensee should not be cited for a violation of the TS limits for permitting the individual to work more than 16 hours straight (as this in not safety related work) as long as a break of at least 8 hours is allowed between work periods.

As an example, a technician worked a double shift of 16 hours and, after being relieved of his duties, was found to be contaminated. After an initial survey, decontamination, re-survey and whole-body count, two hours of additional time elapsed which are not part of normal shift turnover. The technician was not performing technical specification (TS) work during this 2-hour period so the TS that restricts work to 16 hours straight was not violated; however, if the technician reported for his next regular shift he would have been in violation for not having an 8 hour break between work periods. The technicians next shift would have to be modified (pushed back at least two hours). This health physics position was reviewed by the TS Branch for generic applicability and it agrees with the position.

Regulatory references: Technical Specifications

Subject codes: 1.4, 1.5, 1.7

Applicability: Reactors

HPPOS-306 **PDR-93062220148**

Title: Technical Assistance Request, Department of Interior, Anchorage, AK; Use of Temporary Radiation Safety Officer

See the memorandum from J. E. Glenn to R. J. Pate dated June 2, 1992. This NMSS memo responds to a technical assistance request from Region V, dated April 15, 1992, concerning an amendment request from an NRC licensee who wanted a former employee to remain in his position as Radiation Safety Officer (RSO), in a voluntary status, until a new RSO was hired. HPPOS-307 contains a related topic.

Qualified persons may be authorized to act as a temporary RSO provided that the individual commits to a specific amount of time on-site during which he will be available to perform his duties as RSO. Additionally, the individual must be sufficiently available to respond to questions and operational issues on an as needed or emergency basis. The licensee must verify that the temporary RSO will have the authority to properly maintain and effectively manage the radiation safety program for the licensee and that in his absence, adequate control will be maintained of the facility.

The licensee must agree to the above as a license commitment which will be amended if the conditions

of time on-site, availability and control change from those described.

The commitment of time and the level of authority necessary for a temporary RSO to adequately maintain and manage a radiation safety program must be determined and approved on a case-by-case basis by the licensing reviewer. However, the licensee should be aware that it is the responsibility of the licensee, through the RSO, to ensure that the radiation safety activities are performed in accordance with approved procedures and regulatory requirements and that the use of a temporary RSO does not in any way relieve the licensee of the responsibility of ensuring the safe use of byproduct material.

Regulatory references: 10 CFR 35.21, 10 CFR 35.900

Subject codes: 1.4, 1.5

Applicability: All

HPPOS-307 **PDR-9306240030**

Title: Technical Assistance Request, NRC Licensed Facilities Requesting the Use of a Consultant Physicist as Its Radiation Safety Officer

See the memorandum from J. E. Glenn to M. M. Shanbaky dated October 18, 1990. This NMSS memo responds to a technical assistance request from Region I, dated July 10, 1989, regarding an amendment request from an NRC licensee who wished to use a consultant physicist as its Radiation Safety Officer (RSO). Included with the memo is a list of issues that should be addressed prior to approving a consultant as RSO. HPPOS-306 contains a related topic.

Qualified individuals, as outlined in 10 CFR 35.900, may be appointed RSO to an NRC license issued under 10 CFR 35 provided the individual commits to being physically present at the facility for a specified amount of time in order to satisfactorily perform duties of the RSO. The specific time necessary is commensurate with the requirements of the facility and must be determined on a case-by-case basis. The time commitment must be during normal working hours to provide the opportunity for interaction between the consultant and licensee management.

Clarification as to the individuals availability to respond to questions, incidents, and/or emergencies, both by telephone and on-site is needed. However, it should be noted, that there will be some programs where it would be inappropriate to designate a consultant as RSO. These include programs involving radiopharmaceutical therapy, teletherapy, and large scale users of byproduct material. The licensee must agree to the above as a license commitment with the caveat that if at a later date the number of hours and days spent by the RSO at the facility or the consultant's availability are insufficient to fulfill the responsibilities required, the program will be re-evaluated and adjustments made.

Any licensee requesting to designate a consultant as RSO should be reminded that 10 CFR 35.21(a) states "the licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program." The use of a consultant as RSO does not negate the responsibility of the licensee to ensure the safe use of byproduct material.

A list of issues that should be addressed prior to approving a consultant as RSO is included as an enclosure to the memo. These issues were derived from questions from a similar request for technical assistance by Region III. The list of issues, which was reviewed and expanded by NMSS staff, should be addressed in the review process of any request by a licensee to use a consultant as an RSO.

Regulatory references: 10 CFR 35.21, 10 CFR 35.900

Subject codes: 1.4, 1.5

Applicability: All

HPPOS-128 **PDR-9111210336**

Title: Interpretation - RG 1.33, Meaning of "Procedure Implementation ...," STS Section 6.8.1

See the Interpretive Guide in the IE Manual on Regulatory Guide 1.33 dated April 1, 1977. Technical Specifications Section 6.8.1 states that written procedures shall be established, implemented, and maintained for activities listed in Appendix A of RG 1.33. "Implementation" means the actions prescribed by the procedures must be accomplished.

Region V had reviewed the TS requirements for the Radiation Protection Program at Humboldt Bay. While the Region recognized that the requirements were unartfully drafted and that other TS and STS requirements use the words "prepared, maintained, and adhered to", Region V thought that the appropriate interpretation of the word "maintained", in the context of the TS requirements, was that procedures not only be kept up-to-date but that they be followed. Given the age of Humboldt Bay, these procedures were probably among the first written; well before the more precise language of the STS were developed. In summary, Region V thought a broader interpretation of the word "maintain" included "adherence to" and that this interpretation is consistent with the intent of the TS requirements that licensees have a radiation protection program to meet 10 CFR Part 20.

The Administration Control Section of STS Section 6.8.1 states that written procedures shall be established, implemented, and maintained for activities that include applicable procedures recommended in Appendix A of RG 1.33. NRR and IE interpret the term "implemented," as used in Section 6.8.1, to mean "adhered to." It is interesting to note that ANSI N19.7-1976, Section 5.2.2, "Procedure Adherence," states that procedures shall be followed and that the requirements for use of procedures shall be prescribed in writing. Hence, the term "adhered to" means that the actions prescribed by the procedure must be accomplished, it does not mean that the operator, technician, or engineer must have a copy of the procedure in hand and sign off each step as the function is performed.

Regulatory references: Regulatory Guide 1.33, Technical Specifications

Subject codes: 1.7

Applicability: Reactors

HPPOS-129 **PDR-9111210340**

Title: Humboldt Bay Radiation Protection Procedures

See the memorandum from K. D. Cyr to J. Wigginton dated June 17, 1985. This memo provides the following OELD opinion. Technical Specifications that require only that radiation protection procedures be "maintained" should be interpreted to mean that the procedures should be followed. A broader reading of the word "maintain" to include "adherence to" is consistent with the intent of the Technical Specifications that the licensee have a radiation program to meet the requirements of 10 CFR Part 20. HPPOS-128 contains a related topic.

Regulatory references: Technical Specifications

Subject codes: 1.7

Applicability: Reactors

2.2 AUTHORIZED USER

HPPOS-187 **PDR-9111210293**

Title: 10 CFR 34.2(b) and (c) - Definitions of Radiographer and Radiographer's Assistant

See the excerpt from the NRC Inspection Manual entitled as above and dated June 13, 1974. This section states that a radiographer must be physically present at the site when radiography is taking place. Any individual who assists a radiographer by manipulating devices or instruments acts as a radiographer's assistant and must meet the requirements of 10 CFR 34.31(b).

As specified in 10 CFR 34.2(b), a "radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license. 10 CFR 34.2(c) defines a "radiographer's assistant" as any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography.

Licensing has construed (with OGC concurrence) these definitions to mean that a radiographer must be physically present at the site where the radiography is taking place. This does not mean in the vicinity of or near the site of exposure, but the site where the actual radiographic operation is being conducted. A radiographer's assistant may not perform any operation unless the radiographer is physically present to personally supervise the operation.

1. The duties and responsibilities of the radiographer may not be delegated to a radiographer's assistant, and

2. Any individual who assists a radiographer by manipulating radiographic exposure devices, sealed sources, related handling tools, or survey instruments is acting in the capacity of a radiographer's assistant and must meet the requirements of 10 CFR 34.31(b).

It is possible for a radiographer to supervise the activities of more than one radiographer's assistant. For example, an in-plant operation with more than one radiographic cell could involve a number of radiographers' assistants and only one radiographer. In such a situation, the radiographer would need to be physically present while any manipulation of the exposure devices or survey instruments were being performed.

It is usually the intent of radiographic licensees to qualify individuals to act as radiographers. The vast majority of programs do not have "career" radiographers' assistants. The designation of radiographer's assistant is usually intended for a person being trained as a radiographer and who must meet the requirements to act as a radiographer's assistant in order to gain the necessary experience to qualify as a radiographer.

Regulatory references: 10 CFR 34.2, 10 CFR 34.31

Subject codes: 1.3

Applicability: Byproduct Material

HPPOS-025 **PDR-9111210141**

Title: License Condition, "... Used by or Under the Supervision of ..."

See the Interpretive Guide from the IE Manual entitled as above and dated October 1, 1979. It provides guidance on the degree of supervision to be exercised by authorized users, including medical users. An authorized user need not be present at all times but must be readily available for consultation. This guidance applies to all materials licensees except radiography; the requirements for supervision of radiographic operations are defined in 10 CFR 34. HPPOS-145 contains a related topic.

In developing the following interpretation with members of the NRC staff and OELD, it was concluded that it was impractical to try and define numerical times and distances with respect to supervision availability because of the wide variations in circumstances. Similarly, it was impractical to define the frequency of verbal orders or the performance of audits by supervision since these would depend in part on the degree of changes in operations, equipment, personnel, etc. Therefore, considerable judgment by the inspector(s) in implementing the guidance will continue to be required.

1. An authorized user named on an NRC license is considered to be supervising the use of radioactive materials when he directs personnel in the conduct of operations involving the licensed material. This does not imply that the authorized user must be present at all times during the use of such materials. However, the authorized user/ supervisor is responsible for assuring that personnel under his supervision have been properly trained and instructed.

2. The authorized user/supervisor is therefore responsible for the supervision of operations involving the use of radioactive materials whether he is present or absent. When absent, the authorized user should be available for consultation (by telephone) in a reasonable amount of time commensurate with the need for consultation, based on the adequacy of the training of those personnel under the user's supervision.

3. For medical programs, the supervising physician should be located sufficiently close to the hospital in the event he is needed to personally supervise a procedure or interpret the results of a procedure. "Sufficiently close" cannot be defined for the reasons stated above; but the supervisor should be in the same city as the activity or close to the city (if it is a small city or town) so that he can get to the facility in a reasonable period of time. (Many physicians use a paging system so they can be alerted to call a hospital if needed.) A supervisor that goes on vacation or cannot be reached is not considered to be supervising. Further, for physicians licensed to supervise, it is necessary that they be available to interpret the results of a medical procedure whether or not they actually perform the scans, give injections, etc.

Regulatory references: 10 CFR 30, 10 CFR 35, License Conditions

Subject codes: 1.3

Applicability: Byproduct Material

HPPOS-287 **PDR-9306180082**

Title: Technical Assistance Request, American Board of Radiology "Certifications"

See the memorandum from J. E. Glenn to R. R. Bellamy (and others) dated December 9, 1992. This NMSS memo was written in response to a verbal technical assistance request (TAR) from Region IV concerning the nomenclature of various certifications of the American Board of Radiology (ABR).

The ABR "certifications" recognized by NRC for authorized user status for physicians using materials authorized in 10 CFR Parts 35.300 (Radiopharmaceuticals for Therapy), 35.400 (Sources for Brachytherapy), 35.500 (Sealed Sources for Diagnostics), and 35.600 (Teletherapy) are described in 10 CFR Parts 35.930(a)(2), 35.940(a)(1), and 35.960(a)(1). Before 1979, the ABR issued a certification in "radiology" which covered both diagnostic and therapeutic radiology. Since the ABR certification in "radiology" includes both diagnostic and therapeutic radiology, it is acceptable for certification for authorized user status under 10 CFR Parts 35.910, 35.920, 35.930, 35.940, 35.950, and 35.960. However, as with any review of training and experience, the recentness of training and/or certification must be considered. After 1979, the ABR replaced the "radiology" certification with two certifications, "diagnostic radiology" (with an additional designation in "nuclear radiology"), and "therapeutic radiology."

Certification by the ABR in diagnostic radiology is recognized as meeting the training requirements for authorized users using 10 CFR Parts 35.100, 35.200, and 35.500 material, and certification by the ABR in therapeutic radiology is recognized for authorized users using 10 CFR Parts 35.300, 35.400, 35.500, and 35.600 materials. In 1987, the ABR renamed "therapeutic radiology" as "radiation oncology". The criteria for certification in radiation oncology are the same as those previously required for therapeutic radiology, and the name was changed to more adequately describe the practice. Since certification in "therapeutic radiology" and "radiation oncology" are synonymous, both may be accepted to decide authorized user status for physicians using 10 CFR Parts 35.300, 35.400, 35.500, and 35.600 materials on a case-by-case basis until NRC adds the radiology oncology certification to the regulations.

Regulatory references: 10 CFR 35

Subject codes: 1.1, 1.2, 1.3

Applicability: Byproduct Materials

HPPOS-145 PDR-9111210386

Title: Authorized Users' Supervision of Medical Programs

See the memorandum from L. B. Higginbotham to J. H. Joyner (and others) dated December 23, 1981, and the enclosed memorandum from V. L. Miller to L. B. Higginbotham dated November 18, 1981. These memos help to clarify the distinction between conditions in medical licenses that state "Licensed material shall be used by..." and "Licensed material shall be used by, or under the supervision of...." The discussions provided by NMSS are helpful, but do not solve overall problems in distinguishing between compliance and non-compliance situations on matters relating to authorized users and their supervision in medical programs.

A person named as an authorized user on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license. For activities involving "human use" of licensed material, the person must be a physician (10 CFR 35.3).

"LICENSED MATERIAL SHALL BE USED BY _____."

This condition is used on private practice licenses (i.e., those issued pursuant to 10 CFR 35.12). The authorized physician-user has all of the responsibilities of an authorized user on any NRC license. In addition, he/she has the responsibilities listed in the proposed 10 CFR 35.32(b). He/she may delegate (or direct) certain activities of properly trained paramedical personnel.

"LICENSED MATERIAL SHALL BE USED BY, OR UNDER THE SUPERVISION OF _____."

This condition is used primarily on institutional licenses issued pursuant to 10 CFR 35.11, and provides a means whereby unauthorized physicians, under the supervision of an authorized physician-user, can obtain training to enable them to qualify as authorized users. The authorized physician-user has all the duties and responsibilities outlined above, plus, he may provide clinical training for unapproved physicians and delegate to them the activities listed in 10 CFR 35.32(b). Physicians working "under the supervision of" an authorized physician-user should be physicians-in-training. For short periods of time, a physician may work "under the supervision of" an authorized user while the license is being amended to add his name as an authorized user.

An authorized physician-user has the same responsibilities as an authorized user on non-medical licenses (e.g., ensuring radioactive materials are handled and used safely and in accordance with NRC regulations and the terms of the NRC license, and ensuring that personnel such as technologists and physician-trainees have appropriate training and instruction). The authorized physician-user is expected to manage the medical program authorized by the license, to set up the clinical parameters to be used by the personnel he supervises with regard to patient selection, dose selection, clinical interpretation and, at a minimum, to closely review the radiation safety procedures used by, and the diagnostic and/or therapeutic procedures performed by the supervised physician trainee.

One of the authorized physician-users should be present on the licensee's premises for ongoing and reasonable periods of time. If none of the authorized users are present, one of the users should be available by telephone and should be able to get to the licensee's facility within a short time to handle any emergency. If authorized physician-users are ill, or otherwise unable to fulfill the responsibilities described above and in 10 CFR 35.32(b), they should not be considered as supervising or directing other personnel. A physician, not necessarily one of the authorized users, must be readily accessible when radioisotopes are administered (e.g., to treat anaphylactic shock) pursuant to 10 CFR 35.32(b).

Regulatory references: 10 CFR 35, License Conditions

Subject codes: 1.3

Applicability: Byproduct Material

HPPOS-303 PDR-9306220048

Title: Request for OGC Interpretation of 10 CFR 35.25(a), "Instructing the Supervised Individual"

See the memorandum from S. A. Treby to J. E. Glenn dated February 1, 1991. This was written in response to an NMSS memo requesting an OGC interpretation of the term "instruction" in 10 CFR 35.25(a), including

"a determination whether errors that result in a misadministration or performance error leading to a violation would be a violation of the supervision requirement in 10 CFR 35.25." The determination as to whether a particular incident violates the provisions of the regulations, in Section 35.25, for example, can only be made on a case-by-case basis, depending on the facts involved. Therefore, the following discussion is meant to provide general guidance only, in reference to the kinds of incidents described in the NMSS memo, and might not necessarily be dispositive when applied to an actual incident. HPPOS-303 contains a related topic.

OGC has considered the provisions of Section 35.25 and the relevant statements of consideration (SOC), and we agree that any error in the administration of the intended dosage of radiopharmaceutical or radiation that results in a misadministration or performance error would not necessarily be a violation of the supervision requirement. On the other hand, whether or not an administration of byproduct material is in accordance with the physician's directions, if there is a failure to follow the instructions of the supervising authorized user or the procedures of the RSO or to comply with the NRC regulations or license conditions, there would be a violation of Section 35.25.

The "term" instruction is not defined in Part 35. The SOC for Part 35 (51 FR 369322) discusses that term, in the context of responding to comments on the proposed rule, In particular, the SOC states, in the relevant part:

> 3. Instruction. Several commenters asked if instruction for workers had to be in classroom lecture format. The NRC recognizes that instruction can be in the form of lectures, laboratory exercise, audiovisual packages, printed handouts, preceptorials, or apprenticeships. The important point here is not the format of the instruction but rather that the instruction be retained and used by the worker. To help correct misunderstandings, an opportunity for questions and answers should be an integral portion of each instruction module.
>
> The NRC did not address the frequency of review sessions because that judgement must be made on-site. If employees are performing all their assigned tasks correctly, there is no need to spent time reviewing procedures with the employees. If instruction has not been followed by regular use of the procedures taught, then review instruction is probably necessary. If an employee is unable to do things correctly, then review and continued close supervision, or reassignment, is necessary.

The SOC discusses Section 35.25, "Supervision", as follows (in relevant part):

> The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations or this is hazardous to the public health and safety .... NRC recognizes that medical practice is regulated differently in each state, but that, in the end, the physician is responsible for providing quality health care. A prescriptive definition that describes delegable tasks, timely response in case of untoward events, and training requirements that are suited for one setting may hinder the delivery of medical care in another setting. The authorized user physician identified on the license is responsible for delivering quality medical care, and is best situated to determine what tasks a certain physician or technologist is capable of performing.
>
> Under the final regulation, a licensee may delegate to unnamed individuals performance of any task associated with the medical use of byproduct material, from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal. The delegations must be consistent with other institutional requirements and the state's regulation of medicine .... The licensee can not delegate responsibility to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible.
>
> The NRC believes this strikes the best balance between its responsibility to assure the public health and safety and a physician's responsibility to deliver quality medical care.

Section 35.25 obviously requires that the supervised individual follow the instructions of the supervising authorized user, follow the procedures established by the RSO, and comply with the regulations and the license condition with respect to the use of byproduct material. If the supervised individual does not follow these instructions or procedures, or fails to comply

with the regulations and the license conditions, then there would be a violation of Section 35.25. Furthermore, if the instruction or procedure is incorporated into the license, then there would be a violation of the license, which might be the more appropriate citation for enforcement action.

OGC does not interpret Section 35.25 so narrowly as to limit its scope only to a failure to follow a specific instruction, which if adhered to, would have prevented a misadministration or other incident. The language in Section 35.25 clearly requires that the supervised individual also follow certain procedures, regulations, and license conditions. A failure to follow any one of those would be a violation of Section 35.25. Thus, if there was a failure to follow the instruction of the supervising authorized user, the procedures of the RSO, or to comply with the regulations or license conditions, there would be a violation of Section 35.25.

OGC does not believe that any error in the administration of the intended dosage resulting in a misadministration or other incident, absent the failure to follow an instruction, or procedure or to comply with a regulation or license condition, is a violation of Section 35.25. Such an interpretation would negate the long standing position of the NRC that the occurrence of a misadministration is not, in and of itself, the basis for enforcement action, unless there is a failure to timely and properly report the misadministration as required in 10 CFR 35.33, or there is a violation of other applicable requirements, such as might be contained in a regulation or license condition.

Regulatory references: 10 CFR 35.25

Subject codes: 1.3, 1.4, 12.11, 12.19

Applicability: Byproduct Material

HPPOS-304 **PDR-9306230254**

Title: Technical Assistance Request, Misadministration at Hutzel Hospital, Detroit

See the memorandum from J. E. Glenn to J. A. Grobe dated September 23, 1991. This NMSS memo responds to a technical assistance from Region III, dated March 14, 1991, regarding the misadministration that occurred at Hutzel Hospital on January 17, 1991.

Two apparent violations were associated with the misadministration: (1) the failure of the licensee to provide instruction to the technologist involved with the misadministration; and (2) use of materials by unauthorized individuals. The patient's administered dose of 5 mCi was decided upon and administered by individuals other than any of the authorized physician users. NMSS requested guidance from the Office of General Counsel (OGC) in determining whether violations of 10 CFR 35.25 had occurred. HPPOS-304 contains a related topic.

NMSS and OGC concur that a citation against 10 CFR 35.25(a)(1) for failure of the licensee to provide the supervised individual with adequate instruction should be issued. Adequate instruction includes a caution that the prescribed procedure may not be disregarded or changed without permission from an appropriate individual such as an authorized user or the referring physician.

With respect to the use of materials by unauthorized individuals, the answer is not as clear. OGC provided its comments in a note dated June 5, 1991, and discusses additional possible violations of License Condition 12; 10 CFR 35.11(b); and 10 CFR 35.25(a)(2). These citations are discussed below.

License Condition No. 12 and 10 CFR 35.11(b): OGC concluded that if the technologist used licensed material and was not under the supervision of an authorized user as identified in License Condition 12 and allowed by 10 CFR 35.11(b) when he performed a nuclear medicine procedure not approved by an authorized user, then there was a violation of 10 CFR 35.11(b) and License Condition 12.

NMSS concluded the following. In this case, the technologist was working under the supervision of the authorized user while performing tasks associated with the administration of a patient dosage of iodine-131. The individuals were not provided adequate instruction as discussed previously, and clearly the Physician Assistant and technologist demonstrated an error in good judgement. If the technologist had been provided instruction that precluded changing or recommending changes to the prescribed procedure or dose and then changed the prescription without the confirmation of an authorized user, the technologist would be acting as an authorized user.

10 CFR 35.25(a)(2): OGC Enforcement stated that a case could be made that the licensee violated 10 CFR

35.25(a)(2) because of failure to require, by written or verbal instruction, that the technologist to perform procedures as ordered absent permission to do otherwise from an authorized user.

NMSS concluded that the appropriate citation is against 10 CFR 35.25(a)(1) for failure of the licensee to provide the supervised individual with adequate instruction. Therefore, in the absence of adequate instruction, it is inappropriate to cite against 10 CFR 35.25(a)(2) for failure of the licensee to require the supervised individual to follow instructions not given.

In summary, NMSS concluded that the fundamental problem was inadequate instruction and only one citation against 10 CFR 35.25(a)(1) is appropriate.

Regulatory references: 10 CFR 33.11, 10 CFR 35.25, License Conditions

Subject codes: 1.3, 12.11

Applicability: Byproduct Material

HPPOS-310 PDR-9306250064

Title: Technical Assistance Request, Washington University Medical Center, St. Louis, MO; Authorization to Manipulate Low-Dose Afterloading Brachytherapy Devices

See the memorandum from J. E. Glenn to J. A. Grobe dated January 14, 1991. This memo responses to a TAR from Region III, dated September 26, 1990, regarding an amendment request by Washington University Medical Center, St. Louis. The licensee requests authorization to perform various operations that require manipulation of cesium-137 sealed sources from a Low-Dose Afterloading Brachytherapy Devices by or under the supervision of a licensee brachytherapy physicist. The request described in a letter from the licensee, dated August 16, 1990, has been reviewed and the following direction is given.

Request 1. The licensee requests that the license be amended to no longer reference a single individual as having authorization to perform installation, replacement and/or exchange of iridium-192 sources, but rather the institutional RSC be authorized to designate a qualified physicist as a brachytherapy physicist and permit this individual to perform or oversee these activities. The licensee also suggests that these activities might be performed by a full-time brachytherapy technologist under the supervision of a brachytherapy physicist.

Response 1. Qualified physicists authorized by the licensee's RSC as brachytherapy physicists must receive training from the manufacturer in the safe performance of the proposed activities. Policy and Guidance Directive FC 86-4, "Information Required for Licensing Remote Afterloading Devices", requires the licensee to submit training for those individuals who perform source exchanges in addition to the training described in 10 CFR 19.12. The license may be amended to authorize the RSC to designate qualified physicists as brachytherapy physicists, authorizing only these individuals to perform the proposed activities, and in conjunction, prohibiting the delegation of these responsibilities to anyone else except brachytherapy physicists.

Request 2. The licensee requests that the license be amended to permit manual removal of cesium-137 sources from the MicroSelectron storage container by a brachytherapy physicist for the purpose of performing quality assurance tests, dose measurements, and visual inspection of the sources as needed to guarantee safe, dosimetrically accurate and mechanically reliable patient treatments.

Response 2. NMSS believes that the request should be denied. We are aware that this institution performs innovative methods of treatment that might require special source configurations which sometime result in increased device "failure" rates; however, troubleshooting on this unit by the licensee should not be authorized. Based on the information submitted, it is not clear what basis the licensee has for proposing activities other than those currently recommended and described by the manufacturer for the purpose of quality assurance. The licensee should not be authorized access to the afterloader device and radioactive sealed sources, other that recommended by the manufacturer for routine calibration and quality control.

Request 3. The licensee requests modification of the license to allow for emergency manual afterloading of MicroSelectron cesium-137 sources into patients whose treatment has been interrupted by failure of the afterloading device.

Response 3. The license may be amended to authorize emergency manual afterloading of

MicroSelectron cesium-137 sources into patients whose treatment has been interrupted by machine failure. In addition, in cases where the afterloader device has failed during a patient treatment, the licensee should be required to perform routine operational checks on the unit prior to initiating subsequent patient treatments. This preventative measure may help to identify and reduce the frequency of generic device failures, or those failures not attributed to individual geometric configurations.

It should be emphasized that the emergency manual afterloading procedures proposed by the licensee only be used in patients whose treatment has been interrupted by failure of the remote afterloading device. Since the licensee's emergency nursing procedures require that the brachytherapy physicist and implant resident be called in the event of a detached source in the patient, it is assumed that it is the brachytherapy physicist or implant resident that would perform the manual afterloading of the remote afterloader sources in the event of a machine malfunction. In addition, this responsibility must not be delegated to nurses.

The emergency manual use of remote afterloader sources as proposed by the licensee is being authorized for the medical benefit of the patient. As will be discussed in the following item, we do not propose to authorize the manual use of these remote sources on a routine basis.

Request 4. The licensee requests that the license be amended to permit the use of MicroSelectron Heyman-Simon sources as manual afterloading sources on a routing basis. The licensee states that the sources are restricted to use in the Heyman-Simon applicator supplied by Nucletron and would utilize manual afterloading restraining caps that are also supplied by Nucletron. The justification submitted by the licensee appears to be financially motivated, in that, if they were authorized to use the remote afterloader sources for this purpose, they would be able to avoid purchasing replacement manual brachytherapy sources.

Response 4. NMSS believes that the request should be denied. After discussing the proposed use with the Sealed Source Safety Section of this branch, it is our belief that the licensee intends on routinely using the sources in a manner for which they were not designed. Therefore, in order to evaluate the integrity of the sources and device when used in a manual rather than remote mode, the licensee must submit a request containing the appropriate information necessary for the Sealed Source Safety Section to perform a Custom Source Review.

Regulatory references: 10 CFR 19.12, 10 CFR 35

Subject codes: 1.3, 1.7, 11.1

Applicability: Byproduct Material

HPPOS-313 **PDR-9306250172**

Title: Technical Assistance Request on Whether a Cardiologist Must be Authorized by NRC to Interpret Nuclear Medicine Patient Scans, DePaul Hospital, Cheyenne, WY

See the memorandum from J. E. Glenn to W. E. Fisher dated February 14, 1991. This memorandum responds to the technical assistance request dated December 7, 1990, wherein DePaul Hospital in Cheyenne, Wyoming requests clarification as to whether a cardiologist must be authorized by NRC license to interpret nuclear medicine patient scans. The request, described in a letter dated November 14, 1990, submitted by the licensee, has been reviewed and the following directions are given. HPPOS-156 contains a related topic.

In the practice of medicine it is common to secure a second opinion or interpretation of diagnostic test results in order to arrive at a consensus for the diagnosis and treatment of each patient. In order to facilitate this process, we believe that the raw data contained in the nuclear medicine scan images may be made available for interpretation by any physician that is involved with the care of the patient. 10 CFR Part 35 does not prevent any physician from viewing, interpreting, or acting upon an interpretation of a nuclear medicine scan in the process of exercising medical judgement.

However, as described in Regulatory Guide 10.8, Rev. 2, it is the licensee's responsibility to ensure that at least one interpretation of nuclear medicine scans is performed by an authorized user or a physician under the supervision of an authorized user. The licensee must meet their obligation to ensure that a responsible party, i.e., an authorized user or physician under the supervision of an authorized user, performs an interpretation of the scan and reviews all aspects of the patient study to assure that appropriate procedures

were followed and adequate results obtained. Failure of the licensee to meet this obligation may result in a violation of 10 CFR 35.25(a) for failure to supervise, or 10 CFR 35.13(b) for use of radioactive material by an individual not authorized on the license.

Regulatory references: 10 CFR 35, Regulatory Guide 10.8, License Conditions

Subject codes: 1.3, 11.5

Applicability: Byproduct Material

HPPOS-282 PDR-9306160177

Title: Technical Assistance Request, MPI Pharmacy Services, Inc., License Amendment Regarding Authorized Users

See the memorandum from J. E. Glenn to R. R. Bellamy dated January 25, 1993. This memo responds to a technical assistance request, dated November 5, 1992, to review an amendment request by MPI Pharmacy Services, Inc. The amendment request would permit any authorized user on a MPI Pharmacy Services, Inc., license to be an authorized user at the Livingston, New Jersey, nuclear pharmacy. The licensee indicates a copy of the NRC or Agreement State license specifically listing the authorized user will be kept at the Livingston pharmacy for 3 years or until the individuals are specifically listed on the Livingston license. The licensee's request to permit any authorized user on an MPI Agreement State license to be an authorized user on the Livingston license cannot be approved at this time. Reciprocal recognition of Agreement State authorizations may be appropriate at a later date, but currently drafted regulations may change the training and experience requirements for NRC licensees in the near future.

While the remaining part of the licensee's request, permitting any authorized user on an NRC MPI license to be an authorized user on the Livingston license, could be approved, it is recommended that the licensee take the following alternative approach. The licensee should consider selecting one of their NRC licenses as the document that lists all authorized users. The other NRC licenses could then be amended to authorize use of an authorized user on the list. This system has been used successfully by other commercial nuclear pharmacies. It reduces NRC's review of the proposed authorized user's training and experience to a single review. It also minimizes MPI's amendment application fees, and review time while it maximizes MPI's flexibility in assigning and reassigning authorized users to specific nuclear pharmacies. If the licensee does not want to amend all the other licenses at one time, individual licenses can be amended as specific changes or renewals are needed. This system can also be used later to institute generic changes that may be applicable to all licenses.

Regulatory references: 10 CFR 30, 10 CFR 35, License Conditions

Subject codes: 1.3, 12.2

Applicability: Byproduct Material

HPPOS-182 PDR-9111210286

Title: License Requirements Which Stipulate Specific Individuals

See the memorandum from L. B. Higginbotham to A. B. Davis dated February 7, 1979. The memo provides guidance for handling noncompliance involving unauthorized users at hospitals. Non-compliance cases involving a critical service to the public require a decision based on reasoned judgement. The memo is essentially presented in its entirety.

Your memorandum of January 17, 1979 distinguished the RSOs from the users of radioactive materials named on university, hospital and radiography licenses. While the RSO function of health and safety is important, our primary concern should be with the actual users of the material. We have no problem with university and radiography licensees ceasing operations until they recruit and are authorized by NMSS to permit work with new users and RSOs. However, it is not the fault of NMSS if licensees fail to request amendments for new users and RSOs, and IE should not request NMSS to expedite approvals because the licensee did not submit a timely request. Any request for expediting NMSS actions should come from the licensee, and it is up to NMSS to decide whether it will expedite action on the request. With respect to what IE should do in these situations, an IAL is appropriate as an initial step.

In theory, hospitals should be handled the same way; however, we all realize that an immediate action to shut down a hospital could have an effect on patient

treatment by not allowing a physician the use of certain nuclear medical tools. On the other hand, as you have indicated, if we are aware that a licensee is operating in noncompliance and something adverse happens to a patient or a worker we could be held accountable for taking no action. Consequently, in situations involving nuclear medicine programs, the decision on a course of action must be tempered with reasoned judgement. The following guidance is provided:

1. Cases involving unauthorized users in a nuclear medicine program should be brought to the attention of Headquarters. Each case will probably be different, so they should be handled on a case-by-case basis.

2. During inspections we should be primarily concerned with users of the material, and secondarily with the RSOs.

3. We should try to determine if the "unauthorized user" appears to have the requisite qualifications to be named as an authorized user; if not, it would be appropriate to take action to require immediate shut down of the operation - considering carefully the impact on patient care.

4. If the "unauthorized user" appears qualified and the program otherwise appears to be operating within regulatory requirements, the hospital should be told to send in an application to NMSS with a request to expedite approval.

5. If there are no patients undergoing treatment, an immediate requirement should be imposed to cease the operation.

6. If patients are in the middle of a series of treatments, this should not be stopped (see some alternative considerations below).

7. New patients should not be accepted for the program; they should be referred to another hospital with a similar program.

8. Again, the use of an IAL would be appropriate for an initial action.

Further considerations should include transfer of patients undergoing treatment to another hospital, provided that the hospital is nearby, consultation between the two hospitals can be accomplished, and the patient can be moved. Another consideration should be to ascertain whether only diagnostic procedures are performed (less hazardous than therapeutic treatment) and to ascertain the probability of improper diagnoses (by an inexperienced user) and the use of improper drugs. These considerations and others that may come to mind in handling a case are important, and some of them should be discussed with the licensee.

In summary, we (1) emphasize that the cases involving a critical service to the public will require a decision based on reasoned judgement, and (2) request that these sort of cases be promptly discussed with Headquarters.

Regulatory references: License Conditions

Subject codes: 1.3, 12.7

Applicability: Byproduct Material

HPPOS-026 **PDR-9111210144**

Title: Enforcement Pertaining to Unauthorized Users and Unauthorized Materials

See the memorandum from D. Thompson to G. Snyder (and others) dated December 24, 1980. This memo provides enforcement guidance for medical and small industrial licensees when unauthorized users are determined to be qualified. It also provides guidance applicable to the use of materials not authorized in the license.

Supplement VII of 45 FR 66754 establishes the conduct of licensed activities by a technically unqualified or unauthorized person as a Severity III Violation, a violation that normally results in a civil penalty on the first offense. The use of materials not on the license would also warrant a penalty under the criteria.

The routine inspection program discloses many cases of unauthorized or unqualified users or unauthorized materials not included in the license for medical programs and for small industrial licenses such as users of certain gauges and gas chromatographs. In many of these cases, a civil penalty is not appropriate when, in reality, the person(s) is appropriately qualified to use the materials.

The enforcement guidance for medical and small industrial licenses is as follows. An inspector will request the licensee to explain whether or not the current unauthorized user(s) is qualified. If the licensee or inspector and his/her supervisor determine that the user(s) is not qualified, then a Severity III Violation will exist and a civil penalty or order should be processed.

If the licensee concludes that the user(s) is qualified and the inspector and his/her supervisor reach the same conclusion, the violation will be categorized as a Severity IV Violation and handled with a Regional Notice of Violation (NOV). In addition, an Immediate Action Letter (IAL) will be issued requiring the licensee to promptly request a license amendment to resolve the problem of unauthorized user or unauthorized materials for which the person is qualified to use. Should the NRC subsequently determine that the user (depending on the type of licensed program) is not qualified, the NOV will be rescinded and an appropriate enforcement package prepared.

In such cases, an order suspending the license until an authorized, qualified user(s) is obtained or materials for which the user is qualified is placed on the license may be more appropriate than civil penalties. A suspension or a modification order appears to be more appropriate in those cases, where more hazardous materials are used, since a civil penalty may not ensure that unknowledgeable users immediately desist for operations. For example, this action would be more applicable to users in medical programs than to users of gas chromatograph or licensed gauges where the radiation hazards are minimal.

For materials where radiation hazards are minimal, such as materials of gas chromatograph, stationary liquid level gauges, or thickness measuring gauges, the unauthorized user(s) should be the subject of an IAL "suspending" the user until he/she becomes qualified or another qualified user is found. If the IAL is ineffective, an order suspending the user would be appropriate. Generally, these kinds of radioactive materials are inspected only for cause, except initially, since they fall into priorities VI and VII.

Because cases involving unauthorized users and unauthorized materials will most likely be different, the regional offices should consult with appropriate cognizant individuals in EI:HQ.

Regulatory references: 10 CFR 2, License Conditions

Subject codes: 1.3, 3.8, 12.7

Applicability: Byproduct Material

HPPOS-305 **PDR-9306220177**

Title: Installation of Fixed Gauges

See the memorandum from J. E. Glenn to Chiefs of the Division of Radiation Safety and Safeguards of Regions I-V dated September 14, 1990. This memo refers to a earlier June 22, 1992 memorandum from A. B. Beach to R. E. Cunningham concerning the installation of fixed gauges. The so-called Beach memo indicates that although a standard license condition generally prohibits gauge users from installing specifically licensed gauges, some gauge manufacturers may be instructing customers to mount gauges despite the standard condition.

The standard license condition used in specific licenses for possession and use of such gauges generally prohibit these specific licensees from installing these devices. A typical license condition reads as follows:

> Installation, initial radiation survey, relocation, or removal from service of devices containing sealed sources shall be performed by Texas Nuclear Corporation or by persons specifically licensed by the Commission or an Agreement State to perform such services.

Because gauge licensees are not normally required to possess survey instruments nor personnel dosimeters, the licensee has no means of determining the condition of the devices at the time they are uncrated and installed.

In the Beach memo, it is noted that the standard license condition prohibits licensees from mounting and installing fixed gauges unless specifically authorized. Items 7, 10.1, and 10.6 of the licensing guide for nonportable gauging devices generally makes it clear that if the applicant wishes to install gauging devices, the applicant must describe appropriate procedures and employee training provisions. This issue was first raised by TN Technologies, Inc. (formerly Texas Nuclear Corporation) in response to an All Agreement States letter dated April 3, 1987. State Programs, who coordinated the response to TN,

was informed by NMSS that mounting or hanging a device was a part of the installation process and that NRC licensees must be specifically authorized to mount gauges. However, State Programs failed to make this position clear in the letter to TN. While the letters to all Agreement States and TN concerned generally licensed devices, NMSS's position also applies to specifically licensed devices.

NRC has allowed 10 CFR 31.5 general licensees to mount devices, provided they follow the manufacturer's instructions; i.e., the gauge source shutter must remain padlocked as received from the manufacturer. NRC is not aware of any significant mishaps resulting from this practice and believes that this procedure should be acceptable for specific licensees. However, NRC believes that the manufacturer should commit, in its service license, to evaluate the licensee's mounting procedures and discuss any additional safety precautions that may need to be considered. It is not clear that the manufacturers have made such commitments. Some regional licensing personnel have suggested that a revised standard condition to permit mounting of locked gauges may be appropriate. If this is deemed acceptable, NRC will revise the standard license condition to allow gauge licensees to mount locked gauges and will revise the licensing guide and standard review plan to clarify these points.

In the Beach memo, a Temporary Instruction for inspecting field installation work by licensed manufacturers/distributors was requested. NRC Headquarters shared Region IV's concern about these activities but in NRC's opinion, there is not sufficient health and safety risks to redirect inspection resources. However, Headquarters noted the procedure that Region IV used with Kerr McGee Refining Corporation, a new licensee, certainly helped to uncover potential gauge installation problems. After a license was issued to Kerr McGee, NRC requested this licensee to notify Region V when TN was to install the gauges at their site so that Region V inspectors could be present to observe the work. Therefore, NRC suggests the other regions consider this procedure when issuing new fixed gauge licenses. This procedure would meet the Manual Chapter criteria that all new fixed gauge licenses be inspected within six months.

Regulatory references: License Conditions

Subject codes: 1.3, 11.3, 12.19

Applicability: All

2.3 RECORDS AND REPORTS

HPPOS-204 PDR-9111210348

Title: Request for Interpretation Regarding Licensee Recordkeeping

See the memorandum from J. W. N. Hickey to W. L. Axelson dated May 19, 1987. Although computer storage of required records is a broad issue, it appears that, in general, records maintained on computer media would be appropriate. An example, where computer storage is not appropriate, is the situation in which a copy of a document is required to be held. The health physics position was written in the context of 10 CFR 20.311, but it also applies to "new" 10 CFR 20.2006.

Guidance was requested on whether records maintained only on computer media and not in hard copy satisfy the Commission's requirements for recordkeeping. Computer storage of required records is a broad issue, and NRC is not able to address all situations that may arise for all licensees. In general, however, records maintained on computer media would meet the requirements of the regulations in many cases, provided the records are available for inspection and can be produced in hard copy promptly upon request. Computer recordkeeping would not be acceptable for those requirements that specify a copy of a document must be held [see, for example, 10 CFR 20.311(d)(7) and 10 CFR 20.2006(d), specifically Section III.B.5 of Appendix F to 10 CFR 20.1001-20.2401. Note: 10 CFR 30.39(d)(1) is no longer applicable]. It would be the licensee's responsibility to take such measures as are necessary to ensure the reliability of the records, including protection from loss, tampering, alteration, or destruction, as is the case with any required records. Such measures should include storing separately one other copy (backup) of the computer storage medium for the time required.

Regulatory references: 10 CFR 20.311, 10 CFR 20.2006, 10 CFR 30.39

Subject codes: 2.1

Applicability: All

HPPOS-205 PDR-9111210351

Title: Record Retention at Ex-Licensee After a License has been Terminated

See the memorandum from P. Jehle to C. L. Miller dated February 27, 1989. The memo states that once a license is terminated by the NRC, the former licensee is no longer required to retain records. If the NRC believes record retention should continue for a term of years, its termination order could be conditioned on expiration of the term.

On May 27, 1988, the Commission issued a final rule on the Retention Periods for Records that affects 10 CFR Parts 4, 11, 25, 30-35, 40, 50, 60, 61, 70, 71, 73, 74, 75, 95, and 110. These parts contain all the regulatory provisions referring to NRC requirements for retaining records (with the exception of 10 CFR Part 20). The Commission's regulations refer only to a "Licensee" or an "Applicant." There are no references to the applicability of the regulations to an ex-licensee or former licensee. Because of the absence of references to ex-licensees, by inference, record retention regulations do not apply to ex-licensees. Therefore, once a license is terminated by the NRC, the former licensee is no longer required to retain records. This does not suggest that the Commission is without authority to require the retention of necessary records. The Commission may place conditions on an order of termination to be fulfilled before decommissioning is complete. If the Commission believes record retention should continue for a term of years, its termination order could be conditioned on the expiration of the term.

The recordkeeping requirements of 10 CFR Part 20 are the subject of proposed rulemaking. The proposed rules, in all but two sections, state that the licensee shall retain records until the Commission terminates the license requiring the record. The notice of the proposed rule did not state that the regulations have been changed to require that records be maintained until the license is terminated. Therefore an ex-licensee is not required to retain records under 10 CFR Part 20 of current or proposed NRC regulations.

Regulatory references: 10 CFR 20.401, 10 CFR 20.2102, 10 CFR 20.2103

Subject codes: 2.1, 11.4

Applicability: All

HPPOS-050 **PDR-9111210219**

Title: Guidance - Use of NRC Form 4 - Listing of Exposure Periods

See the Interpretive Guide in IE Manual entitled as above and dated November 1, 1978. It provides guidance on the use of NRC Form 4 with respect to listing periods of exposure at different licensee's facilities while employed by another single employer who is not necessarily a licensee. The health physics position was written in the context of 10 CFR 20.102, but it also applies to "new" 10 CFR 20.2104.

The Westinghouse in-service inspection division inquired about the listing of periods of exposure on NRC Form 4 for radiation work conducted at many power plant facilities while employed only by Westinghouse. Westinghouse maintains their own Form 4's, recording the highest exposure received for each plant where work was conducted by comparing the facility badge results with their own. One power plant licensee required a record of each period of exposure for each of the other facilities where inservice work was performed. This would have resulted in several pages for each Form 4 since as many as 30 or more facilities would be involved every six months per man. Instead, Westinghouse requested that they be permitted to continue to add the cumulative exposures for each place where work was conducted and take the result to the facilities as one total exposure to be used as one entry for the Form 4.

On August 8, 1978, the views of OELD were requested on whether item 5 on NRC Form 4, "name and address of employer" [or item 7 on an up-to-date NRC Form 4 (6-92), "name of licensee or facility not licensed by NRC that provided monitoring"] means each employer or each separate facility where an exposure occurred. In a written opinion, OELD stated that the term "employer" means just that. Thus, only one entry on the Form 4 is necessary for the exposures received during the time period for which the employer did not change. This view is consistent with the purpose of Form 4 which is to provide a licensee with a history of the individual's exposure. The circumstances of the previous exposures (i.e., numerous small exposures, a few large exposures, location, etc.) is irrelevant information to the licensee as such information is not necessary for the determination of the accumulated dose.

Regulatory references: 10 CFR 20.102, 10 CFR 20.2104

Subject codes: 2.1, 8.1, 8.7

Applicability: All

HPPOS-047 **PDR-9111210207**

Title: Personnel Monitoring Requirements for an NRC/Agreement State Licensed Contractor Working at a Part 50-Licensed Facility

See the letter from L. B. Higginbotham to D. Romine (Chem Nuclear Systems, Inc.) dated October 3, 1978. When a contractor licensed by the NRC or an Agreement State performs work under its license at a Part 50 facility, only one party need provide personnel monitoring if the other party assures that dosimetry and records are adequate to meet regulatory requirements. The health physics position was written in the context of 10 CFR 20.202 and 20.401, but it also applies to the "new" 10 CFR Part 20, Sections 20.1501, 20.1502, and 20.2106.

NRC was asked to provide an explanation on whether a contractor's records of personnel radiation exposure satisfied regulatory requirements or whether the contractor must obtain radiation exposure records from Part 50-licensed facilities after employees performed work at these facilities. The answer to this question is in several parts, since the responsible party must be identified and, in some cases, the responsibility may fall to more than one party.

If contractor-employees perform work at a Part 50-licensed facility and the work is performed under the Part 50 license, the responsibility to provide appropriate personnel monitoring and maintain exposure records falls to the Part 50 licensee. However, if contractor-employees perform work at a Part 50-licensed facility, but the work is performed under the contractor's NRC or Agreement State license, the responsibility falls to the contractor to provide appro-

priate personnel monitoring and maintenance of exposure records.

In the case where the two licensees (Part 50 and contractor) are subject to this responsibility, it is not necessary for both to provide personnel monitoring equipment. One licensee may accept the dosimetry program and records of the second licensee provided that the dosimetry program and records are adequate to comply with NRC requirements and its license conditions. In a similar manner, a licensee may accept the dosimetry program and records of a non-licensee (contractor) provided the conditions are as described above.

In the situation in question, most of the work was performed under the Part 50 license of the power reactor facility. It was acceptable for the contractor to use its own monitoring equipment and maintain its own records, provided the Part 50 licensee was willing to accept this arrangement. In this situation, the responsibility for compliance with NRC requirements was with the Part 50 licensee and it would have to perform such evaluations as necessary for it to be satisfied that the regulatory obligation was being met by the contractor's equipment. The decision belongs to the Part 50 licensee and it could provide additional monitoring equipment for contractor personnel, if it so desired, to meet its own obligations.

Regulatory references: 10 CFR 20.202, 10 CFR 20.401, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.2106

Subject codes: 2.1, 8.1, 12.2

Applicability: All

HPPOS-215 **PDR-9111220012**

Title: Notifications and Reports to Individuals

See the memorandum from J. D. Buchanan to J. E. Wigginton dated June 21, 1988. Worker requests for occupational exposure reports from licensees need not be in writing.

Region III requested NRR guidance concerning a difference of opinion between a worker and the worker's former employer on whether a request pursuant to 10 CFR 19.13(c) must be written. 10 CFR 19.13 subsections (b), (c), and (e) all require a licensee to respond to certain requests from a worker. However, 10 CFR 19.13 does not specify that these requests be in writing, and therefore, it is apparently not required.

Regulatory references: 10 CFR 19.13

Subject codes: 2.2, 2.3

Applicability: All

HPPOS-270 **PDR-9306100037**

Title: Request for Interpretation of 10 CFR 35.33(c) Regarding Diagnostic Misadministration Reporting Threshold Levels

See the memorandum from S. A. Treby to J. E. Glenn dated May 31, 1991. This OGC memo responds to an Region I request for guidance on which threshold level in 10 CFR 35.33(c) applies for notifying the NRC and the referring physician of a diagnostic misadministration in instances in which "a patient, not scheduled for a nuclear medicine study at all, inadvertently receives a diagnostic dosage of a radiopharmaceutical." It is OGC opinion that any diagnostic misadministration to a patient not intended to receive any radiopharmaceutical is a dosage "five-fold different" from the intended dosage; thus making applicable the reporting requirements of 10 CFR 35.33(c).

According to the request for guidance from Region I, the facts in this incident are as follows: A recent NRC inspection revealed that a diagnostic misadministration of a radiopharmaceutical occurred at Ephrata Community Hospital ("Ephrata") on November 17, 1987. The misadministration occurred because the nursing staff submitted an incorrect request for a "biliary study" instead of a "biliary sono study". The Nuclear Medicine staff performed a "hepatobiliary" study using 4 mCi of Hepatolite Visofenin when the patient should not have received any radiopharmaceutical at all. The dose to the target organ and the whole body of the patient from this misadministration as estimated by the licensee's consultant were supposedly less than 2 rem and 500 mrem, respectively. The licensee's consultant considered that the above criteria in 10 CFR 35.33(c) applies in the instance when a patient who is not scheduled to receive any radiopharmaceuticals receives them.

At the outset, we note that as stated in the request for guidance from Region I, this incident was a diagnostic misadministration. The term misadministration is defined (in relevant part) in 10 CFR 35.2 as an administration of:

(2) a radiopharmaceutical to the wrong patient; or

(4) a diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50%.

The administration of a radiopharmaceutical to a patient who is not supposed to receive any certainly falls within the definition in (2) above. In addition, such an incident is also within the scope of definition (4) above, on the basis that when no dosage of a radiopharmaceutical is prescribed, any dosage is a dosage differing from the prescribed dosage by more than 50 percent.

10 CFR 35.33(c) requires notification of the NRC and the referring physician of a diagnostic misadministration within 15 days:

> ". . . if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater that 2 rem or a whole body dose greater than 500 mrem."

Region I has asked which of the latter two thresholds applies in this case (i.e., the threshold of a dosage five-fold different from the intended dosage or the threshold of an organ dose of greater than 2 rem or a whole body dose greater than 500 mrem). The licensee applied the organ or whole body dose criterion and therefore did not report the misadministration to the NRC.

OGC believes that if either the "five-fold different" dose level threshold or the organ dose/whole body dose threshold in 35.33(c) is exceeded, then a licensee is required to notify the NRC and the referring physician. It is true, as the memorandum requesting guidance states, that application of the "five-fold different" dose threshold in 35.33(c) would mean that any diagnostic administration to a patient not intended to receive a dosage would have to be reported to the NRC because the intended dosage would be zero. OGC does not agree with the conclusion in the memorandum that such a result could be considered as inconsistent with the current requirement in 35.33(c), which makes it clear that not all diagnostic misadministration have to be reported to NRC.

OGC believes that the "five-fold different" threshold does apply, on the basis that when no dosage is intended, any dosage is "five-fold different from the intended dosage." In other words, notification is required for any diagnostic misadministration involving a dosage to a patient not intended to receive any radiopharmaceutical, because any dosage is five-fold different from the intended dosage. There is no legal basis, either in the plain language of 35.33(c) or in the statement of consideration, for concluding that the five-fold different dose threshold should not be applied to an incident such as occurred at Ephrata.

Based on OGC's interpretation of 35.33(c), both dose thresholds in 35.33(c) apply to any diagnostic misadministration and if either threshold is exceeded, notification is required. Therefore, Ephrata was required to notify both the NRC and the referring physician of the November 12, 1987 diagnostic misadministration on the basis that the dosage administered was five fold different from the intended dosage.

Regulatory references: 10 CFR 35.2, 10 CFR 35.33

Subject codes: 2.2, 12.11

Applicability: Byproduct Material

HPPOS-297 **PDR-9306220123**

Title: Legal Interpretation of the Misadministration Reporting Requirements as Applied to the Incident at Tripler Army Medical Center

See the memorandum from J. E. Glenn to R. R. Bellamy (and others) dated November 1, 1990. This NMSS memo was written in response to a request from Region V concerning the reporting requirements applicable to an misadministration incident at Tripler Army Medical Center ("Tripler"). It is OGC opinion (enclosure) that 10 CFR 35.2 is susceptible to varying interpretations on the issue whether the Tripler incident constitutes a diagnostic administration under the present definition and thus reportable as such. However, it should be noted that the proposed enforcement actions based on 10 CFR 35.25(a)(2) does not require a finding that this incident constitutes a

misadministration. Further, this incident could be tracked for regulatory purposes if determined to be an "abnormal occurrence".

The basic facts surrounding this incident are as follows: On June 19, 1990, iodine-131 (I-131) was administered by personnel at Tripler to a woman patient as part of her medical treatment there. The Tripler medical technologist was not aware that the patient was a nursing mother because she did not volunteer that information and the technologist failed to require, prior to the administration of the I-131, that she complete a questionnaire as to whether she was pregnant or nursing, as required by Tripler internal procedures. Adherence to such procedures is required by 10 CFR 35.25(a)(2), which provides in part that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the authorized user.

When the patient returned for a scan on June 21, 1990, Tripler learned that she had nursed her newborn infant during part of the two day interval. This resulted in a large radiation dose to the infant which destroyed the infant's thyroid function. The infant will apparently require synthetic thyroid supplement to grow and develop normally. On June 27, 1990, the Tripler RSO notified the NRC of the incident by telephone and inquired if a written report was required, and on July 20, 1990, Tripler filed a written report on the incident pursuant to 10 CFR 20.405, "Reports of overexposures and excessive levels and concentrations." However, Tripler has asserted that a written report was not required, prompting the request for OCG guidance as to the applicable reporting requirements in NRC regulations.

It is OGC opinion (enclosure) that the written report the licensee submitted was not required by 10 CFR 20.405 [or, at present, 10 CFR 20.2203]. OGC also believes that the language in 10 CFR 35.2 is susceptible to varying interpretations on the issue whether the Tripler incident constitutes a diagnostic misadministration as defined in 10 CFR 35.2; thus making applicable the reporting requirements in 35.33(c). Good arguments can be made on both sides of the question. In view of the ambiguities in both the present and proposed definitions of the term misadministration, OGC is advising the staff (enclosure) that any revised definition of that term should explicitly cover an incident such as that at Tripler. However, it should be noted that the proposed enforcement actions based on 10 CFR 35.25(a)(2) does not require a finding that this incident constitutes a misadministration.

In view of the fact that the staff has proposed that this incident be considered as an "abnormal occurrence", it may be tracked for regulatory purposes as such, regardless whether it constitutes a "misadministration" (SECY-90-330, "Section 208 Report to Congress on Abnormal Occurrences for April-June 1990," September 20, 1990).

Regulatory references: 10 CFR 20.405, 10 CFR 20.2203, 10 CFR 35.2, 10 CFR 35.25, 10 CFR 35.33

Subject codes: 12.11

Applicability: Byproduct Material

HPPOS-052 PDR-9111210224

Title: Effluent Reporting Requirement Per 10 CFR 20.405(a), "Reports of Overexposures and Excessive Levels and Concentrations"

See the letter from T. F. Dorian to A. Mattox (Brandeis University) dated December 21, 1979. It is an OELD opinion that 10 CFR 20.405(a) requires a report on effluent release only if the releases exceed 10 times the limit in 10 CFR 20.106 or in the license when averaged over one year. Limits in Technical Specifications were not addressed in this OELD opinion. The health physics position was written in the context of 10 CFR 20.106, 20.201, and 20.405, but it also applies to the "new" 10 CFR Part 20, Sections 20.1302, 20.1501, and 20.2203.

10 CFR Part 20 was promulgated to establish precautionary requirements for personnel monitoring, posting of areas and containers where radiation or radioactive materials exist, radiation surveying, record keeping, storage of radioactive materials, instruction of personnel, and reporting of radiation overexposure, accidents, and loss or theft of licensed material. The regulation does not specify detailed procedures to be followed in meeting safety standards in most cases, but individual licenses may, and usually do, contain special safety requirements and conditions necessitated by the particular situation. Radiation exposure of personnel is controlled through the licensee's ability to control access to its facility and to direct the actions of individuals within the facility and by protective equip-

ment, devices, and procedures. Exposures to the public are controlled by limiting the quantity and concentration of radioactive material that may be released to areas not controlled by the licensee.

The sections and appendixes incorporating limits on radiation levels and concentrations of radioactive material are designed to assure that individuals in "unrestricted areas" do not receive exposure in excess of 10% of the limits established for persons exposed in restricted areas. For this purpose, these regulations limit levels of radiation and concentrations of radioactive material that may be created in unrestricted areas by licensees, without special authorization from NRC, to extremely low levels. These levels are believed to be sufficiently low to assure that there is no reasonable probability to individuals in unrestricted areas receiving exposures in excess of 10% of the permissible levels for restricted areas under any circumstance. Moreover, as a precautionary procedure, 10 CFR 20.201 [or 10 CFR 20.1501] requires licensees to make (or have made for them) such surveys (and with such frequency) as may be necessary to comply with the regulations in Part 20.

Within this scheme, section 10 CFR 20.405(a) [or 10 CFR 20.2203(a)] requires written reports within 30 days of levels of radiation or concentrations of radioactive material in an unrestricted area in excess of ten times any applicable limit set forth in Part 20 or in the license. The applicable limits in Part 20 are listed in Table II of Appendix B to 10 CFR 20 (§§20.1-20.601) [and Table 2 of Appendix B to 10 CFR 20 (§§20.1001-20.2401)] and are modified to the extent that 10 CFR 20.106 [and 10 CFR 20.1302(b)] allows a licensee to average concentrations over a period not greater than one year. Thus, 10 CFR 20.106 and 20.405 [or 10 CFR 20.1302(b) and 20.2203(a), respectively] are complementary; averaging is, in fact, permitted; and a licensee is not normally required to report in writing releases of single milliliters of air or water that exceed by a factor greater than ten the concentrations specified in Table II of Appendix B to §§20.1-20.601 [or, at present, Table 2 of Appendix B to §§20.1001-20.2401].

Each report under 10 CFR 20.405 [or 10 CFR 20.2203] requires the licensee to "describe the extent of exposure of individuals to radiation or radioactive material, including estimates of each individual's exposure...; levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels or concentrations of radioactive materials involved; and corrective steps taken or planned to assure against a recurrence." [Note: 10 CFR 20.2203 requests additional information such as an individual's dose.] Clearly, the regulations attempt to ensure that NRC knows about abnormal conditions at licensees' facilities; that licensees control their activities, including procedures, equipment and people, to protect against radiation hazards; and that every reasonable effort is made to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable.

Regulatory references: 10 CFR 20.106, 10 CFR 20.405, 10 CFR 20.1302, 10 CFR 20.2203

Subject codes: 2.2, 7.3

Applicability: All

HPPOS-099 PDR-9111210218

Title: Attention to Liquid Dilution Volumes in Semi-annual Radioactive Effluent Release Reports

See the memorandum from C. A. Willis to W. W. Meinke and C. L. Miller dated November 7, 1984. The memo states that for semiannual effluent reports pursuant to Regulatory Guide 1.21, licensees should use the total volume of dilution flow, not just the flow during the time of liquified effluent release. [Note: Effluent reports are now required annually.] The dilutional volume (or flow) must be determined specifically for each plant. In addition, a table of expected dilution volumes may be prepared by the contractor using data from various environmental statements, ODCMs, etc.

Regulatory references: Regulatory Guide 1.21, Technical Specifications

Subject codes: 2.2, 7.3

Applicability: Reactors

HPPOS-041 **PDR-9111210186**

Title: Errors in Dose Assessment Computer Codes and Reporting Requirements Under 10 CFR Part 21

See IE Information Notice No. 85-52 entitled as above and dated July 10, 1985. This notice alerts licensees to: (1) errors in a dose assessment computer code supplied by a vendor, and (2) in general, computer codes can be considered basic components under the requirements of Part 21, and non-conservative errors leading to substantial underestimation of radiation exposures would be considered reportable under 10 CFR 21. The health physics position was written in terms of 10 CFR 20.403, but it also applies to "new" 10 CFR 20.2202.

IEIN-85-52 was issued following an evaluation by NRC staff of an event where errors were found in the prediction of offsite doses using computer software supplied by Nuclear Data, Inc. In the incident, a large discrepancy between the result of the offsite dose calculations made by the licensee and the regional office during an emergency preparedness exercise was noted. The licensee and Region V office used the same input parameters (radiological source term and meteorological conditions); however, the offsite calculated dose determined by the Region V office was an order of magnitude less than the licensee's estimation. The licensee found errors in the dose assessment computer programs that were used to estimate environmental doses for both routine and emergency operation supplied by Nuclear Data, Inc. In coordination with Nuclear Data, the licensee corrected the errors and notified other licensees via INPO's electronic "notepad" of the inherent program error that led to predicting less atmospheric dispersion than the code should have calculated.

If errors result in substantially underestimating or overestimating offsite doses, it could result in inappropriate protective measures. An error that substantially underpredicts offsite doses (non-conservative) would be reportable under 10 CFR 21. The underestimation could cause a delay or deferral of protective action leading to unnecessary exposure to a person in an unprotected area, thereby creating a "substantial safety hazard." An error that substantially over predicts (conservative) is not strictly reportable under 10 CFR 21, since it is unlikely that such an overestimation could result in personnel radiation exposures exceeding the referenced guidelines. However, because of potential non-radiological negative impact from unnecessary protective actions resulting from overly conservative dose estimates, licensees should continue to cooperate with vendors and share information concerning common problems with generic computer codes.

The following NRC staff guidance on the amount of radiation exposure that can be considered to represent a "substantial safety hazard" is taken from NUREG-0302 (Rev.1):

1. A substantial safety hazard means the loss of a safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety. Note that the term "public heath and safety" includes both members of the public and licensee workers/employees.

2. From a radiological perspective, a criterion for determining whether substantial safety hazard exists includes "moderate exposure to, or release of, licensed material."

   a. Guidelines for determining what "moderate exposure to ..." means: greater than 25 rem to the whole body (or its equivalent to other body parts) to occupationally exposed workers; or exposure of 0.5 rem to the whole body (or its equivalent to other body parts) to an individual in an unrestricted area.

   b. Guidelines for determining what "... release of licensed material" means: release of materials in amounts reportable under the provisions of 10 CFR 20.403(b)(2) [or 10 CFR 20.2202(b)(2)].

Regulatory references: 10 CFR 21, NUREG-0302

Subject codes: 2.2, 7.3, 12.12

Applicability: Reactors

HPPOS-140 **PDR-9111210378**

Title: Guidance on Reporting Doses to Members of the Public from Normal Operations.

See the memorandum from D. R. Muller to T. M. Novak and G. C. Lainas dated March 10, 1983. The memo summarizes dose design objectives of 10 CFR 50, Appendix I, and requirements of 40 CFR 190 re-

garding off-site doses from normal operations. The memo also provides guidance on the content of required annual reports.

To meet the dose design objectives of 10 CFR 50, Appendix I, the following conditions must be satisfied.

1. The dose or dose commitment to a member of the public from radioactive materials in liquid effluent from each reactor does not exceed:

   a. during any calendar quarter, 1.5 mrem to the total body or 5 mrem to any organ, or

   b. during any calendar year, 3 mrem to the total body or 10 mrem to any organ.

2. The dose from noble gases in gaseous effluents from each reactor does not exceed:

   a. during any calendar quarter, 5 mrad from gamma radiation or 10 mrad from beta radiation, or

   b. during any calendar year, 10 mrad from gamma radiation or 20 mrad from beta radiation.

3. The dose to a member of the public from radioiodines and particulates in gaseous effluents from each reactor does not exceed:

   a. during any calendar quarter, 7.5 mrem to any organ, or

   b. during any calendar year, 15 mrem to any organ.

The requirements of 40 CFR 190 are met if the dose or dose commitment to any member of the public from uranium fuel cycle source in a calendar years does not exceed:

1. 75 mrem to the thyroid, or

2. 25 mrem to any other organ or to the total body.

The 40 CFR 190 requirements differ in significant ways from the Appendix I criteria. Specifically, for 40 CFR 190 purposes, consideration must include the following (as well as doses from effluents):

1. Direct radiation doses, and

2. Doses from fuel cycle facilities, including other reactors.

The term "members of the general public" includes all persons who are not occupationally associated with the plant. The term does not include employees of the utility, its contractors, or vendors. Also excluded are people who enter the site to inspect, service equipment, or make deliveries. The term includes people who use portions of the site for recreational, occupational, or other purposes not associated with the nuclear plant. "Direct radiation" is radiation which reaches unrestricted areas even though its source is retained within the plant. Examples are gamma rays from the decay of nitrogen-16 in BWR turbine buildings and gamma rays from low level wastes stored on site.

The purpose of an annual report is to summarize the calculations performed during the year to show compliance with Appendix I and with 49 CFR 190 Technical Specifications. The information should be presented as indicated in Table 1 of the enclosure to this memo. Where doses exceed the Appendix I criteria, an explanation should be provided. Compliance with the 40 CFR 190 dose limits must be addressed explicitly. If the dose is below the 40 CFR 190 limits, all that needs to be added are statements addressing doses from other fuel cycle facilities (uranium mills, conversion plants, enrichment plants, fabrication plants, power reactors, reprocessing plants, and waste disposal sites). In most cases, the limits of 40 CFR 190 are satisfied by statements that there are no other fuel cycle facilities within 8 km.

Regulatory references: 10 CFR 50, 40 CFR 190, Technical Specifications

Subject codes: 2.2, 7.3, 12.8

Applicability: Reactors

HPPOS-322 **PDR-9308020160**

Title: Reporting of Damaged Portable Moisture-Density Gauges

See the memorandum from R. E. Cunningham to R. W. Cooper (and others) dated July 1, 1993. This memo clarifies the reporting requirements for damaged moisture-density gauges that often contain up to 10 millicuries of cesium-137 (Cs-137).

Whether licensees must report damaged moisture-density gauges depends on the extent of damage to the gauge. The requirement to report also depends on the level of radiation in an unrestricted area or the doses to individuals resulting from the damaged gauge. The applicable reporting requirements are given in 10 CFR 20.405(a) (1), 20.2203(a), and 30.50(b). The enclosure to this memo provides a detailed analysis of the reporting requirements.

In summary, reporting is required in most incidents when damage to the gauge results in one of several conditions (see enclosure):

1. The protective housing (shielding) is damaged such that the source is not fully shielded, or cannot be moved into the shielded position [10 CFR 30.50];

2. The source is left exposed in an unrestricted area such that the radiation levels exceed 20 mrem in any one hour (10 times the limit of 2 mrem in any one hour) [10 CFR 20.405 and 20.2203]; or

3. The incident results in doses in excess of limits in Part 20 or in the license [10 CFR 20.405 and 20.2203].

Please note that the method of reporting and the associated time for the licensee to make the report are different for conditions 1, 2, and 3 above.

In a more serious case involving a broken sealed source that leads to contamination, reporting within 24 hours is required [10 CFR 30.50(b)(1)]. Likewise, in a case involving a sealed source that causes, or threatens to cause, serious overexposures, immediate notification or 24-hour notification and subsequent written reporting may be required [10 CFR 20.403, 10 CFR 20.2202, and 10 CFR 20.2203]. However, these situations are beyond the scope of most damaged gauge incidents and will not be discussed here.

Finally, immediate telephonic reporting of loss or theft of a portable moisture-density gauge is required in most cases, and a written report within 30 days is required in nearly all cases.

Regulatory references: 10 CFR 20.405, 10 CFR 20.2203, 10 CFR 30.50

Subject codes: 2.2, 3.7, 11.2, 11.3

Applicability: Byproduct Material

HPPOS-222 **PDR-9111220117**

Title: Reportability of Operating Event

See the memorandum from C. E. Rossi to R. L. Spessard dated June 1, 1988. Precautionary evacuation and manning of the Technical Support Center (TSC) are not reportable under 10 CFR Sections 50.72(b)(1)(vi) and 50.72(b)(2)(vi). However, a press release of an operating event requires prompt notification to the NRC under 50.72(b)(vi).

On March 23, 1988, with Susquehanna Unit 2 in Operational Condition 5 (Refueling Outage with the core defueled), the fuel pool cooling filter/demineralizer was inadvertently backflushed while shutting down the fuel pool cooling system. As a result, radioactive resin was flushed into the fuel pool letdown line that runs through the reactor building to the condensate storage tank. Increased radiation levels throughout the reactor building along the letdown lines and in the condensate storage tank were detected. Because of the potential overexposure of personnel working inside the reactor building to these elevated radiation levels, all work inside the reactor building was stopped and all personnel were evacuated from the reactor building. No radioactive material was released from the plant and no plant personnel were overexposed to radiation levels inside the reactor building.

In an enclosed memorandum dated May 3, 1988, the Office for Analysis and Evaluation of Operational Data recommended that NRR take some "appropriate follow-up action." This memorandum states that the event was reportable under the two provisions of 10 CFR 50.72 listed below.

50.72(b)(1)(vi) - "Any event that ... significantly hampers site personnel in the performance of duties necessary for the safe operation of the nuclear power plant."

50.72(b)(2)(vi) - "Any event ... related to the health and safety of the public or onsite personnel

... for which a news release is planned or notification to other government agencies has been or will be made."

It is NRR's understanding that the reactor building evacuation and manning of the TSC were precautionary measures taken by the licensee in response to the unknown cause of the increased radiation levels in the reactor building. This conservative response was commended by the region as "prompt and effective" with "very good control" being maintained. The actual radiological consequences of this event amounted to some localized hotspots on the letdown lines that did not interfere with free transit of the reactor building, or affect the operation of any safety system. Therefore, NRR does not agree that this event was reportable under 50.72(b)(1)(vi), since it did not significantly hamper the performance of duties necessary for safe plant operation.

On March 24, 1988, the licensee made a press release regarding the event. They were required, therefore, to make a prompt notification to the NRC pursuant to 10 CFR 50.72(b)(2)(vi) and their administrative procedure AD-QA-425. In the Inspection Report No. 50-388/88-06 (issued May 4, 1988), the region cited the licensee for failure to promptly notify the NRC following the press release. The Region characterized this violation as a severity level IV. Since the Region has taken appropriate action, NRR plans no further action on this event.

Regulatory references: 10 CFR 50.72

Subject codes: 2.2

Applicability: Reactors

HPPOS-254 **PDR-9303020117**

Title: Definition of Unplanned Release

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated February 18, 1992. This memo provides a definition of "unplanned release" for inclusion as a health physics position.

Definition of unplanned release: The unintended discharge of a volume of liquid or airborne radioactivity to the environment.

Guidance: An unplanned release is the unintended discharge of radioactive material from a source. Typical examples of an unplanned release are the discharge of the contents of the wrong waste gas decay tank or the wrong liquid radwaste release tank. Another example of an unplanned release is the discharge of a source, such as a turbine building sump, that is designed to divert its contents to the liquid radwaste system for processing on either the detection of the activity or a certain level of activity and, instead of being diverted, is discharged off site. It should be noted that instances as described above are rare.

Clarification: It should be noted that a change in activity level from a release source or the release from a new or different source is not necessarily considered an unplanned release. Consider the following cases.

Case 1. Inadvertent release of the contents of a waste gas decay tank through the plant vent. The release point is the same as that for other sources and although the source is new, the important fact is that the discharge is unplanned. Therefore, the release would be considered an unplanned release because no discharge of any waste gas decay tank was planned.

Case 2. Inadvertent release of the contents of the wrong waste gas decay tank through the plant vent. The release point is the same as that for all waste gas decay tanks and although the source is new, the important fact is that the discharge is not the intended one. It is the wrong tank. The release was meant to be the contents of a different tank. Therefore, the release is unplanned.

Case 3. Leakage from various pipes and valves in the Auxiliary Building are released from the plant vent via the Auxiliary Building ventilation system. The function of the Auxiliary Building ventilation system is to ventilate areas of the Auxiliary Building. While performing this function, it is designed to handle the leakage associated with various pipes and valves. This would not be considered an unplanned release since the design of the system is to treat the airborne leakage associated with the various pipes and valves. Normal expected leakage would not be considered an unplanned release since the system is designed to treat routine leakage from various pipes and valves. However, large leaks due to unexpected valve or pipe failures that resulted in a quantity of release such that a 10 CFR 50.72 or a 10 CFR 50.73 report is required, would be considered an unplanned release.

Regulatory references: 10 CFR 50.72, 10 CFR 50.73

Subject codes: 2.2, 2.3

Applicability: Reactors

HPPOS-101 **PDR-9111210227**

Title: Clarification of 10 CFR 50.72 with respect to Maine Yankee

See the memorandum from E. L. Jordan to T. E. Murley dated January 13, 1984. This memo states that 10 CFR 50.72(b)(2)(vi) does not require notification for routine releases. However, when a licensee must report to another agency, NRC requires notification only when that matter involves a news release on an event related to health and safety of the public.

Clarification of the intent of 10 CFR 50.72(b)(2)(vi) as it relates to notifications required for all radioactive releases. The "inadvertent" release of radioactive material was stated in the rule as an example which would require a 4-hour notification, irrespective of magnitude, if a news release or notification to other government agencies is made. The 4-hour notification rule in Section 50.72 is not for "routine" releases, although they may be required to be reported to the State. However, a "routine" release that subsequently receives media attention should be reported to the NRC. The referenced paragraph is as follows:

> (vi) Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made. Such an event may include an onsite fatality or inadvertent release of radioactively contaminated materials.

The key statement is "... event or situation, related to the health and safety ...." Where a state or other government entity has a requirement or agreement with an NRC licensee for routine reporting of other matters, the NRC only requires a report when that matter gets escalated to a "news release" of a "situation."

Regulatory references: 10 CFR 50.72

Subject codes: 2.3, 9.0

Applicability: Reactors

HPPOS-065 **PDR-9111210251**

Title: Inspection Guidance on 10 CFR 50.72, "Immediate Notification Requirement for Operating Power Reactors"

See the memorandum from L. J. Cunningham to L. R. Greger dated November 15, 1983. This memo states that for reporting radioactive releases to unrestricted areas: (1) the annual average meteorological data should be used for determining offsite concentrations, and (2) the expanded definition of unrestricted area in NUREG-0133 should be used.

Clarification was requested on several aspects of the 10 CFR 50.72 notification requirements. These questions related to the requirement that licensees call in notification of radioactive releases that exceed the specified concentrations. Specifically, the questions were: (1) what meteorological data should be used in determining offsite concentrations (e.g., annual average, real time or worst case), and (2) what location should be used (e.g., unrestricted area as defined by Part 20 or the expanded definition as specified in NUREG-0133). In addition, it was noted that revised 10 CFR 50.72 was incorporated into 10 CFR by Supplement No. 12 issued on September 20, 1983, although the rule change was not effective until January 1, 1984. It was noted also that a currently effective version was not in 10 CFR.

Inspection guidance for operating nuclear power reactors concerning 10 CFR 50.72 are as follows:

1. Annual average meteorological data should be used for determining offsite airborne concentrations of radioactivity. This is to maintain consistency with the Technical Specifications.

2. The expanded definition of an unrestricted area as specified in NUREG-0133 should be used. This is to maintain consistency with the Technical Specifications.

3. The lack of a currently effective version of 50.72 in the 10 CFR loose-leaf version is an administrative problem only. Licensees and inspectors should keep

the old pages for reference until January 1, 1984. The old version is still the effective rule until January and deviation from those requirements in favor of the new requirements would be a technical violation. However, in such a case, notation in the inspection report without further enforcement action would be the appropriate approach.

Regulatory references: 10 CFR 50.72, NUREG-0133

Subject codes: 2.3, 4.4, 7.5

Applicability: Reactors

HPPOS-174 **PDR-9111210265**

Title: 10 CFR 50.72, Applicability of Notification Requirement to Non-Power Reactors

See the memorandum from R. L. Nimitz to Radiation Support Section dated April 8, 1981. The requirements of 10 CFR 50.72 do not apply to non-power reactors even though they may be licensed under 10 CFR 50.21.

During an inspection at Rensselaer Polytechnic Institute (RPI) Critical Facility, the question arose whether the licensee was required to report occurrences at their facility in accordance with 10 CFR 50.72. The wording of 50.72 indicates that it applies to "... each licensee of a nuclear power reactor licensed under 50.21 or 50.22 ...." The Critical Facility at RPI is licensed and is about a 1-watt training and research facility.

Although the facility is not a nuclear power reactor used for generating electricity, it is a nuclear reactor and the licensee did not wish to be in noncompliance with this requirement for failing to report an occurrence meeting 10 CFR 50.72 requirements. IE Headquarters was contacted and it was their opinion that the 10 CFR 50.72 requirements did not apply to non-power reactors, but a review is underway to determine if the 10 CFR 50.72 requirements should apply to these non-power reactor facilities. Therefore, based on this discussion, the 10 CFR 50.72 requirements do not apply to non-power reactor facilities even though they may be licensed under 10 CFR 50.21.

Regulatory references: 10 CFR 50.21, 10 CFR 50.72

Subject codes: 2.3, 12.1

Applicability: Non-Power Reactors

HPPOS-157 **PDR-9111220134**

Title: Posting of Notices to Workers - 10 CFR 19.11

See the memorandum from J. G. Davis to J. P. O'Reilly (and others) dated September 12, 1975. This memo states that Notices of Violation (NOV) must be posted per 10 CFR 19.11 only when they contain an item of noncompliance related to radiological working conditions. When such violations are not identified in the NOV, the NOV need not be posted. HPPOS-228 contains a related topic.

10 CFR 19 requires that each licensee post any NOV involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of 10 CFR, and any response from the licensee.

NOVs must be posted pursuant to 10 CFR 19.11 only when they contain one or more specific items of noncompliance related to radiological working conditions. Pursuant to Chapter 0800 of the IE Manual, citations will not be included in the NOV for matters which are identified and corrected by the licensee, and no citation will be made if such matters are not posted at the licensee's facility.

Regulatory references: 10 CFR 19.11

Subject codes: 2.3, 4.7

Applicability: All

HPPOS-228 **PDR-9111220082**

Title: Clarification on 10 CFR 19.11a, "Posting of Notices to Workers"

See the memorandum from J. Buchanan to J. Wigginton dated April 9, 1990. The requirement in 10 CFR 19.11(a) for posting civil penalties, orders, and responses from licensees applies only to those proposed civil penalties, orders, and responses that are

relevant to radiological working conditions. HPPOS-157 contains a related topid.

10 CFR 19.11(a) states that, "Each licensee shall post current copies of the following documents: (1) the regulations in this part and in Part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operation procedures applicable to licensed activities; (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee."

A question was asked whether the requirement for posting proposed civil penalties, orders, and responses from licensees applies only to those proposed civil penalties, orders, and responses relevant to radiological working conditions. The answer is given in the statement of considerations for 10 CFR Part 19 (38 FR 22217, August 17, 1973), as follows: "It has been clarified that the requirement in Section 19.11 for posting notices of violations, notices of proposed imposition of civil penalty, or orders issued pursuant to Subpart B of Part 2 of this chapter, applies only to documents relevant to radiological working conditions."

Regulatory references: 10 CFR 19.11

Subject codes: 2.3, 4.7, 12.7

Applicability: All

2.4 POSSESSION AND TRANSFER

HPPOS-248 **PDR-9206260104**

Title: Guidance on the Applicability of 10 CFR 70.19 to Persons Holding a Specific License

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated April 7, 1992. Region I requested an interpretation of the quantity limitations and labeling requirements of 10 CFR 70.19 as it applied to plutonium calibration sources. The memorandum expresses the Office of General Counsel (OGC) opinion that a specific license does not subject the licensee to the general license quantity limitations and labeling requirements of 10 CFR 70.19 in the use of plutonium calibration sources.

A typical power reactor license contains a provision that states in part, a licensee may receive, possess and use in amounts as required any byproduct, source, or special nuclear material for sample analysis or instrument calibration. Further, 10 CFR 70.19(a)(1) and (3) state that any person who holds a specific license issued by the Commission authorizing them to own, receive, possess, use, and transfer special nuclear material is also issued a general license to own, receive, possess, use, and transfer plutonium calibration or reference sources in accordance with paragraph (c). Paragraph (c) also specifies a general license limit of 5 microcuries for using or storing plutonium in one location and specific labeling and other requirements for plutonium sources.

While these requirements appear contradictory, it is the OGC opinion that a specific license contains all the authority needed and is not limited by a general license. Therefore, a person who possess a specific license is not subject to the quantity limitations and labeling requirements of 10 CFR 70.19 in the use of plutonium calibration sources as would a licensee who has a general license.

Regulatory references: 10 CFR 70.19

Subject codes: 3.3, 11.3, 11.7

Applicability: All

HPPOS-133 **PDR-9111210357**

Title: Exemption of Thorium-Containing Scrap Under 10 CFR 40.13(c)(4)

See the memorandum from L. Dubinski to R. W. Kirkman (and others) dated May 9, 1966. This memo states that the possession of tungsten- or magnesium-thorium scrap with a thorium content <4% by weight, is exempt from regulations pursuant to 10 CFR 40.13(c)(4).

The following is an excerpt from a memorandum from the Enforcement Branch, Division of State and Licensee Relations, with which the Division of Compliance concurred:

> "Under the provisions of 10 CFR 40.13(c)(4) any finished product or part fabricated of or containing magnesium-thorium alloy with a thorium content not exceeding 4% by weight is exempt from the regulations in Part 40, except that the exemption does not extend to the chemical, physical or metallurgical treatment or processing of any such product or part."
>
> "Persons who receive possession of scrap containing magnesium-thorium alloys, in most instances, will have no definitive information as to the chemical content of the metal. Accordingly, it does not seem reasonable or necessary to require these persons to obtain a source material license to authorize possession of such material."
>
> "The Division of Safety Standards recognizes the problem of wording in 10 CFR 40.13(c)(4) and is planning to prepare an appropriate amendment of Part 40 to clarify that no license is needed by persons who receive scrap magnesium-thorium alloy containing not more than 4% by weight of thorium."

The above quotation deals only with magnesium-thorium alloys. However, the conclusion is equally applicable to tungsten-thorium alloys.

The net effect of the explanation is to construe "any finished product or part" to include items that have been discarded as scrap. Note that the exemption does not extend to chemical, physical or metallurgical treatment or processing of the scrap.

Regulatory references: 10 CFR 40.13, 10 CFR 40.22

Subject codes: 3.3, 3.8

Applicability: Source Material

HPPOS-239 **PDR-9111210366**

Title: Clarification of Generic Letter 81-38, "Storage of Low Level Radioactive Wastes at Power Reactor Sites"

See the memorandum from L. J. Cunningham and P. Lohaus to M. R. Knapp (and others) dated January 31, 1991. This memo provides guidance for Generic Letter 81-38 and states that NRC licensees should minimize on-site storage of low-level radioactive waste. Licensees who construct storage facilities, or expand existing facilities with the intention of storing waste for more than five years should obtain a separate Part 30 license. HPPOS-264 and HPPOS-278 contain related topics.

Various questions from Regional inspectors and Headquarter reviewers had arisen concerning whether Generic Letter 81-38 required nuclear power reactor licensees to limit the storage time for radioactive waste generated by normal reactor operation and maintenance to five years or less. Generic Letter 81-38 reflects the position of the NRC that all licensees should minimize on-site storage of low-level radioactive waste. However, the Commission recognizes that reactor licensees need to have interim (short-term) storage capability while disposal capacity is being developed by the States. The intent is that licensees who construct or expand storage facilities with the intention of storing waste for more than five years should obtain a separate Part 30 license. The guidance provided in Generic Letter 81-38 was not intended to be applied to single packages or just a few packages of waste. Likewise, radioactive components, such as replaced steam generators or heat exchangers, generated through non-routine maintenance, were not intended to be included within the scope of Generic Letter 81-38. The Commission is considering a number of low-level waste storage issues, including factors that need to be addressed in deciding whether to authorize storage beyond January 1, 1996. These activities are a part of the Commission's evaluation of possible actions to be taken in response to the 1996 title transfer and possession provisions of the Low-

level Radioactive Waste Policy Amendments Act of 1985.

Generic letter 81-38 can not be used as a basis for citing licensees for storing their normally generated low-level radioactive waste past a defined time period (e.g., 5 years). However, storage of such waste beyond the period allowed by the license (if specified) or referenced in the FSAR, without amending the license or performing a 50.59 evaluation and submitting an updated FSAR in accordance with 50.71(e), may be a basis for enforcement action.

Regulatory references: 10 CFR 61, Generic Letter 81-38

Subject codes: 3.4, 9.0, 9.6

Applicability: Reactors

HPPOS-264 PDR-9306070250

Title: Policy and Guidance Directive FC 90-3, Licensing of Low-Level Radioactive Waste Storage by Materials and Fuel Cycle Licensees.

See the memorandum, issued as Policy and Guidance Directive FC 90-3, from R. E. Cunningham dated March 29, 1990. This memo includes two enclosures, "Guidance for Review of Amendment Requests for Extended Interim Storage of Low-Level Radioactive Waste", and Information Notice (IN) 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees". Directive FC 90-3 provides guidance for the review of amendment requests for extended interim storage of low-level radioactive waste (LLW) by materials and fuel cycle licensees. IN 90-09 contains general guidance for licensees on the information needed in such requests and should be used to determine completeness of an amendment request. The guidance contained in the directive generally tracks the content of IN 90-09. HPPOS-239 and HPPOS-278 contain related topics.

In a memorandum dated February 14, 1990, the Commission informed the staff that "... the Commission will not look favorably upon long-term on-site storage beyond January 1, 1996." That date is the final milestone of the Low-level Radioactive Waste Policy Amendments Act of 1985. States acting alone or as a part of a Regional LLW Compact, which are unable to provide for LLW disposal by that date must take title to and possession of LLW generated in their state as well as be liable for any direct or indirect damages for failing to do so promptly. Any amendment requests received for on-site LLW storage to extend beyond January 1, 1996, should be coordinated with headquarters.

Regulatory references: 10 CFR 30, 10 CFR 40, 10 CFR 70

Subject codes: 3.4, 9.0, 9.6

Applicability: Byproduct, Source, and Special Nuclear Materials, and Fuel Cycle

HPPOS-278 PDR-9306140198

Title: Technical Assistance Request, Department of the Interior, Salt Lake City, UT; Apparent Request to Store Low-Level Waste for Decay for a Time in Excess of Five Years

See the memorandum from J. E. Glenn to L. J. Callan dated October 22, 1991. This memo responds to a technical assistance request from Region IV, dated June 26, 1991, regarding the Department of the Interior, Salt Lake City Research Center's apparent request to store low-level waste for decay for a time in excess of five years (enclosure). The respond to the TAR was coordinated with the Division of Low-Level Waste Management and Decommissioning (LLWM). HPPOS-239 and HPPOS-264 contain related topics.

The licensee stated in the amendment request: "... that shipping will not be done if the radioactive decay renders the waste low enough in activity to be disposed of as regular waste." This statement makes it unclear whether it is for interim storage pending availability of a waste broker for disposal in a licensed site, or for decay-in-storage. At the time of storage, waste must be identified as interim storage or decay-in-storage, and segregated as such.

Waste designated as interim storage must be disposed of at an NRC authorized low-level waste disposal site or transferred to a licensee authorized to receive the waste. The commission has said that it will not look favorably upon long term on-site storage beyond January 1, 1996, for waste destined to a licensed disposal site. Therefore, if the licensee states that it is intending to eventually send the waste to a licensed disposal site, it should be asked to justify a storage

period that exceeds January 1, 1996. It should be noted that Utah is a member of the Northwest Compact region. The licensee has a disposal site available to it. We assume that the motivation for the request is the lack of a broker (see Item 11, Paragraph 3.b.1. of the licensee's submittal).

Waste designated for decay-in-storage should be held for a minimum of ten half-lives or longer, depending on the isotope and total activity, before disposal in regular trash. Requests for decay-in-storage that extend beyond a five-year period are not looked upon favorably.

Before the request can be approved, the licensee must specify more clearly how its waste will be identified, segregated, and what it intends for disposal. The license amendment request will not require an environmental assessment according to 10 CFR 20.301 (B), [10 CFR 20.2001a] 10 CFR 30.41(b)(7), and 10 CFR 51.22(c)(14)(v).

Approval was recommended provided four conditions were followed. First, the licensee specified how waste will be identified, segregated, and disposed. The licensee should also show that the waste would not be held greater than a five-year period. Second, that guidelines outlined in Policy and Guidance Directive FC 90-3; "Licensing of low-level Radioactive Waste Storage of Materials and Fuel Cycle Licensees" were followed as appropriate (e.g., were current possession limits adequate for the waste to be stored up to five years?). Third, survey procedures and instrumentation used for monitoring waste before disposal were reviewed and approved. Finally, specific isotopes with half-lives between 65 and 120 days must be listed on the license. If sulfur-35 is the only radioactive material with a half-life greater than 65 days to be held for decay-in-storage, then it would be appropriate to revise the standard license condition to specify 90 days, rather than 120 days.

Regulatory references: 10 CFR 30, 10 CFR 40, 10 CFR 70

Subject codes: 3.4, 9.0, 9.6

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-056 **PDR-9111210233**

Title: Violations of 10 CFR 20.207(a) or (b), "Security of Stored Material in Unrestricted Areas"

See the memorandum from J. Lieberman to R. Carlson (and others) dated June 1, 1982. Violations of 10 CFR 20.207 should be considered as Severity Level IV when the likelihood of unauthorized removal is small and the threat to public health and safety is minimal. A sample paragraph is provided for the Notice of Violation. This health physics position also applies to the "new" 10 CFR Part 20, Sections 20.1801 and 20.1802.

Region I forwarded two cases at hospitals involving violations of 20.207(a) and (b) [or 10 CFR 20.1801 and 20.1802]. These violations involved the storage of licensed material in unrestricted areas where access was possible and/or constant surveillance was not maintained. In both cases, the likelihood of unauthorized removal of the material was small and the threat to the health and safety of the public was minimal and remote, since (1) the material was in an area of the hospital where assess by unauthorized personnel was unlikely, (2) the radiation levels near the material were low, (3) the half-life of most of the material was short, and (4) the material was clearly labeled and not in an "attractive" form for theft. Because of the above, both Region I and the IE Enforcement Staff agreed that Severity Level IV was the appropriate classification for these violations.

In the future for similar cases, the following should be done.

1. The transmittal letter should contain a paragraph similar to the following:

> Item A described in the attached NOV involving control of licensed material, is classified as a Severity Level IV violation. As indicated in Supplement VI of the NRC Enforcement Policy significant violations of this type are normally classified as Severity Level III. However, after careful consideration of the factors involved in this specific instance, we have exercised our judgement under the NRC Enforcement Policy and have classified this violation as Severity Level IV. Similar violations of this type in the future may result in additional enforcement action.

2. An enforcement conference should be held. A telephone enforcement conference should be adequate unless there are other significant violations.

3. The Notice of Violation can be issued without prior notification of IE Enforcement, but the Director of Enforcement should be included on the distribution.

Regulatory references: 10 CFR 20.207, 10 CFR 20.1801, 10 CFR 20.1802, EGM-82-05

Subject codes: 3.4, 12.7

Applicability: All

HPPOS-154 **PDR-9111220124**

Title: Selection of Appropriate Enforcement Action for Gamma Diagnostic Laboratories, Inc.

See the memorandum from D. H. Thompson to B. H. Grier dated March 4, 1981, and the incoming request from B. H. Grier dated January 16, 1981. Under 10 CFR 71, a private carrier is subject to 10 CFR Part 20. An unattended vehicle with the motor running in which licensed material in transport is stored in locked containers, is not a reasonable effort to secure material and does not meet the intent of 10 CFR Section 20.207. The health physics position was written in the context of 10 CFR 20.207 and 20.402, but it also applies to the "new" 10 CFR Part 20, Sections 20.1801, 20.1802, and 20.2201.

An inspection was conducted on October 6 and 7, 1980, to review the circumstances surrounding the theft and subsequent recovery on September 25, 1980, of a truck belonging to Gamma Diagnostic Laboratories, Inc. The truck was being used by the licensee to deliver licensed materials to various customers. At the time of theft, the truck was parked in front of a hospital with the engine running while the driver was inside making a delivery. The truck contained packages of licensed materials in a locked container that in turn was bolted to the truck. The theft was promptly reported and the truck was recovered a short time later. There was no evidence of any attempt to steal or tamper with the licensed materials within the locked container.

The theft of the truck highlights two questions about which guidance and policy are needed.

1. When a licensee is acting as a private carrier, such as in the situation just described, what regulations are applicable? The regulations in 10 CFR Part 71 and the DOT regulations, the regulations in 10 CFR Part 20, or some combination of these?

2. If it is assumed that a licensee acting as a private carrier must comply with the regulations in Part 20, does storage of licensed materials in a locked box that is physically secured to a truck constitute adequate security against unauthorized removal?

Common and contract carriers are subject to DOT regulations but are exempt from NRC regulations. Private licensee carriers are subject to all DOT regulations and 10 CFR Part 20. However, when DOT and NRC have overlapping requirements, NRC would not ordinarily take actions against the licensee for a violation of Part 20 if the licensee was in compliance with the DOT requirement. For example, private carriers are required to make a report per 10 CFR 20.402 [or 10 CFR 20.2201] for lost or stolen radioactive materials (based on judgmental factors) no matter how the material is contained (see Interpretive Guides 20.402 and 20.402 - Transportation in 10 CFR of the IE Manual). In this case, the licensee apparently did report the stolen truck to local police. They were not required to report the stolen truck to DOT (things reportable to DOT are set forth in second Interpretive Guide listed above).

The intent of 10 CFR 20.207(a) [or 10 CFR 20.1801] is to secure material from unauthorized removal of radioactive materials from any unrestricted area. The rule intentionally does not state how the material must be secured, only that it must be secured. Under 20.207(a) [or 10 CFR 20.1801], the source should be secured in such a way that it cannot (under reasonable circumstances) be removed, including removal of the containment in which the material is located, whether it be a small brick structure, vehicle, or any other kind of containment. NRC believes a reasonable effort would have been to shut off the motor and remove the keys.

In the case at hand, by stealing the vehicle, the material was obviously also stolen, even though the material was secured to the truck. The fact is, the truck was not reasonably secured. Clearly, if the truck theft had been successful, the secured container could have been breached. Therefore, in NRC's view, 10 CFR 20.207 applies in this case and the licensee should be cited but civil penalties should not be

assessed (see EGM-81-08). There are no similar provisions to 10 CFR 20.207(a) and (b) [or 10 CFR 20.1801 and 10 CFR 20.1802, respectively] in DOT regulations, except for any carrier of explosives.

Although in this situation the license authorized transport under 10 CFR Part 71, it must be noted that Section 71.1(b) states: "The packaging and transport of these materials are also subject to other parts of this chapter ...." This means Chapter 1 of Title 10, or in other words, it applies to other regulations in Chapter 1 including 10 CFR Part 20.

Regulatory references: 10 CFR 20.207, 10 CFR 20.1801, 10 CFR 71.1

Subject codes: 3.4, 3.7, 4.4, 12.17

Applicability: All

HPPOS-132 PDR-9111210350

Title: License Requirement for Facilities Repairing Contaminated Equipment

See the letter from K. R. Goller to All Power Reactor Licensees dated November 1, 1977. When contaminated equipment is transferred for repair or service, a license must be held by the service shop or the facility licensee prior to shipment. Reactors in Agreement States can apply to State, others to NRC for use of material at unspecified locations.

It came to NRC's attention that reactor facility licensees occasionally find it necessary to send a contaminated component to manufacturers or service companies for repair or calibration. The manufacturers or service companies do not, in many cases, have appropriate NRC or Agreement State licenses authorizing receipt, possession, use and transfer of byproduct material nor do they have the qualified personnel necessary to obtain such licenses. The shipment of these components by or to unlicensed persons has resulted in enforcement action being taken against the persons shipping or receiving the contaminated components. Urgently needed repairs and service have been delayed while the concerned regulatory agencies attempted to resolve the problem.

It is essential that appropriate licenses be held by the repair shop or the facility licensee in accordance with the guidance of this letter, prior to shipment of the contaminated component. Some NRC facility licensees have obtained NRC or Agreement State licenses, as appropriate, authorizing possession and use of components containing byproduct material at unspecified off site locations throughout the state in which the facility is located. NRC suggests this option be considered to avoid such problems.

Applications to NRC or to an Agreement State by NRC facility licensees for such byproduct materials licenses must be completely supported by necessary information. This includes contract provisions to be employed to demonstrate full licensee control of all related matters such as shipping procedures, health physics support personnel, health physics procedures, training and experience, cleanup operations, and final survey reports. In instances where full licensee control of all matters relating to the contaminated item while in the repair shop is not intended or feasible, the repair shop must obtain the appropriate license to permit the repair. If the licensee is able to satisfy the requirements for a byproduct materials license authorizing possession and use of his contaminated materials at unspecified sites, he may, in accordance with reciprocal NRC or Agreement State regulations, receive, possess, use and transfer such contaminated components at unspecified off-site locations in other states.

If the facility is located in a non-Agreement State, the NRC byproduct material license (issued pursuant to 10 CFR Part 30) would authorize the possession and use of the contaminated component in other non-Agreement States. By notifying the appropriate Agreement State authority by letter, or if necessary by telephone, at least five days prior to shipment of a contaminated component, an NRC licensee authorized to possess and use components containing byproduct material at unspecified off site locations throughout a non-Agreement State can (pursuant to Agreement State regulations similar to 10 CFR 150.20) obtain authorization to conduct the same activities within an Agreement State.

If the licensed facility is located in an Agreement State, the facility licensee must obtain from the Agreement State a license authorizing possession and use of components containing byproduct material at unspecified locations throughout that State. Under the reciprocity provisions of 10 CFR 150.20 and similar provisions in other Agreement State regulations, the licensee is permitted (for up to 180 days in any calendar year) to conduct the same activities in other

Agreement and non-Agreement States. If the shipment is to be made to a location in a non-Agreement State, NRC Form 241 must be submitted at least three days prior to shipment. For shipments to locations in other Agreement States, appropriate notification must be made. If the licensee conducts the same activity for more than 180 days in any calendar year in any other state than the one for which the license was issued, he must obtain another byproduct material license from the NRC or the Agreement State, as appropriate, authorizing it to conduct such activities in that State.

Regulatory references: 10 CFR 30.3, 10 CFR 150.20

Subject codes: 3.5, 12.2, 12.9

Applicability: All

HPPOS-274 **PDR-9306140034**

Title: Technical Assistance Request, Authority to Receive Returned Waste Originally Generated Under an NRC License, Westinghouse Electric Corporation

See the memorandum from J. E. Glenn to R. R. Bellamy dated February 26, 1992, and the memorandum from P. H. Lohaus to J. E. Glen dated January 30, 1992. These memos respond to a TAR from Region I concerning a request from Westinghouse Electric Corporation on guidance on how to receive waste originally generated under an NRC license.

Westinghouse requested guidance regarding whether a license condition must be incorporated into each license issued to Westinghouse by the NRC to explicitly authorize the return of radioactive waste originally generated under license and subsequently processed away from the licensed facility.

A proposed response by Region I suggested that no amendment is necessary to receive such material in accordance with the following conditions:

1. The possession limits on the license are not exceeded;

2. The form of the returned waste is authorized by the license and the radiological hazards from this waste have not been increased significantly by processing (since the facility originally generated the waste, this should not normally be the case, but some processing such as incineration may substantially concentrate the licensed material); and

3. There is adequate and appropriate storage capability for the returned waste at the licensed facility.

In addition, there would need to be reasonable assurance that the waste actually was that generated by the facility.

NMSS and LLWM reviewed the proposed Region I response. LLWM suggested, and NMSS concurred, that a fourth condition be added to the letter to verify that the licensee has specific authority in their license to receive the material. The Office of the General Counsel (OGC) raised this issue relative to the manner in which licenses are conditioned and a rule change is being developed to provide authority for reactor licensees to receive back material. LLWM did not believe that a similar situation exists for material's licenses given the standard wording, included at the top of the material license 374 form, which includes a general statement of authority to receive, possess, and transfer material authorized in the license.

OGC had no legal objections to the recommended course of action.

Regulatory references: License Conditions

Subject codes: 3.5, 9.0

Applicability: Reactor

HPPOS-130 **PDR-9111210344**

Title: Request for Retraction of Violation by Dairyland Power Cooperative

See the memorandum from J. A. Axelrad to W. H. Schultz dated February 10, 1983, and the incoming request from W. H. Schultz dated November 5, 1982. NRC's enforcement responsibilities pursuant to 10 CFR 30.41(b)(5) and (c) with respect to state-licensed waste burial site requirements do not include burial site requirements other than those relating to type, form, and quantity of materials.

A response from a licensee to a Region III Notice of Violation (NOV) requested withdrawal of one of the cited violations. The violation concerned adherence to

an acceptance criterion contained in the burial site license. The violation was based on 10 CFR 30.41(b)(5), that was interpreted to require that applicable byproduct material transfers be made in accordance with (under) terms of a license issued to the transferee. In the case in question, the transferee's license specified that drums must not be laid on their sides in the transport van. This licensee condition was not met, as determined by a South Carolina State inspector.

Since issuance of the NOV, further consideration of the interpretation of 10 CFR 30.41 as a basis for this citation was given. It was concluded that the responsibilities of a person transferring byproduct material under 10 CFR 30.41 are more appropriately defined in 10 CFR 30.41(c), which limits these responsibilities to verifying that the transferee's license authorizes receipt of the type, form, and quantity of byproduct materials to be transferred.

IE reviewed the case and agreed that the violation involving that drums not being lain on their side be retracted. This decision was based on the premise that NRC's enforcement responsibilities, pursuant to 10 CFR 30.41(b)(5) and (c) with respect to state-licensed burial site requirements, do not include burial site requirements not relating to type (radioisotope), form (chemical and/or physical), and quantity (maximum activity). In the subject case, the requirement for positioning the drums should not have been considered a violation. However, if a burial site's license does not authorize it to receive liquids, and a licensee transfers materials to the burial site that have not been dewatered, a citation against 10 CFR 30.41(c) for failure to verify that the burial site is authorized to receive waste containing liquid would be appropriate because the violation involves the form of the waste.

Regulatory references: 10 CFR 30.41, License Conditions

Subject codes: 3.5, 12.7, 12.17

Applicability: All

HPPOS-284 PDR-9306170040

Title: Technical Assistance Request, Interpretation of 10 CFR Part 40 and Certain Decommissioning Issues Regarding Fixed Contamination

See the memorandum from J. E. Glenn to D. M. Collins dated May 26, 1992, and the memorandum from J. H. Austin to J. E. Glenn dated April 29, 1992. ITT Corporation made a telephone request concerning interpretation of 10 CFR Part 40 and certain decommissioning issues related to equipment with fixed contamination. The licensee, ITT, was proposing to terminate a specific license and transfer the material (e.g., a contaminated grinder and saw) to themselves as a general licensee.

The maximum fixed contamination is 15,000 disintegrations per minute (dpm) per 100 square centimeters (100 cm^2) on the grinder and 10,000 dpm/100 cm^2 on the saw. The equipment was to be used with a thorium oxide polishing compound containing 0.16 to 0.20 percent thorium by weight. It was later determined that the licensee disposed of the grinder at an authorized burial site and intended to use only the saw and the polishing compound. The Th-232, which was previously used at this facility in a grinding operation, is a rare earth compound that is exempt under 10 CFR Part 40.13(c)(1)(vi).

In view of this information, NRC recommended that ITT decontaminate the saw according to the current guidelines for decontamination of equipment (average and maximum fixed Th-232 surface contamination of 1000 dpm/100 cm^2 and 3000 dpm/100 cm^2, respectively) before termination of the specific license and release of the saw for unrestricted use. If this level of cleanup is not achievable, ITT should decontaminate the saw to an alternative level that is "As Low As Reasonably Achievable" (ALARA). If the licensee decontaminates the saw to ALARA levels (in excess of existing guidelines), there should be no reason to object to transfer of the saw from a specific license to a general license.

Regulatory references: 10 CFR Part 40.13

Subject codes: 3.5, 5.8, 11.3, 11.4, 11.6, 12.4

Applicability: Source Material

HPPOS-155 PDR-9111220128

Title: Transfer by an NRC Licensee of Radioactive Material or of Radioactive-Contaminated Facility Components to the Department of Energy

See the memorandum from L. B. Higginbotham to G. H. Smith dated October 1, 1979, and the attached memorandum from G. H. Cunningham to R. F. Burnett and D. A. Nussbaumer dated August 22, 1979. The memos express the OELD opinion that a person may transfer licensed material to DOE or to persons working under contract to DOE. If on-site transfer is completed, the NRC licensee has not delivered licensed material to a carrier for transport and 10 CFR 71.12 does not apply.

The expressed OELD opinion is that an NRC licensee may transfer byproduct, source, or special nuclear material or radioactive-contaminated facility components to DOE (or one of its duly authorized representatives) pursuant to the provisions of 10 CFR 30.41, 10 CFR 40.51, and/or 10 CFR 70.42. If on-site transfer to DOE was completed, the NRC licensee would no longer be in the position of delivering "licensed material to the carrier for transport" under the general license provisions of 10 CFR 71.12 and the conditions precedent (e.g., an NRC-approved quality assurance program for shipping packages) to the licensee's use of such a general license would no longer be applicable.

Regulatory references: 10 CFR 71.12

Subject codes: 3.5, 12.13, 12.17

Applicability: All

HPPOS-257 PDR-9306070100

Title: Implementation of Policy and Guidance Directive FC 86-2, Revision 1, "Processing Material License Applications Involving Change of Ownership"

See the memorandum from J. E. Glenn to C. J. Holloway dated August 18, 1989, and the enclosed Policy and Guidance Directive, FC 86-2, Rev. 1. This guidance document changed NMSS policy regarding the issuance of new licenses because of change of ownership of licensed facilities. The new policy states that only an amendment is necessary to reflect the change in identity of the licensee in such a case. HPPOS-124 contains a related topic.

10 CFR Part 30, Section 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and Parts 31 through 35, nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntary or involuntary, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

Similar regulations are contained in 10 CFR Sections 40.46 and 70.36. Thus, the regulations are very clear that the control of licenses cannot be transferred without written permission from the Commission. The burden of adhering to this requirement is on the transferor; however, it may be necessary for the transferee to provide supporting information. The transferor is an NRC licensee that is selling or otherwise giving up control of a licensed operation, and the transferee is an organization that is proposing purchase or otherwise gaining control of an NRC-licensed operation.

FC 86-2, Rev. 1, changed NMSS policy regarding the issuance of new licenses because of change of ownership of licensed facilities. Previous policy required, in part, that a new license be issued if the transferor would remain in business as a separate entity. The new policy state that only an amendment is necessary to reflect the change in identity of the licensee to a transferee in such a case.

This policy reflects the appropriate level of review to assure that health and safety issues are resolved. However, there will be times when for NRC's administrative purposes a new license number will need to be issued. The middle five digits of a byproduct license are referred to as an institution code. The institution code identifies both the licensed entity and a site of operations. Several licenses may be issued using the same institution code. The use of the same institution code for two separate and currently existing entities would defeat the usefulness of this administrative system.

Therefore, NMSS and the Regions will sometimes be issuing new license numbers (institution codes) for licensing actions which, in fact, are amendments to an existing license. There will be no increase in the technical review. The License Tracking System will only permit such an action to be treated as an issuance of a new license. A fee for an amendment rather than a

fee for a new license will be charged in those instances where NMSS or the Regions issue a new license for administrative purpose only. This will save the time of both respective staffs that would otherwise be required to approve these as exceptions on a case-by-case basis.

Regulatory references: 10 CFR 30.34, 10 CFR 40.46, 10 CFR 70.36

Subject codes: 3.5, 11.2, 11.6, 11.7

Applicability: All

HPPOS-142 PDR-9111210381

Title: Licensing of Dial Painting Activities by Jewelers and Watch Repairers

See the memorandum from T. F. Dorian to G. W. Kerr dated October 25, 1976. It is an OELD opinion that Agreement State licensees can manufacture exempt products but they must possess an NRC license to distribute the exempt products.

NRC has retained the authority under 10 CFR 150.15(a)(6) to license under 10 CFR 32.14 and 30.15(a)(1) watch repairers and jewelers who strip radium paint from dials and hands of watches and reapply tritium paint. Subsection 274c. of the Atomic Energy Act (AEA) of 1954, as amended, provides that notwithstanding any agreement between the Commission and any State, the Commission is authorized to require that "the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission."

In issuing 10 CFR Part 150, which implemented certain AEA provisions, the Commission exercised its authority under AEA subsection 274c. by providing in 10 CFR 150.15(a)(6) that persons in Agreement States are not exempt from the Commission's licensing requirements with respect to: "The transfer or possession or control by the manufactures, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public." With respect to the meaning of "products intended for use by the general public," the Statement of Considerations accompanying Part 150 read, in part, as follows: "Control over consumer type devices, such as luminous watches, would be retained by the Commission."

On May 16, 1969, NRC amended 150.15(a)(6), and the Statement of Considerations accompanying the amendment that read, in part, as follows:

"In retaining regulatory authority over transfer of products 'intended for use by the general public' the Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment."

"In view of the increasing difficulty in determining whether or not such products are intended for use by the general public, the Commission has adopted the amendment of Part 150 set out below, which changes 150.15(a)(6) by deleting the phrase 'product ... intended for use by the general public' and substituted the phrase 'product ... whose subsequent possession, use, transfer and disposal by all other persons are exempted for licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter.'"

"Under Part 150 as amended below the transfer or possession or control by a manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material or source material whose subsequent possession, use, transfer, and disposal by all other person are exempted from Commission licensing and regulatory requirements under Parts 30 and 40, is not subject to the licensing and regulatory authority of an Agreement State even though the product is manufactured, processed, or produced pursuant to an Agreement State license. The manufacturer of such products in an Agreement State is subject to the Commission's regulatory authority with respect to transfer of any product which has been so exempted from the Commission's licensing and regulatory requirements. The Commission has confined its regulation of the transfer of exempt products to specifications for the products, quality control procedure, requirements for testing, and labeling. The authority of Agreement States to regulate any radiation hazards that might arise during manufacture of such products is not affected by the amendment. Accordingly, dual regulation will continue to be avoided."

Watch repairers and jewelers engaged either in stripping radium paint from a watch and reapplying tritium paint or in repair or reconditioning a watch and reapplying tritium paint, can be called processors (see, for example, 10 CFR 32.22). This interpretation matches portions of the Statement of Considerations of the amendment to 10 CFR 150.15(a)(6) quoted earlier.

Regulatory references: 10 CFR 150.15

Subject codes: 3.5, 12.2, 12.9

Applicability: Byproduct Material

HPPOS-136 **PDR-9111210365**

Title: Letter Dated February 6, 1978 ... Regarding Redistribution of Backlighted Dials

See the memorandum from J. R. Mapes to G. W. Kerr dated May 31, 1978. It is an OELD opinion that an NRC distribution license is not needed to return to owners repaired watches containing the original tritium sources. If the original tritium source is replaced with a new source, an NRC distribution license is required.

An OELD opinion was sought on the following questions concerning the licensing requirements applicable to the repair and redistribution of watches containing approximately 200 millicuries of tritium enclosed in three glass vials. These watches are generally described as liquid crystal display (LCD) watches back lighted by tritium activated luminous sources. The tritium used in the luminous sources is byproduct material within the meaning of Section 11e of the Atomic Energy Act of 1954, as amended. OELD is of the opinion that under the Commission's existing regulations these questions be answered as follows.

1. Are repair facilities required to have an NRC distribution license to return repaired watches that contain the original tritium sources to the owners?

No. Since repaired watches containing original tritium sources do not lose their status as exempt products under 10 CFR 30.19, an NRC distribution license is not required to return these watches to the owners.

2. Is an NRC distribution license required when the original tritium source is replaced with a new source and returned to the owner?

Yes. When an LCD watch is repaired by replacing the original tritium source or tritium time module with a new source or time module, the repairer must obtain a specific NRC or Agreement State byproduct material license authorizing the repair and a specific NRC distribution license authorizing the return of the watch to the owner.

3. Is it necessary for an individual offering repair services on watches containing 200 millicuries tritium sources to be licensed by the NRC or an Agreement State?

The answer depends on the type of repair service offered. A person performing repairs which do not involve replacement of the original tritium source or tritium time module is not required to be licensed. That same person, however, must obtain a specific byproduct material license either from NRC or an Agreement State in order to perform repairs that involve replacement of the original tritium source or tritium time module with a new tritium source or time module. Persons making such repairs are also required to obtain an NRC distribution license authorizing the return of the repaired watches to their owners.

The preceding analysis and conclusions leave one problem unresolved. If the manner in which the tritium source and/or tritium time module is inserted into an LCD watch is significant from the radiological health and safety standpoint, there would appear to be no justifiable basis for distinguishing between repairs that involve removal and reinsertion of the original tritium source or tritium time module and repairs that involve replacement of the original tritium source or tritium time module with a new tritium source or time module. This concern raises the question of the propriety of treating any repairs of LCD watches involving the tritium source or tritium time module as exempt "uses" within the meaning of 10 CFR 30.19.

The propriety of authorizing distribution of these items as exempt from further regulation in the face of a safety evaluation that virtually calls for (i.e., "anticipates") certain repairs to be done by the manufacturer can also be questioned. How can radiological health and safety be assured when the item (or its user) is exempt from regulation? In the absence of such assurance, how is the exemption justified? Perhaps a

definitive health physics analysis may be needed to answer these questions. In any event, some further thought on this matter seems to be called for.

Regulatory references: 10 CFR 30.19, 10 CFR 32.22, 10 CFR 150.15

Subject codes: 3.5, 3.6, 12.2, 12.9

Applicability: Byproduct Material

HPPOS-189 **PDR-9111210298**

Title: Transfer of Exempt Quantities of By-product Material from a Nuclear Power Plant

See the memorandum from L. J. Cunningham to R. R. Bellamy (and others) dated July 15, 1987. Enclosed with this memorandum are two others: the first from L. J. Cunningham to R. L. Fonner dated May 7, 1987; and the second from R. L. Fonner to L. J. Cunningham dated June 30, 1987. These memos state that exempt quantities of byproduct material, pursuant to 10 CFR 30.18, can be transferred from a nuclear power plant to a non-licensed laboratory provided: the transfer must not be for waste disposal, the transfer must not be for commercial distribution, and the material must not contain special nuclear or byproduct material other than that included in 10 CFR 30.71, Schedule B. HPPOS-131 and HPPOS-203 contain related topics.

The transfer of exempt quantities of byproduct material from a nuclear power plant to a non-licensee is permissible, provided all of the following general conditions are met.

1. The transfer meets all of the applicable requirements of 10 CFR Parts 20-71.

2. The transfer meets all applicable radioactive material transportation requirements of the U.S. Department of Transportation (49 CFR 100-178) and the U.S. Postal Service (39 CFR 124).

3. The transfer does not violate any applicable state regulations.

In more specific terms, the transfer, pursuant to 10 CFR 30.18, must meet all of the following conditions:

1. The transfer must not be for purposes of waste disposal.

2. The transfer must not be for purposes of commercial distribution, except in accordance with a license issued under 10 CFR 32.18 stating that the byproduct material may be transferred to persons exempt under 10 CFR 30.18 or equivalent Agreement State regulations [10 CFR 30.18(c) and (d)].

3. The material transferred must not contain special nuclear material or byproduct material other than that included in 10 CFR 30.71 Schedule B. The reactor licensee transferring exempt quantities of byproduct material must provide reasonable assurance that the material transferred does not contain radionuclides not included in 10 CFR 30.71 Schedule B.

Regulatory references: 10 CFR 30.18, 10 CFR 30.71

Subject codes: 3.5, 11.1, 12.10

Applicability: Reactor

HPPOS-203 **PDR-9111210346**

Title: Transfer of Reactor Activated Materials to Persons Exempt

See the memorandum from S. A. Treby to V. L. Miller dated July 21, 1988. The distribution of irradiated electronic components from neutron activation must be licensed under 10 CFR 32.11. In addition, and in a different context, the commercial transfer of products does not necessarily mean the transfer of money between supplier and consumer. HPPOS-131 and HPPOS-189 contain related topics.

Guidance was sought on whether a possession or distribution license under 10 CFR 32 was required for two separate situations. The first situation involved the irradiation of electronic components for the purpose of determining their "hardness" against radiation exposure. The irradiation of these various components would result in induced radioactivity.

The NRC stated that they had previously addressed the issue of induced radiation in another context (see HPPOS-095). From that issue, the term "introduction" was interpreted as encompassing not only the introduction of byproduct material into another product, but the activation of material within a prod-

uct or material and transforming it into byproduct material. Therefore, if the activated material within the electronic device being irradiated is in exempt concentrations, it may be possessed and transferred pursuant to the exemption provided under 10 CFR 30.14. But, the irradiator introducing the byproduct material must be licensed pursuant to 10 CFR 32.11 if the material is to be transferred to an exempt person under 10 CFR 30.14.

The second situation in which guidance was sought involved the distribution of a small number of exempt quantity "check sources" by an x-ray equipment manufacturer. In this context, the manufacturer takes the position that because it distributes the sources to its customers for "free" (without monetary charge), he is not commercially distributing them.

The manufacturer is interpreting the term "commercial distribution" in a limited manner. The NRC views the meaning of "commercial distribution" as the introduction of a material into the market place, whether or not a charge is assessed for that distribution. Because the NRC is mandated to protect public health and safety from radiation hazards, it would be absurd to determine the protection of the public on the basis of whether a charge was made for a quantity of byproduct material. Therefore, the distribution is a "commercial distribution" and must be licensed pursuant to 10 CFR 30.18(d) and 10 CFR 32.18.

Regulatory references: 10 CFR 30.14, 10 CFR 30.18, 10 CFR 32.11

Subject codes: 3.5, 11.1, 11.3

Applicability: All

HPPOS-095 **PDR-9111210196**

Title: Distribution of Products Irradiated in Research Reactors

See the letter from F. J. Miraglia to All Non-Power Reactor Licensees dated June 25, 1986. The letter states that irradiation of products in a reactor is not prohibited; however, 10 CFR 30.14 prohibits the introduction of byproduct material into products for distribution to unlicensed persons except per license requirements contained in 10 CFR 32.11 or equivalent Agreement State regulations. Included with the letter is an NRC Policy Statement published in the Federal Register on March 16, 1965 (30 FR 3462).

The NRR office had received inquiries concerning products irradiated in research reactors that were subsequently distributed to unlicensed persons. The inquiries were related to the irradiation of gems, silicon chips, and other products.

The NRC is concerned that these products may acquire relatively long-lived induced radioactivity when irradiated in a reactor. Although irradiation of products in a reactor is not prohibited, 10 CFR 30.14 prohibits introduction of byproduct material into a product for distribution to an unlicensed distributor, unless the distributor has a specific license issued pursuant to 10 CFR 32.11. Because Agreement States do not issue this type of license, the NRC has exclusive jurisdiction over reactors and distribution of radioactive consumer products. Licensees are responsible for assuring that distributors of any product that has acquired induced radioactivity in their reactor be licensed to distribute these products in accordance with 10 CFR 30.14(c) and 30.31. If licensees directly distribute irradiated products to unlicensed individuals, a new license must be obtained to reflect this activity.

Regulatory references: 10 CFR 30.14, 10 CFR 32.11

Subject codes: 3.5, 3.8, 12.2

Applicability: All

HPPOS-131 **PDR-9111210347**

Title: No License is Required for a Person to Receive Exempt Quantity Byproduct Material

See the letter from T. F. Dorian to P. F. Gustafson (Illinois Department of Nuclear Safety) dated July 30, 1982. It is an OELD opinion that a person does not need a license to possess an exempt quantity of byproduct material even if it was received from a person not licensed under 10 CFR 32.18 to distribute. There are no restrictions on subsequent transfer, except as provided in 10 CFR 30.18(c) and (d). HPPOS-189 and HPPOS-203 contain related topics.

Prior to answering two specific questions, 10 CFR Sections 30.14 and 30.18 were explained. Section 30.14, "Exempt Concentrations," is divided into four paragraphs. Paragraph (a) exempts persons from

NRC regulations if they receive, possess, use, transfer, own, or acquire products or materials that have less than the concentrations of byproduct material listed in 10 CFR 30.70, "Schedule A - Exempt Concentrations." Paragraph (b) states that 10 CFR 30.14 does not authorize the import of byproduct material or products containing byproduct material. Paragraph (c) exempts from NRC regulations a manufacturer, processor, or producer in an Agreement State of a product or material containing byproduct material if that material is less than the concentrations listed in 10 CFR 30.70 and if it is introduced into the product or material by a specific licensee of the NRC or an Agreement State that expressly authorizes the introduction. This exemption does not apply to the transfer of byproduct material in foods, beverages, etc., used by people. Paragraph (d) specifies that a person who wants to introduce byproduct material into a product or material that is to be transferred to a person exempted under Paragraph (a) or under equivalent Agreement State regulations can do so only under a license issued by the NRC under 10 CFR 32.11 or under the general license provided in 10 CFR 150.20.

10 CFR Section 30.18, "Exempt Quantities," is also divided into four paragraphs. Paragraph (a) exempts persons from the Commission's regulations if they receive, possess, use, transfer, own, or acquire byproduct material in individual quantities, each of which does not exceed that listed in 10 CFR 30.71, "Schedule B." Paragraph (b) exempts from licensing persons who received byproduct material before September 15, 1971, under a general license provided in 10 CFR 31.4. Paragraph (c) states that 10 CFR 30.18 does not authorize for "commercial distribution" the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution. Paragraph (d) specifies that a person can transfer byproduct material for commercial distribution in the quantities listed in 10 CFR 30.71 only in accordance with a license issued under 10 CFR 32.18.

The first question concerned whether a facility must have a license to possess a quantity of radioactive material less than the exempt quantity as stated in 10 CFR 30.71. NRC stated that a facility does not need a specific license to possess an exempt quantity of byproduct material provided it does not plan on possession for the purposes outlined in 10 CFR 30.18(c) and (d). The facility does not need documentation that the byproduct material was received from a person licensed under 10 CFR 30.18. In addition, exempt material may be transferred from a facility that possessed the material as an exempt quantity and the facility is not responsible for providing labeling; a requirement placed on the manufacturer as specified in 10 CFR 32.19.

The second question concerned whether a licensee (Facility A), who had bought an exempt quantity of radioactivity material from the manufacturer, can give the radioactive material to Facility B. (As examples, Facility B is not licensed for the possession of any radioactive material, or Facility B does possess a radioactive material license, but it is not licensed for this radioactive material.) In reply, NRC stated that Facility A may give an exempt quantity of material to Facility B provided that it does not transfer the material as part of a commercial distribution under the provisions of 10 CFR 30.18(c) and (d) or does not have reason to believe Facility B will transfer the material for purposes of commercial distribution to persons exempt under 10 CFR 30.18 or equivalent Agreement State regulations. Therefore, Facility A may transfer the material provided it is an exempt quantity and that paragraphs (c) and (d) of 10 CFR 30.18 do not apply.

Regulatory references: 10 CFR 30.14, 10 CFR 30.18, 10 CFR 30.71

Subject codes: 3.5, 3.8

Applicability: All

HPPOS-272 **PDR-9306100071**

Title: Request for Interpretation of 10 CFR 39.47, "Radioactive Markers"

See the memorandum from J. E. Glenn to R. J. Pate dated January 9, 1992. This NMSS memo responds to Baker Sand Control's October 29, 1991 request to terminate NRC License No. 50-21402-01. In its request, Baker Sand indicated that it would only use (and supposedly receive) 1-microcurie cobalt-60 markers, and pursuant to 10 CFR 30.18, it would not be required to be licensed. While 30.18(a) states, in part, that individuals may transfer "exempt" quantities, this provision has been interpreted by NRC legal staff (Enclosure 1) as meaning an occasional or infrequent transfer on a noncommercial basis. For example, this provision allows laboratories to occasionally transfer

radioactive tissue samples, tagged compounds, counting standards, etc. Often the radioactive properties of the items are only incidental to the transfer of the materials. HPPOS-131 and HPPOS-189 contain related topics.

10 CFR 30.18(a) also states that a person is exempt from the requirements for a license, except as provided in paragraphs (c) and (d) of that section. Paragraph 30.18(c) indicates that the section does not authorize transfer of byproduct material for commercial distribution, and paragraph 30.18(d) indicates that no person may, for purposes of commercial distribution, transfer byproduct material except in accordance with a license pursuant to 10 CFR 32.18. It is NRC legal staff's opinion (Enclosure 1, last paragraph) that "commercial distribution" does not necessarily mean that money must change hands, instead it implies a transfer into the market or to the general public resulting in a benefit for the distributor. [Enclosure 1 is included in this report as HPPOS-203.]

It is NMSS opinion that Baker Sand would clearly be transferring the markers for a commercial benefit. Therefore, transfer of collar markers by Baker Sand is not authorized under the exemption in 10 CFR 30.18. Baker Sand does have the option to obtain an NRC distribution license under 10 CFR Part 32. However, the products must meet the labelling, packaging, and product brochure requirements of 32.18, and Baker Sand must have a possession license for each place of storage.

Generally speaking, only under a specific license issued pursuant to 10 CFR Part 39 is a person authorized to use (attach to pipe collars) and leave unlabeled radioactive markers in wells. In developing Part 39, it was understood that radioactive markers are used and left in the well by licensees. It was also understood that there is a possibility the well markers may later surface if the will casing is removed. Based on information from a technical expert in this field, NRC staff understood that the markers usually fall to the ground as the casing is disassembled, but sometimes the markers might be picked up by the workers conducting these operations. Of course, this raised some health and safety concerns. In an effort to reconcile these concerns, it was decided to restrict the markers to the levels of activity listed in 10 CFR 30.71; thus, reducing any health and safety risks. This issue is further discussed in 50 FR 13797, the proposed rule for 10 CFR Part 39.

The staff also did not intend to require licensees to inventory or track the markers after the markers had been placed in a well. The physical inventory requirements of 10 CFR 39.37 only pertain to the licensee's receipt and storage of the markers. Nor was there any intent to place regulatory responsibility on the well owner or operator after the markers have been placed in a well.

Questions have also been raised concerning reciprocity with Agreement States. If Baker Sand's Texas or Louisiana licenses allow the company to use radioactive markers at temporary job sites, then the company is also allowed to use the markers under the 10 CFR 150.20 general license. NMSS does not consider this activity to be a transfer or disposal. However, Baker Sand would continue to need an NRC license if it intends to possess and store markers at its facilities in Alaska.

Regulatory references: 10 CFR 30.18, 10 CFR 30.71, 10 CFR 39.37, 10 CFR 150.20

Subject codes: 3.5, 11.2, 12.2

Applicability: All

HPPOS-308 **PDR-9306240390**

Title: Technical Assistance Request, Licensee's Request for an Exemption to 10 CFR 35.49(a)

See the memorandum from J. E. Glenn to J. A. Grobe dated December 21, 1990. This memo responds to a technical assistance request from Region III, dated March 28, 1989, concerning guidance in the application of Policy and Guidance Directive FC 84-12, Revision 2, which authorizes the Regions to grant special authorizations and exemptions. Exemption 1c of the directive, which grants an exemption to 10 CFR 35.14(b) [now 10 CFR 35.49(a)], concerns the transfer of byproduct material. HPPOS-131 and HPPOS-189 contain related topics.

In an effort to respond to this request, NRC Headquarters queried the Regions regarding their current practices and/or guidelines concerning the issue. Based on the responses, Headquarters did not identify specific problems with current licensing practices on this matter. In addition, the occurrence for such applications was minimal.

The following responses were compiled from questionnaires sent to the Regions:

Question 1: Is there a maximum number of facilities to which we should allow a license to distribute material?

Several of the Regions suggested that three facilities be the maximum number allowed. Headquarters is not aware of any existing problems with current methods used by each region to determine the maximum number of facilities to which byproduct material may be transferred. Three facilities appear to be acceptable to approve for inter-hospital transfer. In order to provide a more uniform practice in this matter, approvals for more facilities should be coordinated with the Medical and Academic Section.

Question 2: At what point should we require the transferor to obtain a Part 32 license?

A Part 32 license is required when there is a commercial relationship between the supplier and the receiver, such that the supplier is operating a business for monetary profit, i.e., conducting a nuclear pharmacy. At some point, collective purchasing and processing of byproduct material takes on a commercial aspect. Therefore, the justification for inter-hospital transfers should be examined carefully.

Question 3: Should additional fees be charged for those licensees who request authorization to transfer materials if a Part 32 license is not required?

Since the exemptions should cover only transfers and not commercial distributing, the authorized uses and fee categories would not change.

Question 4: What is considered acceptable justification from the licensee before we authorize or deny the transfer of material?

Headquarters is reluctant to state specific requirements for acceptance of denial of routine exemptions to 10 CFR 35.49(a) since the Regional offices would no longer have the flexibility to make those licensing decisions on a case-by-case basis. However, the Regional office should thoroughly investigate the affiliation or relationship between the supplying facility and those receiving the radiopharmaceuticals to ensure that there exists a valid and non-commercial reason for granting an exemption.

In those instances when the Regional office is not comfortable with the nature of the interaction between facilities requesting an exemption to 10 CFR 35.49(a), the number of facilities to which a licensee has applied to distribute, or the necessity of a Part 32 license, technical assistance can be obtained from the Medial and Academic Section. All non-routine authorizations and exemptions should be coordinated with the Medical and Academic Section prior to final licensing action.

Regulatory references: 10 CFR 35.49

Subject codes: 3.5, 11.1, 11.3, 12.19

Applicability: Byproduct Material

HPPOS-137 **PDR-9111210369**

Title: 10 CFR 31.5(c)(9): Aircraft at "Particular Location"

See the memorandum from J. R. Wolf to N. Bassin dated March 13, 1979. This OELD opinion states that under 10 CFR 31.5(c)(9)(i), transfers to general licensees are permitted under this provision only if "the device remains in use at a particular location." An acceptable interpretation of this language is that a specific airplane should be regarded as a "particular location."

The basis for this opinion is that the "particular location" requirement appears in the regulations "to achieve a workable system for identifying users under the general license" (Statement of Consideration, 39 FR 43531, December 16, 1974). Because of the documentation requirements applicable to aircraft, transfers between the manufacturing company and an airline, or between subsequent parties in possession should in no way impair the Commission's ability to identify the users. In addition, a report to the Commission will be required under the second sentence of 10 CFR 31.5(c)(9)(i).

Regulatory references: 10 CFR 31.5

Subject codes: 3.5, 3.8

Applicability: Byproduct Material

HPPOS-285 **PDR-9306180040**

Title: Technical Assistance Request Dated September 11, 1992, Regarding the University of Pittsburgh Incinerator Ash Disposal Request and New Information Applicable to August 6, 1991 TAR

See the memorandum from J. E. Glenn to R. E. Bellamy dated March 19, 1993. This memo responds to a technical assistance request (TAR) from Region I, dated September 11, 1992, regarding the University of Pittsburgh incinerator ash disposal request and new information applicable to a TAR dated August 6, 1991. The latter TAR was written in the context of 10 CFR 20.105, but it also applies to "new" 10 CFR 20.1302.

Regarding the incinerator ash disposal request, the University of Pittsburgh proposes to use concentration limits applicable only to water effluents, in its procedures for disposing of the incinerator ash as "ordinary ash." Although previously allowed by license condition, the concentration limits are not necessarily appropriate for disposal of incinerator ash. The Division of Low-Level Waste Management and Decommissioning estimated that its generic dose assessment for incinerator ash disposal would be done by April 1993. Therefore, reply to this portion of the TAR was withheld until completion of the assessment.

Regarding review of new information applicable to a TAR dated August 6, 1991, the following decisions apply. First, the request for exemption from the posting requirements of 10 CFR 35.205(d) may be granted for emergencies in patient units and critical care situations where movement of the patient would compromise the health of the patient. Second, the request for approval of the higher limits of 10 CFR 20.105(b)(1) and 20.105(b)(2) [or, at present, 10 CFR 20.1302(b)(ii)] in unrestricted areas surrounding the rooms of patients receiving brachytherapy or radiopharmaceutical therapy with iodine-131 does not provide sufficient information about the tracking of patients in adjacent rooms, a system to monitor radiation levels in those rooms, and patient occupancy times, etc. Therefore, the region was advised to request clarification of the tracking system and survey procedures.

Regulatory references: 10 CFR 20.105, 10 CFR 20.1302, 10 CFR 35.205, License Conditions

Subject codes: 3.6, 9.0, 9.3

Applicability: Byproduct Material

HPPOS-044 **PDR-9111210197**

Title: Guidelines for Decontamination of Facilities and Equipment (July 1982 Revision)

See the memorandum from R. E. Cunningham to G. Page (and others) dated July 22, 1982. The memo provides NMSS revision of "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Materials."

More than one branch of the Division of Fuel Cycle and Material Safety have been using a document titled, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Materials." There are, however, two versions of this document, dated November 1976 and June 1980, that have slight differences in wording but not in technical content. In order to provide a single document that can be used uniformly by all branches of the Division, the version dated June 1980 was revised, and this revised version, dated July 1982, should be used by all branches of the Division until a subsequent revision is required.

A copy of the July-1982 revision is provided as an enclosure to the memorandum. The instructions in the report specify the radionuclides and radiation exposure rates which should be used in decontamination and survey of surfaces or premises and equipment prior to abandonment or release for unrestricted use. The limits in Table 1 of the report do not apply to premises, equipment, or scrap containing induced radioactivity for which the radiological considerations pertinent to their use may be different. The release of such facilities or items from regulatory control is considered only on a case-by-case basis.

Regulatory references: 10 CFR 30.3, 10 CFR 40.3, 10 CFR 70.3

Subject codes: 3.6, 5.0, 12.4

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-277 PDR-9306140177

Title: Technical Assistance Request, Schering Plough Corporation, Release of a Facility for Unrestricted Use

See the memorandum from J. E. Glenn to J. D. Kinneman dated August 7, 1991, and the memorandum from J. H. Austin to J. E. Glenn dated July 24, 1991. These memos respond to the TAR by Region I, dated July 19, 1992 (enclosures), regarding the release of a facility for unrestricted use by the Schering Plough Corporation. The Schering Plough Corporation (Schering) Animal Health Research Center in Cream Ridge, New Jersey, was a satellite location for activities authorized by License No. 29-00244-02. The laboratories used for small quantities of H-3, C-14, and I-125 were decommissioned, and a request submitted to release the site for unrestricted use. Confirmatory surveys indicated that the laboratories can be released, but records describe the burial of four cows carcasses on the property. Information regarding the burial is provided in the Schering correspondence (enclosures). However, the burial site at the Schering facility in Cream Ridge cannot be released for unrestricted use by Region I without the concurrence of NMSS. Based on the information submitted by the licensee, especially the memorandum dated November 21, 1989 (enclosures), Region I recommends that you concur in the release without further information from or action by the license. NMSS concurred that the submitted information demonstrates compliance with "0.5 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal..." in accordance with 10 CFR 20.306(b), and agreed that the request should be approved. This health physics position also applies to "new" 10 CFR 20.2005(a).

Regulatory references: 10 CFR 20.306, 10 CFR 20.2005

Subject codes: 3.6, 5.8, 9.0, 9.7

Applicability: All

HPPOS-286 PDR-9306180040

Title: Technical Assistance Request, Angell Memorial Animal Hospital, Boston, MA; Release to Unrestricted Area of Animals Containing Iodine-131

See memorandum from J. E. Glenn to R. E. Bellamy dated March 11, 1993. This memo responds to a technical request from Region I, dated November 25, 1992, regarding Angell Memorial Hospital's request to release animals treated with iodine-131 (I-131) when the dose rate is less than 1 mR/hr at 6 inches.

The licensee was previously authorized to perform radionuclide therapy on animals with iodine-131 (I-131) and phosphorus-32 (P-32). In a previous application for a material license, the licensee provided an "Instruction to Owners" sheet, which appears to have provided adequate care and handling instructions to the owners. Authorization was granted, with the reasoning that human patients are allowed to be released at a level twenty times greater than the limit requested. If the animal had to be held until it reached background levels, the procedure would become prohibitively expensive, and the stress on the animal would also be increased. The dose that the owner would receive should be minimal if they are given instruction and the animal is handled as little as possible.

Therefore, provided that the licensee provides and commits to distribute a similar "Instructions to Owners" sheet to owners of animals undergoing radioiodine therapy, and provides a demonstration that the limits in 10 CFR 20.1301 will not be exceeded for any member of the public, licensee's request was approved.

Regulatory References: 10 CFR 20.1301, 10 CFR 35, License Conditions

Subject codes: 3.6, 11.2, 11.5

Applicability: Byproduct Material

HPPOS-314 **PDR-9306250188**

Title: Technical Assistance Request, Community Memorial Hospital, Toms River, NJ, Regarding Exemption from 10 CFR 35.75 (b)

See the memorandum from J. E. Glenn to R. R. Bellamy dated February 26, 1991. This memo responds to the TAR dated November 21, 1988, regarding an exemption request by Community Memorial Hospital, Toms River, New Jersey. The licensee requests an exemption from 10 CFR 35.75(b) in order to release patients containing iodine-125 (I-125) permanent implants with shielded dose rates of 5 mR/hr or less at one meter. An exemption from the current rule is necessary for this practice since the intention of the rule is to require a dose rate measurement with a survey measurement instrument without the presence of interposed shielding at the time of that measurement.

NMSS used the assistance of four NRC medical consultants, including two physicists and two radiation therapists, in evaluating this exemption request. Per our request, the licensee submitted additional information in a letter dated December 3, 1990, regarding patient treatment areas and shielding construction. In addition, the licensee proposed the use of palladium-103 (Pd-103) permanent implants. Based on reviews of information submitted by the licensee, NMSS believes that the exemption request may be granted for the use of I-125 and Pd-103 for the treatment of head and neck soft tissue sarcomas. The use of I-125 or Pd-103 implants for the treatment of sarcomas located in other body parts, as proposed by the licensee, should not be authorized based on the impracticality of attempting to design shielding devices that the patient would find comfortable for the duration of the treatment.

Safety regulations regarding the medical use of byproduct material should not unduly infringe on the practice of medicine nor severely impact upon patients. However, The licensee must comply with requirements in the following sections of 10 CFR Part 35 Subpart G: Section 35.400, "Use of sources for brachytherapy"; Section 35.406, "Brachytherapy source inventory"; Section 35.410, "Safety instruction"; Section 35.415, "Safety precautions"; and Section 35.420, "Possession of survey instruments". In addition, NMSS recommends that the following radiation safety guidance be sufficiently addressed by the licensee prior to granting an exemption for the use of interposed shielding to meet the release criteria described in 10 CFR 35.75(b):

1. The licensee should agree to provide the patient with an identification bracelet and a wallet card. The bracelet must contain plain wording to indicate that the patient has been implanted with radioactive material and a reference to the wallet card which would contain the following information: (a) radionuclide and activity implanted; (b) exposure rate at the time of release; (c) a 24-hour emergency telephone number; and (d) a contact person in the event of a medical emergency or dislodged source.

Explicit information regarding the implanted radioactive material could be essential to medical personnel in the event of an emergency. A physicist or radiation safety officer could determine any necessary radiation safety protection measures to be taken by the medical personnel, as well as, the significance of any possible radiation exposure received by a member of the public from the patient if the appropriate radionuclide information is promptly available. In addition, identification of patients implanted with radioactive material could also decrease the chance of accidental burial of a radioactive source in the event of an unexpected death.

2. Prior to release from hospitalization, the licensee should agree to provide the patient with safety instruction equivalent to the instruction required for licensee personnel described in 10 CFR 35.410, and safety precautions as described in 35.415(a)(5) and 35.415(b). In addition, the instruction should include the following radiation safety guidance: (a) the purpose and proper use of the lead shield; (b) the conditions under which it must be worn; and (c) the importance of wearing the ID bracelet and carrying the wallet card.

The instruction should be in oral and written form so that the patient has a copy of the radiation safety guidelines available after release from hospitalization. It is recommended that the instruction be routinely conducted by an individual that is knowledgeable of brachytherapy procedures and associated regulatory requirements, such as, the radiation therapy physician, radiation safety officer, or a qualified designee that is knowledgeable of brachytherapy procedures and associated regulatory requirements. It is also recommended that a responsible member of the patient's household be present at the time of instruction so that an individual, other than the patient, has received

instructions and can assist the patient in complying with the radiation safety guidance.

3. The licensee should develop methods of compliance with radiation safety guidance. For example: (a) the interposed shielding device should be in a configuration to provide for maximum comfort and radiation protection for the duration of the treatment period; (b) prior to implantation, the licensee must reach a conclusion based on available information that the patient is reasonably able to comply with the radiation safety instruction given prior to release from hospitalization; and (c) the licensee should provide some follow-up mechanism(s), such as, conducting (1) periodic visits to the patient's residence, (2) periodic telephone contacts with the patient, or (3) periodic follow-up evaluations to ensure regulatory compliance. These periodic checks may be performed by the RSO or a qualified individual designated by the RSO.

4. The exemption should be limited to a set number of patients and re-evaluated after a portion has been treated and released under this practice. In addition, the licensee needs to evaluate patient compliance and report the results of the evaluations to the Regional office on a periodic basis.

By requiring licensees to address these radiation safety concerns, when releasing patients treated with permanent implants with shielded dose rates of 5 mR/hr or less at one meter, we can ensure public health and safety without significantly infringing on the medical use of byproduct material. Further, we believe this practice should be the exception rather than the rule.

Regulatory references: 10 CFR 20.1301, 10 CFR 35, License Conditions

Subject codes: 3.6, 11.1

Applicability: Byproduct Material

HPPOS-260 **PDR-9306070194**

Title: Policy and Guidance Directive FC 92-03, "Exemptions from 10 CFR 35.400 for Uses Not Currently Authorized for Iridium-192 Seeds Encased in Nylon Ribbon and Palladium-103 Seeds as Brachytherapy Sources"

See the memorandum from R. E. Cunningham to R. W. Cooper, II, (and others) dated August 17, 1992. This directive provides guidance on granting exemptions from 10 CFR 35.400, "Uses of Sources for Brachytherapy" for iridium-192 (Ir-192) and palladium-103 (Pd-103). An exemption from the regulation is needed when the licensee proposes to use brachytherapy sources in a manner not listed. Regional personnel receiving license amendment requests for authorization of gold-198 (Au-198) and iodine-125 (I-125) seeds for intracavitary and topical applications should not follow the exemption guidance herein, but continue to forward the proposed amendment response to the Medical, Academic, and Commercial Use Safety Branch via a Technical Assistance Request for review and concurrence.

It is not the intent of 10 CFR Part 35 to prohibit appropriate medical practices. One of the objectives of the listing of 10 CFR 35.400 is to ensure that sealed sources used in brachytherapy procedures have undergone appropriate safety review. The current sources listed in 10 CFR 35.400 , with their specific types or conditions of use, i.e, intracavitary, interstitial, and topical, have been subjected to specific testing criteria to evaluate the integrity of the source when used in that manner. When a manufacturer or end user requests that a safety review be performed for a proposed type of use, the integrity of the source is tested against the criteria for the type of use requested and not against all testing criteria associated with the other types of use.

Ir-192 and Pd-103 seeds authorized for interstitial use only, appear to have been routinely used for intracavitary use for many years with no apparent health and safety problems. The Sealed Source Safety Section concludes that registered sources which have passed the testing criteria for interstitial use could be used in intracavitary or topical applications without requiring the licensee to commit to additional administrative controls to ensure safe use of these sources.

For Ir-192 seeds encased in nylon ribbon and Pd-103 seeds, the region may approve a request for exemption

from the requirements of 10 CFR 35.400 (d) and (g) to allow other than interstitial treatment of cancer. The region may amend the license without additional radiation safety procedures. The region should amend the license with the following license condition. .

"Notwithstanding the requirements of 10 CFR 35.400 (d) and (g) the licensee may use iridium-192 seeds encased in nylon ribbon and Pd-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee."

Requests for exemptions from the uses specified for other sealed sources will be handled on a case-by-case basis.

Regulatory references: 10 CFR 35.400

Subject codes: 3.8, 11.1

Applicability: Byproduct Material

HPPOS-156 **PDR-9111220130**

Title: Apparent Unauthorized Use of Byproduct Material, Resurrection Hospital, Chicago, Illinois

See the memorandum from L. B. Higginbotham to J. M. Allan dated August 14, 1975. If a licensee administers a radiopharmaceutical for an authorized procedure, it may conduct additional unauthorized procedures, provided that additional administrations are not given. HPPOS-313 contains a related topic.

An interpretation of what constitutes a venogram in nuclear medicine was sought. A venogram is defined as blood vein imaging that includes both blood pool imaging and blood flow studies. For all practical purposes, these two studies are inseparable; that is, blood pool images will also define the rate of blood flow depending on the presence of embolisms in the venous system being imaged. Such embolisms could include blood clots in the veins. Venous imaging is usually necessary to evaluate the outcome of lung scans and is commonly used in conjunction with lung scans.

If a licensee administers a radiopharmaceutical for a license-authorized procedure, it may conduct any number of additional procedures whether they are authorized or not provided that additional administrations are not performed for purposes of the unauthorized procedure (although additional administrations may be needed for the authorized procedure). The basis for the above is that once a dose is administered to a patient for a procedure that is authorized, no additional harm from radioactive materials can result to the patient during the conduct of other medical procedures. Of course, administering a dose solely for an unauthorized procedure is in noncompliance with NRC regulatory requirements.

The above interpretation has the concurrence of OELD and DBER.

Regulatory references: License Conditions

Subject codes: 3.8

Applicability: Byproduct Material

HPPOS-176 **PDR-9111210268**

Title: Authority to Penalize Willful False Exposure of Personnel Monitoring Device and Other Hoaxes

See the memorandum from J. Lieberman to J. R. Metzger dated August 26, 1980, and the incoming request from J. P. Stohr dated May 7, 1980. It is an OELD opinion that using licensed materials for malicious purposes or obtaining false dosimeter readings is not authorized by licenses. A person who does so is conducting activities without a license. Depending on the circumstances, such a person could be subject to enforcement sanctions.

Region II pointed out the apparent deliberate exposure of five personnel dosimeter devices (film badges) at Whittaker Memorial Hospital to between 38 and 71 rem as representative of false alarms and hoaxes that have exercised licensees, NRC Regional Offices, and State Agencies with increasing frequency in recent years. This results in the dilution of safety programs and the waste and misdirection of limited resources. The question involves NRC authority to penalize this type of behavior.

It is an OELD opinion that a person conducting activities without a license is in violation of the Atomic Energy Act. A person as used here could mean a licensee, employee, etc. It must not be construed that licensees should always be cited for

something an employee does in the way of hoaxes, where the licensee has no control and no regulatory requirement exists. Of course, this should be determined on a case-by-case basis.

One case mentioned by OELD involved two employees damaging some fuel bundles with corrosive material. Some 68 allegations were made and an investigation showed none of them to be valid. An extensive search of the Atomic Energy Act by OELD indicated that the licensee could not be found in violation of the Act because of what the employees had done. In this case, the licensee pressed charges and the employees were found guilty and sentenced to jail terms.

Hoaxes, willful false dosimeter exposures, or other similar events should be brought to the attention of HQ. It may be that the licensee was at fault, such as failure to follow approved security measures. If an employee commits an offense against the licensee, there may be something NRC can do depending on the circumstances, but it is doubtful. The most likely course of action would be for the licensee to dismiss the employee or to ask for local police assistance and press charges if the licensee desires.

Regulatory references: 10 CFR 30.3

Subject codes: 3.8

Applicability: All

HPPOS-124 **PDR-9111210287**

Title: Regarding Transfer of Control of a Corporation Holding NRC Licensees

See the letter from V. L. Miller to A. C. Myers (Attorney at Law) dated March 24, 1981. NRC approval for transfer of control of a corporation, which owns subsidiaries with NRC licenses, is not required if (1) the name of the licensee does not change, and (2) the personnel actually involved in licensed operations are not substantially changed. HPPOS-257 contains a related topic.

Guidance was sought concerning NRC policy regarding transfer of control of a corporation that owns two subsidiaries holding NRC source material licenses. NRC approval would not be required on such a transfer, provided that (1) the name of the licensee does not change, and (2) the personnel actually involved in the day-to-day licensed operations are not substantially changed. Otherwise, an application for license amendment should be submitted by the subsidiary for NRC review. Also, a license amendment must be applied for if expansion or relocation of the places of use of radioactive material are planned.

Regulatory references: 10 CFR 30.34, 10 CFR 40.46, 10 CFR 70.36

Subject codes: 3.8, 12.19

Applicability: Byproduct Material

2.5 ACCESS CONTROL

HPPOS-014 **PDR-9111210110**

Title: Access Control to High Radiation Areas - Turkey Point

See the memorandum from L. B. Higginbotham to J. T. Sutherland dated March 8, 1979. A licensee may establish controls at locations beyond the immediate boundaries of a High Radiation Area to take advantage of natural or existing boundaries. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1601.

Headquarters reviewed a citation made for conditions at Turkey Point and the licensee's written objection to the citation. This citation was against the technical specification that requires each High Radiation Area in which the intensity of radiation is greater than 1,000 mrem/hr to be provided with locked doors. The citation identified the regenerative heat exchangers and reactor cavity filters, that were both within containment, as creating High Radiation Areas.

The licensee responded that they did not believe the conditions cited constituted an item of noncompliance. They stated that reactor containment was identified as a High Radiation Area, it was maintained locked except when access was required, and personnel access was controlled in accordance with 10 CFR 20.203 (c)(2)(iii) when the door was not locked. A security guard was positioned near the containment air lock for recording dosimeter numbers and readings upon entry and exit of individuals into and out of containment; and the two above components within containment were barricaded and posted as High Radiation Areas.

The interpretation of present NRC regulations and STS requirements is that a licensee may establish controls to take advantage of natural or existing barriers. This means that one locked door, or one control point, where positive control over personnel entry is exercised, may be utilized to establish control over multiple High Radiation Areas. Although the regulations refer to "each" High Radiation Area, they do not preclude the implementation of controls over a broader area that encompasses one or more High Radiation Areas. NRC recognizes that there are limitations to the application of this "broad area control" concept; however, these limitations are rather subjective and must be evaluated in terms of the degree of access control necessary in light of the magnitude of radiation fields, accessibility to the radiation fields, and other administrative or physical controls utilized within the "broader area."

Under the current STS there are no provisions that substitute for 10 CFR 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)]. Therefore, when entry is necessary, the control specified in 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)] must be imposed. However, the positive control required for 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)] is not defined. Since the STS does spell out specific controls for High Radiation Areas (i.e, posting, barricading, RWP, and instruments), these controls can be used as a reasonable guide for the "positive control" that must be implemented in addition to providing access control which serves as a substitute for the locked door.

For situations where a reactor containment structure is designated as a High Radiation Area (>1,000 mr/hr), access control may be established at the access hatch for periods when personnel entries are necessary. The degree of access control may vary based on how and where the other controls are implemented. For example, if the High Radiation Areas (>1,000 mr/hr) within containment are readily recognizable (e.g., posted and barricaded), less stringent access control is required at the hatch than if the individual High Radiation Areas are not posted and barricaded. Also, if personnel are likely to enter radiation fields of 100 to 1,000 mr/hr while in containment, the requirement for providing individuals with a monitoring device that continuously indicates dose rate must be imposed at the access hatch.

Based on our evaluation of the situation at Turkey Point, NRC does not support the Region II citation. Although the Region appears to have had some concerns about the adequacy of the positive control exercised over personnel access to and activities within containment, this aspect was not adequately developed and the specific citation did not reflect this concern. In light of the licensee's positive response concerning the control of radiation exposure to their workers and the corrective action that will be taken, NRC sees no benefit in pursuing the adequacy of the licensee's access control at this time. There is a need to clarify some aspects of the STS requirements and discussion has already been initiated as a preliminary effort to obtain a change to the STS.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Regulatory Guide 8.38, Technical Specifications

Subject codes: 4.1, 4.7

Applicability: Reactors

HPPOS-015 **PDR-9111210114**

Title: Safety Evaluation of the Proposed Yankee Atomic Power Company's Modification of their Technical Specifications Relating to High Radiation Areas

See the memorandum from D. G. Eisenhut to K. R. Goller, dated March 16, 1977. Enclosures with the document provided the basis for revised Technical Specifications relevant to entry into high radiation areas. These allow entry controlled by RWP and radiation monitoring, alarming dosimeter, or health physics qualified individual. (It should be noted that new Technical Specifications clarify the requirements for high radiation areas in containment.) The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 10.1601.

Enclosure 2 states that in lieu of the "control device" or alarm signal required by paragraph 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)], each high radiation area in which the intensity of radiation is between 100 and 1000 mrem/hour must be barricaded and conspicuously posted as a high radiation area and entrance controlled by requiring the issuance of a Radiation Work Permit (RWP). Any individual or group of individuals permitted to enter these areas must be provided with one or more of the following:

1. A radiation monitoring device that continuously indicates the radiation dose rate in the area.

2. A radiation monitoring device that continuously integrates the radiation dose rate in the area and alarms when a preset integrated dose is received. Entry into high radiation areas with this type of monitoring device may be made only after the dose rate levels in the area have been established and personnel have been made knowledgeable of them.

3. A health physics qualified individual (i.e., qualified in radiation protection procedures) with a radiation dose rate monitoring device and who is responsible for providing positive control over the activities within the area and performs periodic radiation surveillance at the frequency specified in the RWP and established by the Plant Health Physicist.

Health physics personnel are exempt from RWP issuance requirements during the performance of their assigned radiation protection duties, providing they are following plant radiation protection procedures for entry into high radiation areas.

The above procedures also apply to each high radiation area in which the intensity of radiation is greater than 1000 mrem/hr. To prevent unauthorized entry into high radiation areas, locked doors with the keys maintained under the administrative control of the on-duty shift supervisor and/or the Plant Health Physicist must be provided.

Individuals are considered qualified in radiation protection procedures when they are certified as capable of successfully accomplishing the following activities as required by federal regulations, license conditions, and facility procedures pertaining to radiation protection:

1. Conducting and evaluating special and routine radiation, contamination and airborne radioactivity surveys.

2. Establishing protective barriers and posting appropriate radiological signs.

3. Establishing a means of limiting exposure rates and accumulated radiation doses, including the use of protective clothing and respiratory protection equipment.

4. Performing operability checks of radiation monitors and survey meters.

5. Recommending appropriate immediate actions in the event of a radiological problem, and performing necessary activities until the arrival of health physics personnel.

6. Conducting other routine radiological duties as required on backshifts or weekends.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Technical Specifications

Subject codes: 1.7, 4.1, 7.1

Applicability: Reactors

HPPOS-237 **PDR-9111210358**

Title: Request for Comments on Responses to Licensee Questions on High Radiation Area Controls

See the memorandum from J. Wigginton to W. J. Pasciak (and others) dated June 21, 1989. This memo provides guidance on the temporary use of lead shielding as a long-term solution in reducing radiation levels and states that magnetic computer cards meet the locking requirements of 10 CFR 20.203(c)(2)(iii). The health physics position also applies to "new" 10 CFR 20.1601(a)(3).

The NRC was asked to provide guidance to a licensee concerning implementation of 10 CFR Part 20 and Technical Specifications (Administration Section 6) requirements for high radiation area controls. The licensee had questions concerning IEIN-88-79 that alerted licensees to several instances where plants had not properly controlled areas having greater than 1000 mR/hr (improper use of the "flashing light" option). Specifically, the licensee asked whether temporary shielding may be used as a long-term solution in reducing radiation levels below 1000 mR/hr (to avoid locking an area >1000 mR/hr). The licensee also requested guidance concerning the use of a computer card (magnetic card) used in lieu of a classical, physical key-lock to meet the locking requirements of 10 CFR 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)].

The NRC stated that other techniques to reduce source term should be used (e.g., chemical decon, permanent shielding); however, as long as reasonable progress is made toward the long-term fix (and an effective system to preclude unauthorized removal of temporary shielding exists), the judicious use of temporary shielding could be justified on an interim basis. In general, the radiation source in-growth rate should allow for prudent and timely compensatory action to avoid frequent use of temporary shielding for this purpose.

An access control system governed by computer mag-cards is acceptable and meets the STS and 10 CFR 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)] requirements for locking high radiation areas pursuant to the security requirements of 10 CFR 73 [Physical Protection of Plants and Material, Paragraph 73.2(m)]. However, the licensee must maintain positive control over each entry and satisfy all other existing entry and surveillance requirements for high radiation areas.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Technical Specifications

Subject codes: 4.1, 5.3

Applicability: Reactors

HPPOS-016 **PDR-9111210116**

Title: Applicability of Access Controls for Spent Fuel Pools

See the memorandum from L. B. Higginbotham to A. B. Davis dated July 9, 1980. Spent fuel pool areas are not high radiation areas due to the inaccessibility of highly radioactive materials stored in the pool. If a diver enters the pool or upon movement of highly radioactive materials stored in the pool, then proper health physics controls must be instituted. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1601.

A review was made of the applicability of 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)] to spent fuel pools. Materials in spent fuel pools that could cause an individual to receive a dose equivalent to the total body in excess of 100 mrem in one hour are normally ten or more feet below the surface of the pool. Under these conditions, spent fuel-pool areas are not high radiation areas due to their inaccessibility to personnel performing "above pool-surface duties", and therefore, the requirements of 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)] do not apply.

However, when a diver enters the pool to perform "under pool-surface duties" or upon movement of highly radioactive materials stored in the pool, proper health physics controls must be instituted. See IE Information Notice No. 83-31 dated July 28, 1982 (HPPOS-002).

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Regulatory Guide 8.38, Technical Specifications

Subject codes: 4.1

Applicability: Reactors

HPPOS-245 **PDR-9111220092**

Title: Access Controls for Spent Fuel Storage Pools

See the memorandum from L. J. Cunningham to J. H. Joyner dated November 9, 1990. This memo provides guidance concerning the "establishment of locked high radiation areas." Radioactive materials that could result in dose rates greater than 1000 mrem/hr are stored under water in a spent fuel storage (SFS) pool. These radioactive materials are sometimes contained in buckets hung from railings around the SFS pool. It is assumed that when the materials are stored in the pool, the dose rates above the pool in the vicinity of the stored materials are less than 100 mrem/hr. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1601. HPPOS-106 contains a related topic.

HPPOS-016 states that because of the inaccessibility to personnel of the area in which radioactive materials are stored (under water), SFS pools are not considered to be high radiation areas and therefore the requirements of 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)] do not apply. HPPOS-016 also states that when a diver enters the pool or upon movement of highly radioactive materials stored in the pool, proper health physics controls must be instituted. Movement of radioactive material stored in the pool has the potential to create a high radiation area around the pool; however, a high radiation area is not created until movement of the material actually results in a radiation level, in an area that is accessible to personnel, that could result in a dose in excess of 100 mrem in any one hour. Therefore, the relative accessibility of radioactive material stored in buckets hung from railings around the pool is not applicable to the requirements of 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)].

IE Information Notice 90-33, dated May 9, 1990, provides suggestions for radiological control considerations that can help minimize the possibility of unexpected exposure from radiation sources in SFS pools. The suggestions include: "Measures to ensure that highly radioactive objects stored under water at one end of a line whose other end is secured above the surface of the pool are not unexpectedly pulled to the surface." Such measures may include locking mechanisms that prevent inadvertent and unauthorized withdrawal of such sources. This practice is not a regulatory requirement; however, the requirements for "Instructions to Workers" in 10 CFR 19.12 are applicable. Workers in SFS pool areas must "be kept informed of the storage, transfer, or use of radioactive materials" stored in the pool and must be instructed in "precautions or procedures to minimize exposure" that may result from this method of storage. Appropriate formal training and posting of signs that warn of the hazards of source withdrawal are among the ways to meet this requirement.

Regulatory references: 10 CFR 19.12, 10 CFR 20.203, 10 CFR 20.1601

Subject codes: 4.1

Applicability: Reactors

HPPOS-068 **PDR-9111210154**

Title: Response to Region II Interpretation for Control of High Radiation Areas

See the memorandum from E. L. Jordan to J. A. Olshinski dated November 7, 1983. For Standard Technical Specification 6.12.1(c) regarding presence of an HP Tech with a work party in a high radiation field, continuous "eye-ball" coverage is not required. One hundred percent coverage of an HP Tech for all high radiation work is counter to ALARA requirements. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1601.

IE was requested to review a Region II interpretation of STS Section 6.12.1, "High Radiation Control." In addition, IE was requested to consult with NRR and provide inspection and enforcement guidance. After review of the position with NRR, IE cannot support the STS interpretation because it is inconsistent with the intent of the specification.

A typical STS Section 6.12.1 states that any individual or group of individuals permitted to enter such areas

will be provided with or accompanied by one or more of the following:

1. A radiation monitoring device which continuously indicates the radiation dose rate in the area, or

2. A radiation monitoring device which continuously integrates the radiation dose rates in the area and alarms when a preset integrated dose is received. Entry into such areas with this monitoring device may be made after the dose rate levels in the area have been established and personnel have been made knowledgeable of them, or

3. An individual qualified in radiation protection procedures with a radiation dose rate monitoring device, who is responsible for providing positive control over activities within the area and shall perform periodic radiation surveillance at the frequency specified by the Radiation Protection Manager in the RWP.

Only provision (3) of STS 6.12.1 is causing problems for Region II. In part, "... Region II interprets positive control as continued visual contact between the accompanying HP Tech and those workers ...." The position to require continual, visual contact by the HP Tech is inconsistent with the specification. To require "eye-ball" coverage for each and every task performed within a high radiation area goes contrary to the intent of the STS to allow licensee management personnel to exercise their professional judgement in deciding what level of HP coverage is needed. This level covers a broad spectrum, ranging from a single visit to the work area (spot check of radiation conditions, compliance to RWP, etc.) up to continual, line-of-sight coverage (of those jobs with high potential for drastic, fast changing radiological conditions).

Several negative outcomes could result from the suggested "continual coverage" interpretation. Licensees, viewing it as an onerous choice, would probably be more apt to select "worker-self coverage" options (1) and (2). By increasing their reliance on these non-HP coverages, IE believes the overall quality of radiological protection provided to workers would decrease. Going in the other direction, another problem could be increasing the logistics/manpower burden. To provide 100 percent job coverage for all high radiation area work may well be beyond the licensee's resource capability. The additional burden of increased radiation exposures to HP Techs would be counter to ALARA principles, and again could strain the finite resource pool of qualified HP Techs.

Additionally, care must be taken not to mix genuine ALARA concerns and STS 6.12.1 requirements. As an option for the high radiation control requirements of 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)], the specification's basic purpose is to require licensees to maintain positive controls over entries/work activities in high radiation areas. Thus, the primary focus and objective of the inspection program in this STS 6.12.1 area should be directed toward ensuring that the licensee's positive controls program adequately minimizes the possibility of excessive exposures. Voluntary ALARA commitments made by the licensees for external exposure reduction should form the basis for ALARA inspection and enforcement activities, not STS 6.12.1.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Technical Specifications

Subject codes: 4.1, 8.5

Applicability: Reactors

HPPOS-180 **PDR-9111210282**

Title: Applicability of 10 CFR 20.203(c) to Plants With Standard Technical Specifications 6.12

See the memorandum from L. J. Cunningham to R. R. Bellamy (and others) dated May 9, 1990. The high radiation area access control Technical Specifications (STS 6.12) provide an alternate control method "in lieu of the control device" [10 CFR 20.203(c)(i)] or "alarm signal" [10 CFR 20.203(c)(ii)]. This TS does not supersede the other provisions of 10 CFR 20.203(c). This health physics position also applies to "new" 10 CFR 20.1601.

Issues have come up regarding the applicability of 10 CFR 20.203(c) [or 10 CFR 20.1601] for licensees with High Radiation Area Access Technical Specifications. In two cases, licensees have requested unnecessary TS changes to allow direct surveillance to prevent unauthorized entries into high radiation areas (instead of locking them) in accordance with 10 CFR 20.203(c)(4) [or 10 CFR 20.1601(b)]. In a third case, questions were asked on whether it was allowable for a licensee to provide remote surveillance through a

video camera for positive access control of an unlocked area since it was not in its Technical Specifications.

In all three cases, the licensees and the inspectors involved expressed confusion over the relationship of the High Radiation Technical Specifications and 10 CFR 20.203(c) [or 10 CFR 20.1601]. The High Radiation Area Access Control Technical Specifications (STS 6.12) provide an alternate control method "in lieu of the control device" [10 CFR 203(c)(2)(i) and 10 CFR 20.1601(a)(1)] or "alarm signal" [10 CFR 20.203(c)(2)(ii) and 10 CFR 20.1601(a)(2)]. This TS does not supersede the other provisions in 10 CFR 20.203(c) [or 10 CFR 20.1601], and it does not preclude a licensee from locking a High Radiation Area (<1000 mR/hr) and controlling access pursuant to 10 CFR 20.203(c)(2)(iii) [or 10 CFR 20.1601(a)(3)].

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Technical Specifications

Subject codes: 4.1

Applicability: Reactors

HPPOS-234 PDR-9111210345

Title: Access Control to High Radiation Areas at Nuclear Power Plants

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated August 2, 1991. A step-off pad (SOP) at the access point to a high radiation area does not constitute a barricade as required by Technical Specifications. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1601.

Most Technical Specifications, in Section 6.12, "High Radiation Area," require that each area in which the dose rate is between 100 and 1000 mrem/hr be "barricaded and conspicuously posted as a high radiation area ...." A Region I licensee instituted a policy in which the "barricade" consists of a SOP at the access to the high radiation area. The area is roped off and posted but the entry at the SOP is not roped off. The licensee maintained that the SOP satisfies the barricading requirement in Technical Specifications. This policy is used only in situations where the area is a contamination area as well as a high radiation area.

Technical Specifications with this barricade and posting requirement provide a method for control of high radiation areas that is an alternative to the method specified in 10 CFR 20.203(c)(2) [or 10 CFR 20.1601(a)]. Although not explicitly stated, these controls are designed to prevent inadvertent entry into the area. Controls specified in Technical Specifications are intended to achieve the same basic aim, namely prevention of inadvertent entry, but in a different manner from that specified in Part 20. The difference is to allow for the different nature of the sources at nuclear power plants as well as the different administrative controls and training found at such facilities.

Inadvertent entry is interpreted in this context to mean entry by an individual who is not paying sufficient attention to postings and who may walk into the high radiation area unless his or her attention is drawn to these postings. The assumption is that if an individual's attention is drawn to the postings, that individual will recognize their implications and take appropriate action. A barricade is one mechanism to accomplish this purpose. The dictionary defines a barricade as "any barrier that obstructs passage." A SOP is not a barrier to movement into the area and therefore does not qualify as a barricade required by Technical Specifications. Implicit in the requirement for the barricade is that the barricade can be partially taken down for periods of access. This is acceptable as long as the access point is attended by an individual who will prevent inadvertent/authorized access to the high radiation area.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1601, Technical Specifications

Subject codes: 4.1, 4.7

Applicability: Reactors

HPPOS-235 PDR-9111210349

Title: Health Physics Position on the Controlling of Beam Ports, Thermal Columns, and Flux Traps as High Radiation Areas

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated May 31, 1991. The narrow radiation beams from beam ports, thermal columns and flux traps at reactor facilities may expose major portions of the head and trunk, and therefore,

must be controlled as high radiation areas. The health physics position was written in the context of 10 CFR 20.201 and 20.203, but it also applies to "new" 10 CFR 20.1601 and 20.1902.

This memo clarified the NRC staff position that the subject areas must be controlled as high radiation areas. A number of Notices of Violation (NOV) concerning the posting and control requirements of 10 CFR 20.201 and 20.203 have occurred at research and test reactors. These licensees were not properly controlling high radiation areas, specifically those involving beam ports. [Note: The posting and control requirements for high radiation areas are contained in "new" 10 CFR 20.1601 and 20.1902.]

The argument is made by licensees that the radiation streaming from these beam ports will not cause an exposure to the whole body. These licensees have taken the position that narrow beams don't meet the current 10 CFR 20.202(b)(3) definition that state in part, " ... a major portion of the body could receive, in any one hour, a dose in excess of 100 millirems."

The 10 CFR Part 20 definition of the whole body as specified in 10 CFR 20.101(b)(3) includes the head and trunk; active blood forming organs; lens of the eyes; or gonads. [Note: The "new" 10 CFR 20.1003 definition states: "Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee."] Whether these beams are narrow or not, if they could possibly expose the lens of the eyes, the gonads or any other major portion of the head and trunk or active blood forming organs, then the beams must be controlled as high radiation areas. The revised Part 20 will support this position, and will further clarify it by avoiding the term "the major portion of the whole body," when defining a high radiation area. [Note: The "new" 10 CFR 20.1003 definition states: "High radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates."]

Pursuant to 10 CFR 20.203(c)(5) [or 10 CFR 20.1601(c)], if the stated alternatives of 10 CFR 20.203(c)(2) and (4) [or 10 CFR 20.1601(a) and (b)] are not feasible, a licensee may apply to the Commission for approval of methods not included in paragraphs 20.203(c)(2) and (4) [or paragraphs 20.1601(a) and (b)] for controlling access to high radiation areas. If a licensee chooses 10 CFR 20.203 (c)(2)(iii) [or 10 CFR 20.1601(a)(3)] as the control option, positive entry control is required. Methods of positive entry control may include, but are not limited to, the following:

All entries into high radiation areas are controlled by requiring issuance of a Radiation Work Permit (RWP) or a work procedure. This controlling permit or procedure contains any special instructions and the requirements for entry into the high radiation area, which may include: a pre-briefing on the actions to be performed, a review of current radiation surveys, the requirements of a film badge or TLD, and a pocket ionization chamber or extremity dosimeters, signs and barriers to avoid contact with the beam, and directions not to alter any shielding or experiment without health physics supervision.

Due to the nature of the potential hazards involved, all facilities having these types of radiation beams need to control these areas as high radiation areas. However, given the diverse nature of reactor types and experimental configurations in the nonpower reactor community, we could expect these licensees to implement a wide variety of practices and controls to satisfy the regulatory requirement for positive entry control.

This Health Physics Position has been reviewed by all Regions; the Division of Advanced Reactors and Special Projects, NRR; the Office of Nuclear Material Safety and Safeguards; and the Office of Enforcement.

Regulatory references: 10 CFR 20.201, 10 CFR 20.203, 10 CFR 20.1601, 10 CFR 20.1902

Subject codes: 4.1, 4.7

Applicability: Reactors

HPPOS-251 **PDR-9208170087**

Title: Redefinition of Restricted Area Boundaries to Exclude an Area to be used for Residential Quarters

See the memorandum with enclosure from L. J. Cunningham to R. W. Cooper (and others) dated July 6, 1992. This memo states that a licensee may allow residential quarters in areas originally defined as restricted after the area has been redefined as unrestricted. The health physics positions is written in the

context of 10 CFR 20.3, 20.105, and 20.106, but it also applies to the "new" 10 CFR Part 20, Sections 20.1003, 20.1301, and 20.1302.

The boundaries between restricted areas and unrestricted areas are defined by licensees. A nuclear power reactor had defined the boundaries of its restricted area in plant procedures and the area was bounded by a security fence. When it appeared that some plant workers might go out on strike, the plant management considered moving trailers inside the fenced area for use as temporary residential quarters for managers during the strike. A question arose whether the contemplated use of trailers within the fenced area would be consistent with NRC requirements. In more general terms, once a licensee has established the boundaries of a restricted area as defined in 10 CFR 20.3, may the licensee allow residential quarters within that area without violating the requirements of 10 CFR Part 20?

10 CFR 20.3 includes the following definitions for restricted and unrestricted areas. [Note: Equivalent definitions for "restricted area" and "unrestricted area" are found in "new" 10 CFR 20.1003.] Restricted area means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area. Unrestricted area means any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials and any area used for residential quarters.

The answer is that the licensee may allow residential quarters within the area in question if:

1. The licensee first redefines the boundaries of the restricted area to exclude the area to be used for residential quarters.

2. The licensee ensures that the radiation levels and concentrations of radioactive material in the area used for residential quarters meet the requirements of 10 CFR 20.105 and 20.106, respectively, for unrestricted areas. [Note: Equivalent requirements are found in "new" 10 CFR 20.1301 and 20.1302.]

When redefining the boundaries of a restricted area to allow residential quarters within an area, licensees need to ensure that regulatory requirements will be met for the newly-created unrestricted area by making appropriate revisions or additions to their procedures. Topics to be considered in meeting these requirements may include instructions to workers concerning the residential quarters; access control; monitoring individuals for contamination before they enter the unrestricted area; monitoring materials for contamination within the unrestricted area; and provisions for individuals residing in the residential quarters in emergencies.

Regulatory references: 10 CFR 20.3, 10 CFR 20.105, 10 CFR 20.106, 10 CFR 20.1003, 10 CFR 20.1301, 10 CFR 20.1302

Subject codes: 1.7, 4.3, 4.4, 12.8

Applicability: Reactors

HPPOS-316 **PDR-9306280230**

Title: Technical Assistance Request, National Institutes of Health, Bethesda, Maryland, Regarding Exemption from 10 CFR 35.315(a)(7)

See the memorandum from J. E. Glenn to R. R. Bellamy dated July 7, 1992. This NMSS memo responds to technical assistance request from Region I, dated May 26, 1992, regarding an amendment request from the National Institutes of Health (NIH), Bethesda, Maryland. NIH had requested an exception to 10 CFR 35.315(a)(7) to allow dedication of certain patient rooms for sequential radiopharmaceutical therapies prior to decontamination to levels required for unrestricted occupancy and assignment to a non-therapy patient. The licensee does not survey and decontaminate the patient room after release of each therapy patient, but rather after every two therapy patients. As noted in the inspection report, this practice requires an exemption from the requirements of 10 CFR 35.315(a)(7) because the regulation does not anticipate subsequent use of the room by therapy patients and the required decontamination level of 200 disintegration per minute (dpm) per 100 square centimeters (100 cm^2) is for release of the room as an unrestricted area. HPPOS-259 contains a related topic.

In a letter dated May 15, 1992, the licensee submitted procedures to ensure the safety of facility personnel who frequent the vicinity of a dedicated therapy patient room. These were:

1. The licensee stated that the door to a contaminated therapy room would remain closed when the room is unoccupied.

The therapy room door should remain locked whenever possible to prevent unauthorized entry to an unoccupied restricted area.

2. The licensee stated that patient care staff are fully aware that contaminated rooms may not be used by non-therapy patients until the room has been decontaminated to levels required for unrestricted occupancy and the caution signs have been removed by the NIH Radiation Safety Branch staff.

The licensee does not describe a positive mechanism to ensure that the patient care staff does not release a contaminated room for unrestricted use. Relying only on the absence of radioactive material caution signs may not be adequate. The licensee should provide additional procedures to ensure that patient care staff are formally notified by NIH Radiation Safety Branch staff when a therapy room can be released for unrestricted use.

3. It is NRC's understanding that the licensee does not attempt to decontaminate the therapy room to a specific contamination level between subsequent therapies.

The licensee should be required to decontaminate the dedicated therapy room, prior to use by any other therapy patient, to the restricted area action level for removable surface contamination of 2200 dpm/100 cm^2 as described in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions."

In summary, the licensee's request for an exemption (to be provided by license amendment) from the requirements of 10 CFR 35.315(a)(7) may be granted at such time the licensee provides additional commitments that include the decontamination level limits described in Item 3 above.

Regulatory references: 10 CFR 35.315, Regulatory Guide 8.23

Subject codes: 4.3, 4.4, 5.0, 11.1

Applicability: Byproduct Material

HPPOS-321 PDR-9307060029

Title: Technical Assistance Request, Walter Reed Army Hospital, Washington,DC, Guidance on Setting Action Levels for Exemption from Requirement to Decontaminate Therapy Room for Unrestricted Use

See the memorandum from J. E. Glenn to R. R. Bellamy dated September 24, 1992. The memorandum responds to a TAR dated June 10, 1992, regarding an amendment request from Walter Reed Army Medical Center. In a letter dated April 8, 1992, the licensee requested an exception to 10 CFR 35.315 (a)(7) to allow dedication of a single patient room for radiopharmaceutical therapies without being required to decontaminate to the levels required for unrestricted occupancy and assignment to a non-therapy patient. Enclosed with the memorandum was NUREG-1388, a report written by E. Y. Shum, R. J. Starmer, and M. H. Young entitled Environmental Monitoring of Low-Level Radioactive Waste Disposal Facility and published in December 1989. This branch technical position (BTP) paper on the environmental monitoring program for a low-level waste disposal facility provides general guidance on what is required by 10 CFR 61.53 of applicants submitting a license application for such a facility. Guidance is also provided in the BTP on the choice of which constituents to measure, setting action levels, relating measurements to appropriate actions in a corrective action plan, and quality assurance. HPPOS-316 contains a related topic.

In the above TAR, it was NRC's understanding that the licensee restricted the patient room to iodine-therapy patients and surveyed and decontaminated the room after release of each therapy patient. The licensee requested relief from the requirement of decontaminating the room to the level required for release as an unrestricted area. If granted, an exemption from the requirements of 10 CFR 35.315(a)(7) would be required since the regulation does not anticipate subsequent use of the room by therapy patients. The required decontamination level of 200 dpm/100 cm^2 is for the release of the room as an unrestricted area.

In its April 8, 1992, letter, the licensee submitted procedures to ensure the safety of facility personnel who frequent the vicinity of a dedicated therapy patient room.

1. The licensee stated that the door to the contaminated therapy room would remain closed and locked when the room was unoccupied.

2. The licensee stated that access to the unoccupied and locked room would be under the control of the Health Physics Office (HPO) at all times and could only be opened by HPO personnel.

The licensees request should be approved provided the following conditions are met, in addition to those specified in items 1 and 2 above. The licensee should be required to decontaminate the dedicated therapy room before use by any other therapy patient to the restricted area action level for removable surface contamination of 2200 dpm/100 cm^2 as described in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions," or the licensee may be approved to decontaminate based upon action levels determined to meet the following criteria:

a. No primary radiation protection standards will be exceeded (personal dose, member of the public dose, or environmental release limits); and

b. The action levels are determined to be ALARA based upon a consideration of worker, environmental, and public exposures.

The licensee must describe the procedures to be followed to determine these criteria are met.

Regulatory references: 10 CFR 35.315(a)(7), 10 CFR 61

Subject codes: 4.3, 4.4, 5.0, 11.1

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-317 **PDR-9306280268**

Title: Technical Assistance Request, Use of Portable Shields for a High Dose Rate Afterloader Facility at Washington Hospital Center, Washington, D.C.

See the memorandum from J. E. Glenn to R. R. Bellamy dated June 25, 1992. This NMSS memo responds to a technical assistance request from Region I, dated March 26, 1992, concerning Washington Hospital Center's request to relocate their high dose rate afterloader to a new location and use portable lead shadow shields to obtain compliance with the dose limits of 10 CFR 20.1301 for members of the public. The request was reviewed and the following guidance is given.

Although NRC's Policy and Guidance Directive, FC 86-4, for licensing high dose rate afterloaders presumes the necessary room shielding is obtained by the use of appropriate fixed wall, floor, and ceiling materials, it does not explicitly require it. However, portable shield should not be permitted as a permanent means of providing shielding for high dose rate afterloading facilities. This requirement is consistent with the recommendations contained in the most recent draft of the AAPM Task Group on Remote Afterloading Systems.

Washington Hospital Center may be allowed to use the portable shields on a temporary or emergency basis to insure patient care is not impacted. If portable shield are used, a positive method of ensuring the shield(s) are correctly positioned for each treatment must be provided, and "per patient" surveys must be performed for each treatment to insure that exposure rates in unrestricted areas comply with 10 CFR 20. The licensee would be expected to commit to the installation of appropriate permanent shielding within a reasonable period of time. The hospital must be made aware that the use of a cantilevered shield for limiting the exposure to the adjacent uncontrolled area above the treatment room may raise additional safety concerns about patient injury from improper design, maintenance, or mishandling during positioning of the shield.

After review of the technical assistance request, the licensee apparently omitted any description of the area security for the treatment room. Such a description is required by V(c) of FC 86-4. Since the licensee is proposing to locate the high dose rate afterloader with an existing superficial treatment machine, it is essential that they implement and describe a means of assuring that only one of the two radiation producing devices can be operated at a time. Also, the proposed shadow shield for the door and window would appear to obscure observation of the patient during treatment. If this is the case, the licensee must provide an alternate means of viewing the patient during treatment.

Regulatory references: 10 CFR 20.1301, 10 CFR 20.1302

Subject codes: 4.4, 5.3, 7.1, 12.8

Applicability: Byproduct Material

2.6 POSTING AND LABELING

HPPOS-242 **PDR-9111220087**

Title: Health Physics Position on Posting of High Radiation Areas

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated August 8, 1991. An area containing fields that would require classification as a locked high radiation area was enclosed by a licensee using an inaccessible wire cage which is sometimes referred to as a cocoon. Although staff practice has been that the cocoon need not be posted, it is a good safety practice to identify the area as hazardous by putting up a sign saying "CONTACT HEALTH PHYSICS BEFORE ENTRY" or other appropriate warning. The health physics position was written in the context of 10 CFR 20.201 and 20.203, but it also applies to the "new" 10 CFR Part 20, Sections 20.1003 and 20.1902.

A licensee in Region V enclosed an area containing radiation sources in a wire cage (or cocoon) that extended from the floor to the ceiling with no gate or access point. The sources of radiation were some valves and associated piping that produced a radiation field of up to 1.5 R/hr at 18 inches from their surfaces. Such fields would require that the area be controlled as a locked high radiation area. However, instead of locking the whole area, which was a room, the licensee constructed a wire cage around the source. The cage was of such a size that the radiation fields outside the cage were consistent with the postings for the room. No postings were attached to the cage.

According to 10 CFR 20.203(c), "Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol ...." The requirement does not indicate whether the posting is designed only for access control purposes, or also to identify the area itself, regardless of immediate intent to enter it. [Note: 10 CFR 20.1902(b) states: "The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol ..."]

10 CFR 20.202(b)(3) defines a high radiation area as "any area, accessible to personnel, in which there exists radiation ...." Therefore, an area that is not accessible would not be classified by staff as a high radiation area requiring posting. Since the cocoon is constructed to

be inaccessible, the staff practice has been that it need not be posted. However, the cocoon may be made accessible by breaking the barrier, such as, for example, by cutting a hole in the wire cage. Once opened and "accessible", the area becomes a high radiation area requiring posting. [Note: 10 CFR 20.1003 defines a high radiation area as "an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates."]

Although staff practice has been that posting the cocoon does not involve the posting requirement of 10 CFR 20.203(c) [or 10 CFR 20.1902(b)], identification of hazardous areas, such as putting up a sign saying "CONTACT HEALTH PHYSICS BEFORE ENTRY," is good safety practice. Records that identify the nature of the hazard in the cocoon may be lost or may not be readily available to persons who may have to enter the area, especially in an emergency. Although a cocoon does not have an access point such as a door, a major leak, fire, or similar contingency may make it necessary to break the cocoon and enter. The absence of postings in such situations could present a hazard to personnel making the entry. In addition, once the cocoon has been broken and the area has been made accessible, the licensee would be in violation unless proper postings had been made before opening the cocoon.

Regardless of the policy adopted for areas enclosed in a cocoon, that policy must be included in the radiation worker training material to satisfy the requirement of 10 CFR 19.12, "Instructions to Workers." This health physics position was developed by NRR's Radiation Protection Branch and has been coordinated with all NRC Regional Offices and NMSS. The Office of the General Counsel has no legal objections.

Regulatory references: 10 CFR 19.12, 10 CFR 20.202, 10 CFR 20.203, 10 CFR 20.1003, 10 CFR 20.1902

Subject codes: 1.2, 4.1, 4.7

Applicability: Reactors

HPPOS-036 **PDR-9111210167**

Title: Posting of Entrances to a Large Room or Building as a Radiation Area

See the letter from J. P. O'Reilly to E. E. Utley (Carolina Power and Light Company) dated January 27, 1984. The NRC position is that posting practices for a large room or building must adequately alert personnel to the presence of radiation areas such that they may minimize exposures they receive. Posting only entrances to reactor buildings does not provide personnel with sufficient information for them to be able to minimize exposures from the radiation areas within the reactor building. The health physics position was written in the context of 10 CFR 20.1, 20.6, 20.202, and 20.203, but it also applies to the "new" 10 CFR 20 Part 20, Sections 20.1003, 20.1006, 20.1101 and 20.1902.

In a letter dated June 15, 1981, NRC stated that Violation D of Inspection Report Nos. 50-325/80-45 and 50-324/80-43, regarding radiation area posting of reactor buildings was under review and that a final decision would be issued at a later date. On October 7, 1981, in a letter to NRR, a licensee requested a written interpretation of the requirements set forth in the definition of a radiation area in 10 CFR 20.202(b)(2) [or 10 CFR 20.1003] and the requirements for posting of a radiation area in 10 CFR 20.203(b) [or 10 CFR 1902(a)]. That request was subsequently forwarded to Region II for evaluation and action. The licensee's request that Violation D be withdrawn and a request for interpretation were evaluated by the NRC staff. The NRC position is that posting practices must adequately alert personnel to the presence of radiation areas such that they may minimize exposures. The practice of posting only the entrances to a reactor building does not provide personnel with sufficient information for them to be able to minimize exposures from the radiation areas within the reactor building.

The intent of 10 CFR 20.202(b)(2) and 20.203(b) [or 10 CFR 20.1003 and 20.1902(a), respectively] is to alert personnel to the presence of radiation and to aid them in minimizing exposures. NRC realizes that circumstances of each case must be evaluated to assure that posting practices do not detract from this intent by: (1) desensitizing personnel through over-posting, or (2) failing to sufficiently alert personnel to the presence and location of radiation areas. Thus, radiation area postings should warn individuals in the

vicinity of radiation areas of specific radiological conditions in their immediate vicinity. By the same token, it is also considered outside of the regulations and counter-productive if substantial areas which are not radiation areas are posted as such. Since the regulations do not provide implementing details such as whether a room or building containing a radiation area may be posted at the entrance or whether every discrete radiation area must be posted, the following is used as guidance: Posting the entrances to a very large room or building is inappropriate if most of the area is not a radiation area and only discrete areas or individual rooms actually meet the criteria for a radiation area. If discrete areas or rooms within a large area or building can be reasonably posted to alert individuals to radiation areas, these discrete areas or rooms should be posted individually.

The interpretation is the official NRC staff position, but as such, is not binding on the Commission. Such binding interpretations can only be issued by the Office of the General Counsel pursuant to 10 CFR 20.6 [or 10 CFR 20.1006]. The office of the General Counsel normally refers technical matters such as this issue to the NRC staff for resolution. The licensee's letter of October 7, 1981, enumerated six reasons for posting the entrances to buildings as radiation areas instead of discrete areas within the buildings. None of the reasons were sufficient individually or collectively to effectively aid workers in minimizing their exposure. They do not provide a substitute for the information or worker awareness provided by a posted sign that identifies the presence and approximate boundary of specific radiation areas and do not support ALARA as discussed in 10 CFR 20.1(c) [or 10 CFR 20.1101(b)]. NRC continues to maintain that most of the area within the reactor building fails to meet the criteria for a radiation area. Consequently, posting just the entrances to the reactor building does not meet the intent of the regulations.

Regulatory references: 10 CFR 20.202, 10 CFR 20.203, 10 CFR 20.1003, 10 CFR 20.1902

Subject codes: 4.2, 4.7

Applicability: All

HPPOS-066 **PDR-9111210252**

Title: Guidance for Posting Radiation Areas

See IE Information Notice No. 84-82 entitled as above and dated November 19, 1984. Posting only the entrance to a large room or building is inappropriate if most of the area is not a radiation area and only discrete areas are radiation areas. If discrete areas can reasonably be posted, they should be. The health physics position was written in the context of 10 CFR 20.203, but it also applies to "new" 10 CFR 20.1902.

A "radiation area" is defined in 10 CFR 20.202(b)(2) as any area, accessible to personnel, in which radiation, originating in whole or in part within licensed material, exists at such levels that a major portion of the body could receive a dose greater than 5 millirem in 1 hour or greater than 100 millirem in 5 consecutive days. [Note: 10 CFR 20.1003 defines a radiation area as "an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 millirem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that radiation penetrates."] The provisions of 10 CFR 20.203(b) [or 10 CFR 20.1902(a)] require that each radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: "CAUTION, RADIATION AREA."

Some power reactor licensees do not adequately post radiation areas in large buildings such as auxiliary buildings or reactor buildings. It has been argued that posting only the entrances to buildings and large areas meets the literal requirements for posting radiation areas in 10 CFR 203(b) [or 10 CFR 20.1902(a)]. However, in many cases this posting may fail to properly inform workers of radiological hazards in their work areas.

In response to past requests for guidance from nuclear power reactor licensees concerning proper implementation of the posting requirements for radiation areas, the following NRC staff position was developed and transmitted to several power plant licensees. The intent of 10 CFR 20.203(b) [or 10 CFR 20.1902(a)] is to alert personnel to the presence of radiation and to aid them in minimizing exposures. The circumstances of each situation must be evaluated to ensure that posting practices do not detract from this intent by (1) desensitizing personnel through overposting or

(2) failing to sufficiently alert personnel to the presence and location of radiation areas.

Radiation area posting should warn individuals of specific radiological conditions in their immediate vicinity. It is counterproductive to post substantial areas which are not radiation areas. Since the regulations do not provide implementing details, such as whether a room or building containing a radiation area must be posted only at the entrance, or whether every discrete radiation area must be posted, the following should be used as guidance.

1. Posting only the entrances to a very large room or building is inappropriate if most of the area is not a radiation area and only discrete areas or individual rooms (cubicles) actually meet the criteria for a radiation area.

2. If discrete areas or rooms within a large area or building can be reasonably posted to alert individuals to radiation areas, these discrete areas or rooms should be posted individually.

3. Items (1) and (2) above are not mutually exclusive. Where much of a large area falls within the definition of a radiation area, but where smaller, discrete areas within that radiation area have radiation levels that are substantially above the general area levels, it may be appropriate and more informative to the workers to:

   a. Post, as a radiation area, the entrances to the very large room or building.

   b. Define (and alert workers to) discrete, smaller areas or rooms (within the larger, posted area) in which the radiation exposure rates are substantially higher than the predominant exposure rates of the larger, posted area.

Good posting programs focus on making the workers aware of their radiological environment so that the workers can minimize their exposure. By using an appropriate combination of posting and periodic worker awareness training, licensees can aid workers in minimizing their exposures.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1902

Subject codes: 4.2, 4.7

Applicability: Reactors

HPPOS-210 **PDR-9111210371**

Title: Hot Spot Interpretation

See the memorandum from L. J. Cunningham to R. R. Bellamy (and others) dated March 8, 1990. A licensee was cited for failure to provide hot spot tags as required by its internal procedures. Although a licensee can be cited for not following its own procedures, hot spot tags are not required in 10 CFR 20.203 nor are they alternatives to the conspicuous posting of radiation areas as required in the regulations. This health physics position also applies to "new" 10 CFR 20.1902.

A resident inspector cited a licensee against their procedures for failure to provide Hot Spot tags that could be identified from both sides as required by those procedures. In the inspection report, Section 10 CFR 20.203(b) that requires radiation areas be conspicuously posted, was used as the basis for requiring Hot Spot tags to be identifiable from both sides.

Although, in this case, NRC agrees the licensee can be cited for not complying with their own procedures, NRC does not agree with the rationale in the inspection report. Hot spot tags are not required in 10 CFR 20.203 [or 10 CFR 20.1902] nor are they an acceptable alternative to conspicuous posting of radiation areas as required in the regulations. In addition, there is nothing in 10 CFR Part 20 that requires tags and postings to have the same information on both sides. This citation should not be mistaken as an NRC position on Hot Spot posting.

Resident inspectors are reviewing more health physics issues under the current inspection program than they did under the previous inspection program. A review scheme to ensure that technical positions taken by residents for HP issues are consistent with the regulations and established NRC positions may need to be established.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1902

Subject codes: 4.2, 4.7

Applicability: Reactors

HPPOS-296 **PDR-9306220099**

Title: Technical Assistance Request Concerning Posting per 10 CFR 34.42 and Surveys per 10 CFR 20.201

See the memorandum from J. E. Glenn to R. Cooper dated July 7, 1990. This memo responds to a technical request from Region I, dated May 18, 1990, on the above subjects. In general, the staff may by 10 CFR 20.501 [or, at present, 10 CFR 20.2301] and 10 CFR 34.51 consider any application for an exemption to the regulations in 10 CFR Part 20 or 10 CFR Part 34 if it determines the exemption is (1) authorized by law, (2) will not result in undue hazard to life or property, and (3) the applicant has submitted sufficient justification. However, the staff is not required to grant an exemption request.

Provided below are answers to specific questions regarding posting and surveys when performing radiography on pipeline welds:

1. Posting of radiation areas per 10 CFR 34.42: Does NRC consider exceptions to the posting requirements in such practical field situations as thick brush or woods immediately adjacent to the radiography operation, or radiography operations that are adjacent to a heavily-travelled highway? Can dirt from the pipe ditch be used as a partial shield, or can the ditch itself be used as a barrier preventing access to the radiation area in lieu of posting?

The regulation clearly requires that areas in which radiography is being performed be conspicuously posted. That is, all potential pathways to radiation and high radiation areas must contain the appropriate posting. Exemptions have not been made for wooded or thick brush areas, ditches, or heavily travelled highways in the past. The convenience or inconvenience of the posting is not a sufficient criterion alone to grant an exemption.

2. Performance of radiation area surveys per 10 CFR 20.201 [or, at present, 10 CFR 20.1501]: How often does one need to survey to confirm the radiation and high radiation areas when performing radiography along a pipeline where weld exposure geometries are essentially the same but shielding provided by adjacent terrain varies?

The licensee is required to make an evaluation of radiation hazard any time the conditions of the radiation exposure changes. Accordingly, even though the weld-to-weld exposure geometries are essentially the same, if the shielding provided by adjacent terrain varies, a new survey/evaluation is required. Note that a measurement is not necessarily required in order to make an evaluation.

Regulatory references: 10 CFR 20.201, 10 CFR 20.501, 10 CFR 20.1501, 10 CFR 20.2301, 10 CFR 34.42, 10 CFR 34.51

Subject codes: 4.7, 7.1

Applicability: Radiography

HPPOS-027 **PDR-9111210147**

Title: 10 CFR 20.203(f) Enforcement Guidance for Container Labels

See the memorandum from A. F. Gibson to Radiation Support Section dated March 7, 1980. This memo contains enforcement guidance for container labels in 10 CFR 20.203(f) and states that the purpose of labels is to ensure adequate information is available to enable a worker to handle the materials safely. The health physics position was written in the context of 10 CFR 20.203, but it also applies to the "new" 10 CFR Part 20, Sections 20.1904 and 20.1905. HPPOS-028 contains a related topic.

A label required pursuant to 10 CFR 20.203(f) [and 10 CFR 20.1904] must bear the radiation caution symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL", as well as provide sufficient information that includes the radiation levels, kinds of material, estimates of activity, date the activity was estimated, mass enrichment, etc. This is required to permit individuals handling or using the container or working in the area to take necessary precautions to avoid or minimize exposure and ensure worker safety.

Unlabeled containers are almost a certainty in any large facility, such as a power plant. If the discovery of unlabeled containers constitutes isolated occurrences, enforcement action may not be appropriate. However, a very high radiation level container left unlabeled would be a safety hazard, as well as a strong indicator of a defect in the licensee's radioactive materials control program. Should noncompliance with 10 CFR 20.203 [or 10 CFR 20.1904] be suspected, it must be determined whether control is being exercised by other methods described in 10 CFR 20.203(f)(3) [or 10 CFR 20.1905]. In addition, the calculations used to determine greater than Appendix C quantities present in the container should be included in the discussion section of the Inspection Report. It must be emphasized to the licensee that the purpose of 10 CFR 20.203(f) [and 10 CFR 20.1904] is to ensure adequate information is available to workers to enable them to safely handle radioactive materials and minimize exposure.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1904, 10 CFR 20.1905

Subject codes: 4.7, 12.7

Applicability: All

HPPOS-028 **PDR-9111210150**

Title: Further Guidance on Labeling Requirements

See the letter from H. D. Thornburg to D. C. Trimble dated September 14, 1981, and the incoming request from D. C. Trimble (Arkansas Power & Light Company) dated June 19, 1981. In general, a container should be labeled when radioactive material is added to it. However, conditions may exist when addition of appropriate information to the label may be delayed. The health physics position was written in the context of 10 CFR 20.203, but it also applies to the "new" 10 CFR Part 20, Sections 20.1904 and 20.1905.

An NRC Radiological Assessment Team Appraisal resulted in a citation for failing to label containers of radioactive material in accordance with 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)]. While Arkansas Power & Light Company (AP&L) believed the specific situation cited was a violation of the 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)] guidelines, the Radiological Assessment Team and the Regional NRC Inspector's interpretation of these 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)] requirements were viewed as impractical and costly if applied to all radioactive materials on the Arkansas Nuclear One (ANO) site. In the course of one day, ANO has generated as many as 2,000 bags of contaminated trash and tools. Most of these packages contain material with contamination levels less than 20,000 dpm per 100 square centimeters or exposure rates less than 1 mR per hour. It is AP&L's belief that the intent of the regulation was to prevent severe overexposures (internal or external) and to ensure minimal personnel exposure when working in areas containing packages of radioactive material.

Specific problems with the NRC Region IV interpretation of the regulation involve the following: (1) the labeling of every package without regard for the radiological contents of the container or the area in which the package is used, (2) the type of information required on the label (no allowance is made for alternative steps such as color coding to display the potential hazard of the material), and (3) the point in time or situation where the label must be affixed to the package. To aid in clarification of 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)] requirements and ensure consistency in radiation protection practices, AP&L requested an NRR statement regarding the following: (1) the definition of a container, and (2) the situation or time when labeling must commence.

Some degree of flexibility with respect to 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)] requirements are allowed through the exceptions provided in 10 CFR 20.203(f)(3) [or 10 CFR 20.1905]. If these exceptions do not provide the relief necessary to make a radioactive materials control program practical to implement, exemptions may be requested in accordance with 10 CFR 20.501 [or 10 CFR 20.2301]. Since there is no special definition of "container" in 10 CFR Part 20, the usual (dictionary) meaning of the term applies (i.e., a container is "a thing in which material is held or carried"). In general, a container should be labeled when the radioactive material is added to it. However, we appreciate that certain conditions may exist where the addition of appropriate information to the label may necessitate some delay. For example, dose rate information may not be added until the container is filled, or the final dose rate information may not be added until the container can be moved to a low-background area for measurement.

In summary, although 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)] do not provide the "flexibility" you desire, we suggest that you consider the following possibilities for reducing the burden of labeling containers of dry radioactive waste. First, consider the possibility of utilizing the exceptions provided in 10 CFR 20.203(f)(3) [or 10 CFR 20.1905]. Second, consider applying for an exemption, pursuant to 10 CFR 20.501, from the requirements of 10 CFR 20.203(f) [or 10 CFR 20.1904]. In any case, to be acceptable, alternative methods of control (such as those suggested by you of color coding and establishing posted local radioactive materials storage areas) must provide worker protection and material controls equivalent to those of the labeling described in 10 CFR 20.203(f)(1) and (2) [or 10 CFR 20.1904(a)]. These alternative methods should assure that exposures are ALARA and should be formally documented in procedures and included in training. Third, should you find that these approaches do not provide the desired flexibility, you might consider submitting a petition for rulemaking, pursuant to 10 CFR 2.802. Under this provision, interested persons may petition the NRC to issue, amend, or rescind any of its regulations.

Regulatory references: 10 CFR 20.203, 10 CFR 20.1904, 10 CFR 20.1905

Subject codes: 4.7

Applicability: All

HPPOS-159 **PDR-9111220141**

Title: NMSS Guidance to Manufacturers Regarding Labeling of Gas and Aerosol Detectors

See the letter from V. L. Miller to Distribution (Certain NRC Licensees) dated August 7, 1980. This letter was written to provide guidance to manufacturers regarding labeling of gas and aerosol detectors (smoke detectors). HPPOS-150 contains a related topic.

On June 9, 1980, the NRC published changes to NRC regulations for the labeling of gas and aerosol detectors (smoke detectors). The revised labeling requirements applied to manufacturers and other persons licensed by the NRC to transfer gas and aerosol detectors for use by persons exempt from NRC's regulations. The letter was written in a question/answer style format. Specific topics covered in the letter included the following:

The labeling requirements became effective on January 1, 1981, and that date was considered to be the "label application date." Although a cut-off date was not established for transfer of detectors labeled in accordance with the new requirements, 10 CFR 32.26 specific licensees had until June 30, 1981, to transfer all such detectors manufactured prior to January 1, 1981. Detectors intended for export need not be labeled and packaged as specified in the revised rules, but could be exported under the general license of 10 CFR 110.24.

Under the new requirements, manufacturers would not be required to provide disposal instructions for smoke detectors nor provide disposal service.

After January 1, 1981, the label on the detector must state "CONTAINS RADIOACTIVE MATERIAL." Although a minimum size for the type or label was not specified, letter sizes acceptable in the past were still considered acceptable. The label on a detector returned for warranty service after January 1, 1981, does not need to be replaced unless the original label was destroyed during service. The manufacturer does not need to identify himself on the label, but may instead state his license number as: "U.S. NRC License No. xxx" or "Produced under U. S. NRC License No. xxx." No abbreviations for radionuclides or the quantity of activity can be used.

Regulatory references: 10 CFR 30.20, 10 CFR 32.26, 10 CFR 32.29

Subject codes: 3.2, 3.5, 4.7, 9.0

Applicability: Byproduct Material

2.7 FACILITIES AND EQUIPMENT

HPPOS-318 PDR-9306280312

Title: Technical Assistance Request, Authorization of Employee Eating and Drinking Areas in Labs at Veterans Administration Medical Center, Martinez, California

See the memorandum from J. E. Glenn to R. J. Pate dated March 27, 1992. This NMSS memo responds to a technical assistance request from Region V, dated January 17, 1992, regarding designation of two employee eating and drinking areas in research laboratories at the Veterans Administration Medical Center in Martinez, California (VA-Martinez). Review of this issue reveals a number of health physics considerations. However, NMSS cannot justify an absolute requirement that all areas for eating and drinking be separated from use areas by physical barriers such as doors.

The eating and drinking areas may be authorized, provided the following radiation safety concerns are sufficiently addressed by VA-Martinez:

1. The licensee must specify the typical procedures carried out, quantities involved, and radioactivity measured for each isotope in each lab. Large quantities of radioisotopes may cause greater health and safety concerns. For example, the procedures conducted in lab area 113A may involve the use of phosphorous-32 or iodine-125 in millicurie quantities which could result in considerable spread of contamination and could not be approved without a barrier such as a door.

2. The licensee must develop sufficient safety measures to assure that there is no transfer of food, drink, or radioactive materials between the radioactive material use area and the eating area. For example, what measures will be taken to assure that employees remove their protective gloves and wash their hands before entering the eating area?

3. The licensee must detail how the eating area will be separated from the working area and how the flow of radioactive material into the area will be restricted. For example, the area could be marked by tape and posted with signs, provided such notices are clearly visible to prevent inadvertent entry with radioactive material.

4. The licensee must confirm that food, drink, or personal effects will not be stored with radioactive materials. Specifically, does the eating area designated in room 112A also serve as a radioactive storage area (is radioactive material stored in the freezer, refrigerator, or cabinet)?

5. The licensee must designate one sink in each lab that will only be used for non-radioactive hand, utensil, and/or dish washing. The sink must be restricted from radioactive material and, if possible, should be in close proximity to the eating area. This sink should be included in the routine laboratory surveys.

6. The licensee must address the frequency of radiation surveys and types of measurements to be made in each of the labs. Alternatively, the licensee may provide evidence that the existing frequency of scheduled surveys for each lab and corresponding air filtration systems will be effective in monitoring the safety of the designated eating areas. For example, one area of concern is whether wipe tests for removable contamination of tritium and carbon-14 will be performed at effective intervals in area 115A.

7. The licensee must describe both initial and periodic training. The training must specifically inform employees of the restrictions in place and precautions to be followed. Both new and current laboratory personnel, including janitorial and other assisting staffs who have access to the laboratory, must receive training.

8. The licensee must assure that entry and exit to the designated eating and drinking areas can be obtained without bringing food and drink through a radioactive materials use area. This appears to be a problem with room 112A.

The determination of the adequacy of the responses provided by VA-Martinez to authorize the two eating and drinking areas is the decision of the regional office.

Regulatory references: 10 CFR 20.1201, 10 CFR 20.1501

Subject codes: 5.0, 11.2

Applicability: All

HPPOS-011 **PDR-9111210103**

Title: Clarification of the 11 Criteria of NUREG-0737 on Postaccident Sampling System (PASS) Capability

See the letter from S. A. Varga to J. A. Jones (Vice President, Carolina Power and Light Company) dated September 24, 1982. Enclosed with this letter were the 11 criteria contained in NUREG-0737, Item II.B.3, on PASS capability and clarification developed by the NRR staff. These 11 criteria are briefly discussed below; however, the document must be reviewed in its entirety. The licensee must:

1. Provide information on sampling and analytical laboratory locations and their relative elevations, distances, as well as sample handling, transport, recirculation, analytical time limits, and provisions for sampling during loss of off-site power sufficient to meet a 3-hour sampling and analysis time limit.

2. Provide discussions of counting equipment capabilities including provisions for sample handling and background radiation reduction to personnel (ALARA), procedures relating radionuclide concentrations to reactor core damage including the monitoring for short and long lived volatile and nonvolatile radionuclides, as well as provisions for estimating core damage based on radionuclide concentrations, core temperatures and sample location; discuss the capability of obtaining a grab sample, transport and analyzing for hydrogen; discuss capabilities to sample and analyze for accident sample species; and discuss the suitability, reliability and maintenance information of selected on-line instruments.

3. Provide system schematics and discussions that clearly demonstrate PASS, including recirculation, is possible without using isolated auxiliary systems.

4. Discuss methodologies for measuring total dissolved gas or hydrogen and oxygen and how this information is related to reactor coolant system concentrations. In addition, if chlorides exceed 0.15 ppm, verification that dissolved oxygen is <0.1 ppm is required.

5. BWR's located near or using sea or brackish water in heat exchangers with single barrier protection are required to analyze chloride within 24 hours. All other plants have 96 hours. Initial chloride analysis must use dilutions of <1:1000, be reported in units of ppm, and have <0.1 ppm dissolved oxygen.

6. Provide information on predicted personnel exposures based on person-motion sampling, transport and analysis of samples.

7. PWR's must perform boron analysis on primary coolant. BWR's must have the capability to perform boron analysis, but need not do them providing boron was not injected.

8. Have the capability to obtain diluted and undiluted backup samples when required. If off-site laboratories will do the backup analysis, an explanation of the capability to obtain and ship one sample per week until accident conditions do not exist is needed.

9. Discuss the predicted activity in the samples to be taken and the methods of handling/dilution used to reduce activity sufficiently for the required analysis. The predicted background radiation levels in the counting room, including the contribution from other samples, must be stated.

10. Discuss the accuracy, range, and sensitivity of the methods of analysis. These must be adequate to provide the operator sufficient and pertinent data describing the radiological and chemical status of the reactor coolant system. The recommended accuracy, sensitivity, and ranges for numerous compounds are described in this criterion.

11. Describe provisions for purging sample lines, reducing sample line plateout, decreasing sample loss and distortion, preventing sample line blockage, sample disposal, and limiting reactor coolant loss from ruptured sample lines. The ventilated exhaust from the sampling station must be filtered with charcoal absorbers and HEPA filters, however, the ventilation system need not be dedicated.

Regulatory references: NUREG-0737, Technical Specifications

Subject codes: 5.0, 7.6, 8.3, 10.1, 12.16

Applicability: Reactors

HPPOS-107 PDR-9111210254

Title: Air Intrusion into BWR Primary Systems

See the memorandum from J. E. Wigginton to R. R. Bellamy (and others) dated April 15, 1983. The memo states that high radiation in main steam lines is likely from resin or amine injection from condensate demineralizers and not a result of air intrusion. High main steam radiation levels should prompt licensees to note changes in other parameters.

Several facilities had attributed increased main steam line radiation levels to increased N-16 production from free oxygen. The consensus opinion following informal discussions with representatives from General Electric, the Chemical Engineering Branch of NRR, and INPO, however, was that the more likely cause for the increased radiation levels could be resin and/or amine injection from condensate demineralizers. Since a stagnant, offline demineralizer can produce amines, General Electric recommends a thorough rinse prior to returning an idle bed online. An improperly regenerated resin bed could also be a source of amines. High main steam radiation levels should prompt licensees to note changes in other chemical parameters (i.e., pH, chloride, conductivity) sensitive to potential intrusions and not concentrate solely on fission product analysis.

Regulatory references: None

Subject codes: 5.0, 6.2, 7.1, 10.2

Applicability: Reactors

HPPOS-079 PDR-9111210213

Title: Contamination of Nonradioactive System and Resulting Potential for Unmonitored, Uncontrolled Release of Radioactivity to the Environment

See IE Bulletin No. 80-10 entitled as above and dated May 6, 1980. Action Item 3 of this bulletin states that if a nonradioactive system becomes contaminated and it is considered necessary to continue operation, an immediate safety evaluation must be performed in accordance with 10 CFR 50.59.

An auxiliary boiler had been operated for an extended period of time with contaminated water containing up to 2×10^{-2} μCi/ml. The contamination was caused by a tube leak in a temporary hose connecting the auxiliary boiler to a radioactive waste evaporator concentrate tank. Upon cooling and condensation of steam in the hose, contaminated water siphoned from the concentrate tank back to the auxiliary boiler. Because of additional and continuing leaks in the heat exchanger of the waste evaporator, the licensee's efforts to decontaminate the auxiliary boiler feedwater were ineffective. Maintenance of proper boiler chemistry was difficult because blowdown options were restricted due to contamination. As a result, 100 mCi of radioactive material were released off-site in steam via the auxiliary boiler fire box and smokestack. The release resulted in increased environmental levels of cesium and activation products being detected eight miles downwind from the site boundary.

Actions to be taken by licensees with operating licenses to preclude the described situation include:

1. Review facility design and operations to identify systems considered as nonradioactive (or described as nonradioactive in the FSAR) that may become contaminated by radioactive systems. Consideration should be given to the following: auxiliary boiler system, demineralized water system, isolation condenser system, PWR secondary water clean-up system, instrument air system, and sanitary waste system.

2. Establish a routine sampling/analysis program for these systems to detect radioactive contamination.

3. If nonradioactive systems are or become contaminated, further use of the system shall be restricted until the cause is identified, corrected, and decontaminated. However, if it is considered necessary to continue operation with the contaminated system, an immediate safety evaluation of the operation of the system as a radioactive system must be performed in accordance with the requirements of 10 CFR 50.59. The 10 CFR 50.59 safety evaluation must consider the level of contamination and any potential releases of radioactivity to the environment. The relationship of such releases to the radioactive effluent limits of 10

CFR 20 [§§20.1001-20.2401], the facility's Technical Specifications, and to the environmental radiation dose limits of 40 CFR 190 must also be evaluated. The record of the safety evaluation must set forth the basis and criteria on which the determination was made.

4. If it is determined in the 10 CFR 50.59 safety evaluation that operation of the system as a radioactive system is acceptable, provisions must be made to comply with the requirements of 10 CFR 20.201 [or, at present, 10 CFR 20.1501], General Design Criterion 64 to 10 CFR 50, Appendix I to 10 CFR 50, and the facility's Technical Specifications. Specifically, any potential release points must be monitored and all releases must be controlled and maintained to ALARA levels described in 10 CFR 50 Appendix I and within the corresponding environmental dose limits of 40 CFR 190. If in the 10 CFR 50.59 determination it is concluded that operation of the system as a radioactive system constitutes an unreviewed safety question or requires a change to the Technical Specifications, the system shall not be operated as contaminated without prior commission approval.

Regulatory references: 10 CFR 50.59

Subject codes: 5.0, 7.3, 9.2

Applicability: Reactors

HPPOS-086 **PDR-9111210238**

Title: 10 CFR 50.59 Safety Evaluations for Changes to Radioactive Waste Treatment Systems

See IE Circular No. 80-18 entitled as above and dated August 22, 1980. For changes in a facility radioactive waste system as described in the SAR, a safety evaluation is required per 10 CFR 50.59. It also provides detailed guidance on application of 10 CFR 50.59 to radwaste systems.

Recent inspections at operating power reactors have revealed numerous instances in which licensees have failed to perform adequate safety evaluations to support changes made to the design and/or operation of facility radioactive waste treatment systems. These safety evaluations are required by 10 CFR 50.59 whenever changes are made in the facility as described in the Safety Analysis Report (SAR).

The inadequacies of the evaluations have caused radiological safety hazards to occur unidentified and therefore to remain unevaluated and uncorrected. In two particular cases, the inadequately evaluated system changes resulted in system failures that caused an uncontrolled release of radioactivity to the environment. In each of these situations, a proper 10 CFR 50.59 safety evaluation would have identified and corrected deficiencies in the system modification and/or operation and would have prevented the inadvertent release of radioactivity.

NRC follow-up examination of the situation indicates that the inconsistency and/or inadequacy of licensee safety evaluations may be widespread. A wide range of opinions seems to exist among licensees as to what constitutes an appropriate 10 CFR 50.59 safety evaluation, particularly for radwaste systems. Therefore, discussion and guidance are provided for licensee use in preparing future 10 CFR 50.59 safety evaluations to support changes in the design and/or operation of the radioactive waste treatment systems of licensed facilities.

Although the detailed discussions of this guidance document are specifically directed to radioactive waste systems, the general principles and philosophy of the 10 CFR 50.59 safety evaluation guidance are also applicable to facility design and operation as a whole; thus, the application of 10 CFR 50.59 should reflect a consistent approach.

Regulatory references: 10 CFR 50.59, Regulatory Guide 1.21, Final Safety Analysis Report

Subject codes: 5.0, 9.0

Applicability: Reactors

HPPOS-091 **PDR-9111210180**

Title: Lead Shielding Attached to Safety Related Systems Without 10 CFR 50.59 Evaluations

See IE Information Notice No. 83-64 entitled as above and dated September 29, 1983. This document informs licensees that failure to analyze for possible seismic and structural effects, both dynamic and static, from lead shielding on safety-related systems constitutes an unreviewed safety question. In addition to this document, see IE Circular No. 80-18, "10 CFR

50.59 Safety Evaluation for Changes to Radioactive Waste Treatment System" (see HPPOS-086).

During a routine inspection, an NRC inspector noted that portions of safety-related piping in the primary auxiliary building of a power station was covered with lead shielding. Discussions with the plant engineering staff revealed that licensee safety evaluations supporting this modification had not been done. The licensee had neither formal control mechanisms to govern the installation, use, and accounting of the temporary shielding, nor records to document the dates and locations of the shielding installations. The shielding was placed on plant systems during a period when high fuel element failure rates led to increased radiation fields throughout the plant. After a refueling outage, the licensee began a program to identify and remove temporary shielding installed on systems inside the containment building, but failed to do this in other plant areas. Improvements in the maintenance and design program would have prevented shielding installation without required 10 CFR 50.59 evaluations.

Failure to analyze for possible seismic/structural effects (both dynamic and static) of lead shielding on safety-related systems constitutes an unreviewed safety question. In regards to the above situation, safety-related systems were modified with additional shielding without supporting engineering evaluations to ensure system operability under design-basis event conditions. Although it is focused on radioactive waste treatment systems, IE Circular No. 80-18, "10 CFR 50.59 Safety Evaluation for Changes to Radioactive Waste Treatment System", provides general guidance and clarification regarding the requirements of 10 CFR 50.59 (see HPPOS-086).

Regulatory references: 10 CFR 50.59

Subject codes: 5.3, 8.5

Applicability: Reactors

HPPOS-069 **PDR-9111210156**

Title: Guidance on Test conditions for Activated Charcoal Using Methyl Iodide

See the letter from W. Gammill to F. D. Leckie (Nuclear Containment Systems, Inc.) dated September 24, 1981. Guidance was provided on test conditions for activated charcoal using methyl iodide. Technically, the best approach is to use ANSI N509-1980, since it is an update and refers to the latest industry-approved test procedures.

Guidance was requested on Regulatory Guide 1.52 for used carbon, as to the proper temperature, relative humidity and the allowable percent penetration. NRC replied that plant Technical Specifications are the over-riding and controlling document. If the Technical Specifications list specific conditions, the test must be performed under those conditions. If some, but not all conditions are specified, then the ASTM procedures in ASTM D3803-1979 "Standard Test Methods for Radioiodine Testing of Nuclear-Grade Gas Phase Adsorbents" should be used to satisfy the remaining conditions. If the Technical Specifications refer to Regulatory Guide 1.52, Revision 2, March 1978, then page 6 of the document provides the proper course of action. Technically however, the best course of action is to follow ANSI N509-1980, since it is an update and refers to the latest industry approved test procedures (ASTM D3803-1979).

Regulatory references: ANSI N509-1980, ASTM D3803-1979, Regulatory Guide 1.52, Technical Specifications

Subject codes: 5.4

Applicability: Reactors

HPPOS-323 **PDR-9308260238**

Title: Technical Assistance Request Regarding the Auxiliary Building Ventilation System at Zion Nuclear Power Station

See the memorandum from J. A. Zwolinski to E. G. Greenman dated June 23, 1993. This NRR memo contains the NRR responses to questions asked by Region III regarding the auxiliary building ventilation system at Zion Nuclear Power Station. The licensee had taken the position that the UFSAR contains two types of information: descriptive and design. They indicated that paragraphs labeled "system description" are general design and operating features intended to provide an understanding of the overall plant operation. The licensee also stated that only paragraphs labeled "design basis" can be considered as design basis. This issue is concern at Zion and is generic to other nuclear power plants.

Question 1: Is the whole UFSAR considered in the design basis of the plant, or only sections specifically labeled as such?

The definition of Design Bases in 10 CFR 50.2 means that information that identifies the specific functions to be done by a structure, system, or component of a facility and the specific values or range of values chosen for controlling parameters chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted "state of the art" practices for achieving functional goals, or requirements derived from analysis of the effects of a postulated accident for which a structure, system or component must meet its functional goals. Regardless of what a paragraph in an UFSAR or FSAR is called, if a specification was assumed in an accident analysis, then it is part of the design basis.

Question 2: Is the concept that NRC only cares about maintaining negative pressure within contaminated cubicles in the auxiliary building the design basis or is maintaining a negative pressure within the whole auxiliary building the design basis?

The design basis and the licensing basis for the auxiliary building ventilation system serving all areas of the auxiliary building and the spent fuel pool building are to maintain the auxiliary building at a negative pressure of about 0.25 inch of water relative to ambient under normal and abnormal operation and to maintain the cubicles at a negative pressure of about 0.25 inch of water relative to the auxiliary building; hence, a negative pressure of about 0.5 inch of water relative to the outside. The objective is to maintain the auxiliary building at a negative pressure with respect to all adjacent areas so that contamination is not transported to areas that are at a lower pressure than the auxiliary building.

Question 3: Does the auxiliary building wall/door have any function with regard to keeping contaminated airborne material inside?

The design functions of the outer walls and doors serve in situations not involving an accident are structural and missile protection and control of the spread of contamination by allowing the required vacuum to be maintained. Auxiliary building access doors should not routinely be left open during normal operations since this may affect the normal ventilation flow path and/or function of maintaining a negative pressure of about 0.25 inch of water in the auxiliary building. This negative pressure is designed to prevent the release of radioactive material from the auxiliary building. The proper system flow balance is required to prevent the spread of airborne radioactive material from areas of high concentration to areas of lower concentration.

Question 4: Can licensees justify operability with a probability risk assessment (PRA) and can licensees use PRA to delay a test or an operability determination?

These practices are unacceptable.

Question 5: Is there some design function for the auxiliary building outer walls relating to the confinement of radioactive materials that may be present in the auxiliary building during non-accident conditions?

The design function of the outer walls and doors not involving an accident are structural and missile protection and control of the spread of contamination by allowing the required vacuum to be maintained. Maintaining 0.25 inch of negative pressure in potentially contaminated areas serves to confine radioactive materials to the auxiliary building under non-accident conditions.

Question 6: Is the "interfacing system LOCA" considered a postulated accident and is the occurrence of such an event considered part of the design basis?

The answer is no to both questions.

Guidance was also sought on the role of PRA in the preparation of 10 CFR 50.59 safety evaluations by licensees. 10 CFR 50.59 identifies the use of probability in reference to the determination of an unreviewed safety question. Prior to PRA, the increase in probability of occurrence for a 10 CFR 50.59 evaluation was judged on design basis considerations and engineering judgement. With the current PRA methods, reliability data, and plant specific PRAs, it is reasonable to expect these to be used to estimate changes in probability associated with proposed plant modifications. However, the results of licensee 10 CFR 50.59 evaluations should not be based solely on bottom line PRA numbers. Other considerations such as engineering judgement and operating experience should be factored in when appropriate.

Regulatory references: 10 CFR 50.2, 10 CFR 50.59

Subject codes: 5.0, 5.5

Applicability: Reactors

HPPOS-326 **PDR-9308260262**

Title: Technical Assistant Request, Venting of Turbine Building at Grand Gulf Nuclear Station

See the memorandum from L. J. Cunningham to E. G. Adensam dated June 23, 1993. This RSS memo responds to a technical assistance request from Region II, dated October 22, 1992, regarding the unidentified and unmonitored release pathway for noble gases and iodine from the turbine building roof hatches of the Grand Gulf Nuclear Station. HPPOS-099 and HPPOS-254 contain related topics.

RSS provided the following responses to specific questions in the TAR from Region II.

Question 1: Was it acceptable for the turbine building roof hatches to remain open, creating an unmonitored release pathway?

The turbine building roof hatches were designed to provide additional ventilation in the turbine building in case of fire. The Grand Gulf Nuclear Station SER, Section 9.4.4, Turbine Area Ventilation System, noted that failure of the system does not compromise the operation of any essential systems and does not affect the capability to safely shutdown the plant. Although no immediate safety threat was imposed, an unmonitored release pathway was created by inadvertently leaving the turbine buildings roof hatches open. Therefore, it is not acceptable to allow them to be left open and unattended for an extended period.

Question 2: Would it have been reasonable to evaluate the extent of the radiation hazards that may be present as required by 10 CFR 20.201 [or, at present, 10 CFR 20.1501]?

The licensee said that an assessment of the potential releases from the hatches was made before they were opened. The licensee consulted information from continuous air sampling and monitoring equipment located within a reasonable distance of the hatches. The air sampling equipment included charcoal filters to monitor for radioiodine. The licensee concluded that this monitoring information represented the concentrations of radioactive material in the air that would be released through the hatches. For a controlled release of short duration, such an assessment of the potential release is an adequate survey as required by 10 CFR 20.201 [or 10 CFR 20.1501]. However, the hatches were inadvertently left open and unattended for an extended period. No conscious assessment of the potential release from the hatches for the extended period was done before the hatches were opened. In cases where the hatches are to be left open for an extended period, a quantitative method of assessing the potential release should be provided. NRC does not believe the event warrants a citation for violation of 10 CFR 20.201 [or 10 CFR 20.1501]; the major issue concerns the breakdown of administrative controls.

Question 3: Should the unplanned and unmonitored release by the turbine building roof hatches be reported in the Semiannual Effluent Release Report?

According to the Grand Gulf Technical Specifications 6.9.1.8 and 6.9.1.9, a summary of all planned and unplanned quantities of radioactive liquid and gaseous effluents from the unit must be included in the Semi-Annual Effluent Release Report. Using the continuous air sampling and monitoring information, the licensee should provide a bounding estimate of the amount of radioactive material released from the hatches and include it in the Semiannual Effluent Release Report. [Note: Effluent reports are now required annually.]

The issue of unmonitored release pathways through turbine building roof hatches is not uncommon to BWRs and the necessity of monitoring turbine building effluents has been recognized. SRP 11.5, "Process and Effluent Monitoring," GDC 64, and 10 CFR 50, Appendix I, call for such monitoring. While the activity released from the roof vents may represent a small fraction of the total activity released from the plant, experience has shown that when considering the meteorology associated with a ground level release, the ground level source can account for most of the dose commitment from a facility.

In summary, the licensee left the turbine roof hatches open and unattended over an extended period due to administrative oversight. Although the licensee conducted a reasonable survey before opening the hatches for a controlled release of short duration, it was not acceptable for the turbine building roof

hatches to remain open and unattended for an extended period without a continuous quantitative method for monitoring potential releases and creating an unidentified and unmonitored release pathway.

Regulatory references: 10 CFR 20.201, 10 CFR 50, Regulatory Guide 1.21, Technical Specifications

Subject codes: 2.2, 5.0, 5.5, 7.3

Applicability: Reactors

HPPOS-281 **PDR-9306160199**

Title: Exceptions for EcoTek, Inc., as a Decommissioning Contractor

See the memorandum from R. E. Cunningham to J. P. Stohr dated February 4, 1993. The memo states: (1) decommissioning contractors may operate under their own license when they are providing the radiation safety programs under which the work is being done at a temporary job site; and (2) decommissioning contractors may be exempted from financial assurance requirements to the extent that the licensed materials remain at the temporary job site or are transferred to another licensee for disposal. This is a change in NRC policy. The previous NRC policy was that contractors who perform decommissioning activities at NRC licensed facilities do not require separate licenses, but rather perform these operations under the current NRC license for the facility.

After receiving the position paper from EcoTek dated September 23, 1992, concerning application of the financial assurance requirements to their service license, the NMSS staff met with the LLWM and OGC staffs to discuss the policy of issuing service licenses for work at temporary job sites. As a result of this meeting, we concluded that there are cases where the radiation safety programs in place at an NRC licensed facility may not be broad enough to ensure the safety of decommissioning activities performed by a service contractor. In such instances, it is appropriate for service contractors to operate under their own license when they are providing the radiation safety programs under which the work is being performed. This differs from the policy established in 1989 concerning licenses for decommissioning contractors (see Enclosure 2). Before starting work, contractors should establish a written agreement with their customers specifying which activities will be performed under the contractor's license and supervision, and which activities will be performed under the customer's license and supervision. This will assure that responsibility for job site radiation safety is clearly defined, provide for further assurance that operations will be conducted safely by the customer and the contractor, and identify the responsible licensee for purposes of inspection and enforcement.

We also concluded that decommissioning contractors may be exempted from the requirement to establish decommissioning financial assurance to the extent that licensed materials remain at the temporary job site or are transferred to another licensee for disposal. We have suggested changes to the EcoTek license to address these and other issues (see Enclosure 1) if EcoTek wishes to proceed with a formal request for an exemption. A policy and guidance directive will be developed for reviewing applications for service licenses, and a draft of this directive will be provided to the Regions for comment.

Regulatory references: 10 CFR 30, 10 CFR 40, 10 CFR 70, License Conditions

Subject codes: 5.8, 11.2, 12.19

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-312 **PDR-9306250123**

Title: Technical Assistance Request, Virginia Electric and Power Company, Response to 10 CFR 30.35

See the memorandum from J. E. Glenn to W. E. Cline dated February 4, 1991. This NMSS memo responds to a technical assistance request from Region II, dated January 25, 1991, concerning whether an electric utility that has complied with 10 CFR 50.75 must make the submission directed by 10 CFR 30.35 for its byproduct material license. Virginia Electric and Power Company's License No. 45-13670-04 authorizes up to 3 curies of any byproduct material for the transfer, possession and use incident to repair, maintenance and decontamination of reactor components and associated tools and equipment. The licensed material is authorized to be used at temporary job sites anywhere in the United States.

The licensee thought that decommissioning costs were bounded by normal operations and no additional

financial assurance was required. NMSS and Low-Level Waste Management and Decommissioning (LLWM) disagreed with this position and cited a response to a request from Region I dated November 6, 1990 (enclosure) which advised:

1. If the byproduct material license is for activities performed offsite, then the 10 CFR 30.35 financial assurance submission is required.

2. If the byproduct material license is for activities performed onsite, then the 10 CFR 30.35 financial assurance submission is not required, PROVIDED that the utility verifies that all decommissioning activities related to its materials license will be included in the 10 CFR Part 50 preliminary and final plant submittals.

Since License No. 45-43670-04 authorizes the use of licensed material "Anywhere in the United States," the power company is required to make a financial assurance submission in accordance with 10 CFR 30.35.

Regulatory references: 10 CFR 30.35

Subject codes: 5.8, 11.2

Applicability: Reactors

HPPOS-309 **PDR-9306240427**

Title: Technical Assistance Request, Application of the Financial Assurance Requirement in 10 CFR 30.35, 40.36, and 70.25 to Waste Brokers Located in Agreement States

See the memorandum from J. E. Glenn to R. R. Bellamy dated September 31, 1990. This memo responds to a technical assistance request (TAR), dated October 24, 1990, inquiring about the applicability of the financial assurance requirements of 10 CFR Parts 30, 40, and 70 to Radiac Research Corporation and NDL Organization, Inc., waste brokers in agreement states. The TAR was referred by NMSS to the Division of Low-Level Waste Management and Decommissioning (LLWM) who coordinated its response with the Office of the General Counsel (OGC).

Radiac Research Corporation and NDL Organization, Inc., each have an NRC license which allows them to receive and possess packaged solid waste byproduct, source, and special nuclear material, and to transfer such packages to authorized land burial facilities. The possession limits listed in their licenses are such that financial assurance would be required pursuant to 10 CFR Parts 30, 40, and 70. However, their licenses do not permit storage at any location owned or controlled by the licensee in a non-Agreement State. Both licensees also have an Agreement State license from New York State which allows them to store radioactive material at their facility in New York. During routine operations, the licensee sends a truck to customer facilities which picks up prepackaged waste and then either returns to the licensee's Agreement State facility or proceeds to the licensed burial site. Hence, the licensee has no NRC licensed facilities other than their trucks and these are returned to the Agreement State for decontamination.

Upon consultation with OGC, it was determined by LLWM that the Decommissioning Rule requirements apply to these waste broker licensees. Implementation of the regulation occurs when possession limit thresholds are met, not by storage or transportation statues described in this situation. Since the licensees' possession quantities of radioactive materials exceeds 10^5 times the applicable quantities set forth in Appendix C to 10 CFR Part 20, they are required to provide pursuant to 10 CFR 30.35(a), a decommissioning funding plan for the eventual decontamination and disposal of their trucks and facilities. Each decommissioning plan pursuant to 10 CFR 30.35(e) must provide a cost estimate for decommissioning (the cost estimate may be greater or lesser than the amounts of financial assurance prescribed by paragraph (d) of 10 CFR 30.35), a selection of a financial assurance method for assuring funds for decommissioning, a copy of the method used to obtain the dollar value that is reflected in the cost estimate, and a means of adjusting the cost estimates and associated funding levels periodically over the life of the facilities. However, licensees are always entitled, pursuant to 10 CFR 30.11(a), to request an exemption to the Decommissioning Rule requirements and such requests are evaluated on the merits of each specific case.

It was also noted that the Decommissioning Rule is a matter of compatibility with Agreement States.

The key points in LLWM's response to the TAR are as follows:

1. The financial assurance requirements apply to waste brokers because of the quantities of licensed material they are authorized to possess.

2. The waste brokers must submit a decommissioning funding plan (DFP) for the eventual decontamination of their trucks, equipment, and facilities.

3. The DFP, which may be for an amount greater or less than that prescribed in 10 CFR 30.35(d) (and equivalent provisions of 10 CFR Parts 40 and 70), must contain all the information specified in 10 CFR 30.35(e).

4. The waste brokers may request, pursuant to 10 CFR 30.11, an exemption from their financial assurance requirements.

5. The provisions of 10 CFR 30.35, 40.36, and 70.25 are a matter of compatibility with the Agreement States.

Regulatory references: 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25

Subject codes: 5.8, 9.0, 12.2

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-269 PDR-9306090321

Title: Technical Assistance Request, Yuma Proving Ground, Department of the Army, Statement of Intent for a Government Licensee

See the memorandum from J. E. Glenn to R. J. Pate dated August 12, 1991, and the memorandum from J. H. Austin to J. E. Glenn dated August 6, 1992. These memos respond to the TAR from Region V, dated July 15, 1991, regarding the Department of Army's Statement of Intent related to the decontamination and decommissioning of the Yuma Proving Ground. NMSS has reviewed the financial assurance and revised cost estimate documents in a Statement of Intent as cited in NUREG-1337, Rev. 1, page A-6. The cost estimate and the assumptions used in the cost details are reasonable. As a matter of information to the Regional licensing staff, we are enclosing a November 21, 1990 memorandum sent to the Regions which included recommended wording for a statement of intent for a government licensee which may be used by Regions in future cases.

Government licensees required to submit financial assurance under the decommissioning rule may use a statement of intent as their financial assurance mechanism. Most government licensees required to make submittals are expected to use this option. However, no recommended wording for a statement of intent was provided in the standard format and content guidance originally published as NUREG-1336 and later issued as Regulatory Guide 3.66. We are enclosing recommended wording to provide an example of an acceptable statement of intent. This recommended wording will be incorporated into the standard review plan for license applications (FC 90-2) until it can be added to Regulatory Guide 3.66.

In addition to the wording for a statement of intent, questions have been raised concerning what financial assurance is required from the Navy and Air Force master materials licensees. The Navy and Air Force have made preliminary financial assurance submittals to comply with the July 27, 1990 submittal deadline. However, the decommissioning regulations also require that the Navy and Air Force each submit a decommissioning funding plan with site-specific cost estimates at renewal. However, the lack of a renewal date leaves the due date for submittal of a complete funding plan in question.

The intent of the rule is that the Navy and Air Force should submit plans within the next five years which assure a specified level of funding for decommissioning their facilities. A reasonable approach would be for them to systematically review the activities authorized at each site, and perform a site-specific cost estimate for each site which would require decommissioning financial assurance if licensed separately. For the other activities and sites which do not reach this threshold, a general combined cost estimate would be acceptable. A total cost should be determined and a statement of intent or other mechanism for that dollar amount should be provided.

This is an especially opportune time for the military to be considering decommissioning plans because they recently received the GAO report issued in March 1990 entitled, "The Military Would Benefit From a Comprehensive Waste Disposal Program," which was circulated to the regions in May 1990. We request that Regions II and IV approach the Navy and the Air Force, respectively, to discuss our expectations that they submit decommissioning funding plans with site-specific cost estimates within the next five years.

Regulatory references: 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25, Regulatory Guide 3.66

Subject codes: 5.8, 11.2, 12.13

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-315 **PDR-9306250281**

Title: Technical Assistance Request, Statements of Intent by Government "Controlled" Entities

See the memorandum from J. E. Glenn to R. R. Bellamy dated February 27, 1991. This NMSS memo responds to a technical assistance request (TAR) from Region I for guidance on how to determine whether a university or hospital may use a statement of intent to fulfill its financial assurance requirement as specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25. HPPOS-269 contains a related topic.

The TAR was referred to the Division of Low-Level Waste Management and Decommissioning who provided the following guidance.

1. If an institution is identified as a "public institution" in either the "Directory of Post Secondary Institutions" or the "American Hospital Association Guide to the Health Care Field," then that institution is assumed to be controlled by a government agency.

2. The government agency may provide all or part of the financial assurance.

3. If the government agency uses a statement of intent to provide all or part of the financial assurance, the statement must be signed by a person authorized to make the guarantee.

4. If the government agency provides only part of the required assurance, the remainder of the required assurance must be covered by an acceptable mechanism.

Regulatory references: 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25

Subject codes: 5.8, 12.13

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-266 **PDR-9306070308**

Title: Policy and Guidance Directive FC 83-23, "Termination of Byproduct, Source and Special Nuclear Material Licenses"

See the memorandum from R. E. Cunningham to J. E. Glenn (and others) dated November 4, 1983. This directive provides guidance for Regions and Headquarters staff on findings that need to be made before terminating any byproduct, source, or special materials license.

The enclosed final rule (Enclosure 1) specifies licensee responsibility and requirements for terminating a license issued under 10 CFR Part 30, 10 CFR Part 40 and 10 CFR Part 70. Among other things, a licensee is required to submit on or before the expiration date a radiation survey report confirming the absence of radioactive materials or specifying existing levels of residual radioactive contamination present from past operations. A survey report is not required if a licensee can show the absence of radioactive contamination in some other manner, such as the use of only sealed sources that never showed evidence of leakage. If detectable levels of residual radioactive contamination attributable to licensed operations are found, the license continues in force until the Commission notifies the licensee in writing that the license is terminated.

Review Procedure: Before terminating a license where residual radioactive material contamination is present from past licensed operations, NRC should determine whether:

1. A reasonable effort was made to eliminate residual contamination, and

2. Residual radioactive contamination is acceptably low to permit unrestricted release of the affected facilities.

If the levels of residual radioactive contamination on surfaces and in soil are a small fraction of those normally acceptable for unrestricted release, it is not necessary for the licensee to describe the efforts made to reduce contamination levels.

Policy and Guidance Directive FC 83-3, "Standard Review Plan (SRP) for Termination of Special Nuclear Material Licenses for Fuel Cycle Facilities",

contains information that is useful for terminating any byproduct, source, or special nuclear material license.

In most cases involving short half-live radionuclides or operations involving only sealed sources, an independent confirmatory survey by NRC will not be necessary. Confirmatory surveys should always be made if the licensee's survey report appears suspect or past licensee operations involved the chemical processing of hundreds of milligrams of plutonium, tens of kilograms of enriched uranium-235, or hundreds of kilograms of source material. For materials licensees that used and processed hundreds of millicuries of long half-life radionuclides (>1 year), confirmatory surveys should be made in all cases. If it is determined that a confirmatory survey will be made, a notice should be sent to the licensee informing them that the equipment and facilities should be held for NRC inspection. Discretion may be exercised whether a confirmatory survey is necessary if information, such as inspection reports, is available that provides a basis for acceptance of the licensee's survey.

Contamination Levels Generally Acceptable for Unrestricted Areas: If the levels of contamination exceed the levels discussed below and a judgment is made that further efforts to reduce the contamination are not necessary for termination of the license, an environmental impact assessment should be made to support the termination. Such cases should be reported to the Director of the Division of Fuel Cycle and Material Safety, NMSS, before termination of the license.

1. Surface contamination: See Enclosure 2 to memo.

2. Soil contamination: See Enclosure 3 to memo

3. Water contamination: If surface or ground water contamination is below EPA's National Interim Primary Water Regulations (EPA 570-9-76-003), the contamination is acceptable for unrestricted areas.

Regulatory references: 10 CFR 30.36, 10 CFR 40.42, 10 CFR 70.38

Subject codes: 5.8, 11.4

Applicability: Byproduct, Source, and Special Nuclear Materials

HPPOS-292 PDR-9306210248

Title: Technical Assistance Request, Westinghouse Electrical Company, Evaluation of Residual Contamination

See the memorandum from J. E. Glenn to R. R. Bellamy dated May 18, 1992. This memo responds to a technical assistance request from Region I, dated April 14, 1992 (Enclosure 1), for confirmation of their interpretation of the Branch Technical Position (BTP) for evaluation of residual concentrations of processed uranium on the Bloomfield, NJ site and generic applicability to other remediated facilities with processed uranium waste. The interpretation of Region I is correct (Enclosure 2) and is applicable to other remediated sites. For unenriched uranium, with no decay products of uranium-234 (U-234) present, the applicable values in the BTP are those for depleted uranium.

Westinghouse Electric Company's Bloomfield Lamp Plant is currently being remediated to remove thorium and processed uranium waste and contamination resulting from past operations at the facility. The Branch Technical Position for Disposal or Onsite Storage of Thorium and Uranium Wastes from Past Operations (BTP) provides guidance on acceptable concentration limits for various types of materials for five disposal options. While the BTP provides numerical guidance for thorium (natural thorium), there is no criteria for processed uranium.

The Branch Technical Position (46 FR 52061-52063) describes five options for disposal of certain uranium or thorium wastes. For each option, a disposal methodology is described and a concentration limit for each of four various kinds of material is tabulated. For Option 1, these values are as follows: natural thorium (Th-232 plus Th-228) if all daughters are present and in equilibrium, 10 picocuries per gram (pCi/g); depleted uranium, 35 pCi/g; enriched uranium, 30 pCi/g; and natural uranium ores (U-238 plus U-234) if all daughters are present and in equilibrium, 10 pCi/g. For other options, higher concentrations apply. One problem with the BTP is that there is no stated disposal option nor concentration limit for processed uranium; i.e., waste materials containing uranium, in which the uranium is neither enriched nor depleted and is not natural uranium ore with all daughters present and in equilibrium. There is a need for a concentration limit for disposal of this type of material in order to evaluate the remediation that has

been performed at this site and other sites contaminated with material of this kind.

The concentration limits for wastes containing processed uranium should be the same as that tabulated for depleted uranium since processed uranium most closely resembles the radiological characteristics of depleted uranium; i.e., U-235 makes up only about 0.7% of natural uranium, and based on Section II.B of Enclosure 3 to the Branch Technical Position, the U-235 decay chain is generally unimportant compared with the U-238 chain. For Disposal Option 1, the appropriate concentration limit for processed uranium would thus be 35 pCi/g.

NMSS agrees with the interpretation. The basis is the contribution of U-238 to the inhalation and ingestion doses relative to that of U-234. For both natural and depleted uranium, U-238 contributes a substantial fraction of the radioactivity; whereas the radioactivity is completely dominated by the U-234 with regard to inhalation and ingestion doses with enriched uranium,

Regulatory references: None

Subject codes: 5.8, 9.0

Applicability: All

2.8 INSTRUMENTATION

HPPOS-328 **PDR-9312130314**

Title: Proper Operation and Use of Alarm Dosimeters at Nuclear Power Plants

See the memorandum with enclosure from L. J. Cunningham to J. H. Joyner (and others) dated November 15, 1993. This NRR memo was written by the Radiation Protection Branch in response to numerous inspection report findings and regional requests for guidance on the proper use and operation of alarm dosimeters. NMSS, RES, and Regional comments were considered in the development of this health physics position.

IMPROPER USE AND OPERATION OF ALARM DOSIMETERS: The following examples illustrate the types of problems occurring with alarm dosimeters (ADs) at nuclear power plants:

1. ADs not operated in the proper mode for their intended use [e.g., ADs used in the accumulated dose (integrating) mode when the licensee procedure or RWP requires use in the dose-rate mode].

2. Personnel continuing to work in high radiation areas rather than leaving when their AD alarms in the integrating mode.

3. HP personnel issuing ADs to individuals without telling them the proper mode of operation or the alarm setpoints.

4. Contract HP technicians not receiving training on the AD in use at the current facility (different facilities use different ADs).

5. ADs routinely being placed in plastic bags or inside the pockets of PCs to prevent contamination. These actions decrease the ability of the wearer to hear the AD alarms, particularly in high noise areas requiring hearing protection.

CALIBRATION OF ALARM DOSIMETERS: Regulatory Guide 8.28, "Audible-Alarm Dosimeters," states that audible-alarm dosimeters are not generally substituted for conventional survey meters. While this is technically correct and consistent with good HP practice, TS 6.12.1 allows an audible-alarm dosimeter

to be used instead of a survey meter or HPT accompaniment after the dose rates in the area have been measured with a survey meter and the workers in the area have been informed of the measured dose rates.

10 CFR 20.1501(b) states: "the licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured." Using an ADs cumulative alarm setpoint to initiate worker actions in HRAs (i.e., exit an area when the alarm sounds) meets the intent of the above regulation. Based on the above requirements, ADs should be part of a routine instrument calibration program if they are used to satisfy the requirements under 10 CFR 20.1501(b) or if used under 10 CFR 20.1601(c) "alternative methods" as specified in TS 6.12.1 as a condition for entry into high radiation areas.

TRAINING IN PROPER USE OF ALARM DOSIMETERS: In 10 CFR 19.12, "Instructions to Workers", it is stated: "all individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the restricted area; . . . shall be instructed in the purposes and functions of protective devices employed, . . . and instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material."

To meet these 10 CFR Part 19 requirements, a licensee needs to train personnel in the proper operation of ADs. This training should minimally include: (1) different modes of operation, integrated dose and dose-rate; (2) the different types of alarms, including the different sounds of each alarm; (3) actions to be taken when receiving an alarm, leave the area and contact health physics or move to a lower dose-rate area; and (4) guidance for proper use of the ADs. The guidance for proper use as adapted from RG 8.28 is as follows:

1. An AD should not routinely be used as a survey meter (removed from the body and used to check dose rates in the area).

2. Care should be taken to avoid dropping ADs, but if dropped, the ADs proper operation should be verified.

3. ADs should normally not be used in high noise areas, when a user has a pronounced hearing loss, or when the AD would be muffled by heavy clothing (e.g., PCs). When ADs are used in high noise areas, workers should be instructed to frequently check their ADs visually (similar to reading a pocket ion chamber) or be equipped with a warning device (e.g., remote ear-piece or visual flashing light).

4. Source and battery checks should be done daily when the ADs are in use and before the first use.

Regulatory references: 10 CFR 19.12, 10 CFR 20.1501, 10 CFR 20.1601, ANSI N13.27-1981, Regulatory Guide 8.28, Technical Specifications

Subject codes: 1.2, 6.1, 6.4, 7.1, 8.1

Applicability: Reactors

HPPOS-001 **PDR-9111210074**

Title: Proposed Guidance for Calibration and Surveillance Requirements to Meet Item II.F.1 of NUREG-0737

See the memorandum from D. G. Eisenhut to Regional Administrators dated August 16, 1982. This memo includes "Proposed Guidance for Calibration and Surveillance Requirements for Equipment Provided to Meet Item II.F.1," prepared by the Division of Systems Integration, NRR. Presented below is a brief description of the Proposed Guidance. It is strongly recommended that the entire document be reviewed. The health physics position was written in the context of 10 CFR 20.201, but it also applies to "new" 10 CFR 20.1501(a) and 20.1501(b).

The noble gas effluent monitors, particulate and radioiodine samplers, and in-containment radiation monitors described in NUREG-0737, Item II.F.1, Attachments 1, 2, and 3, are substantial departures from conventional designs and operating concepts in detecting and measuring plant radiological conditions. The nature and purpose of these monitors and samplers dictates an approach to calibration and surveillance requirements that differs widely from existing requirements and procedures established for conventional monitors. The proposed guidance addresses concerns relative to review of licensees implementing procedures and provides guidance on certain matters pertaining to calibration.

APPLICATION OF ANSI N323-1978: ANSI N323-1978 recommendations as requirements for the review of fixed area and effluent monitors are not appropriate for either normal range or NUREG-0737 monitors. The standards contained in ANSI N323-1978 specifically address hand-portable survey instrumentation and are not applicable to fixed area or effluent monitors.

MC 2515, INSPECTION PROCEDURE 84710: MC 2515, Inspection Procedure 84710 was written specifically for monitors designed to operate at very low concentrations of radioactive materials and is not appropriate for use in conjunction with NUREG-0737 noble gas effluent monitors for the following reasons: (1) ALARA considerations limit the handling of gamma-emitting noble gases in concentrations sufficient to perform onsite upper range calibration of these monitors; (2) Inspection Procedure 84710 suggests using Kr-85, a gas not suitable for calibration of most NUREG-0737 effluent monitors; (3) the only practicable means of in-place calibration of NUREG-0737 effluent monitors in the upper ranges, "solid" sources, is not consistent with 84710; and (4) release of calibration gases to the environment after calibration could result in violations of plant Technical Specifications.

NRR STAFF RECOMMENDATIONS FOR CALIBRATION OF NOBLE GAS EFFLUENT MONITORS: An acceptable approach calls for a one-time "type" calibration of a limited number of production-model monitors using radioactive gases, an acceptable alternative to in-place testing with radioactive gases due to ALARA considerations. The calibration, at either the manufacturer's facility or suitable contractor facility, would use NBS-traceable radioactive gas sources of the appropriate emissive characteristics at a minimum of three on-scale values separated by not less than two decades of scale. One or more "Laboratory Standard Sources" could be established using solid radioactive source material having emissive radiation characteristics similar to those of the calibration gas. The solid sources could then be used to develop "Secondary Calibration Sources" used for on-site in-place calibration. It is suggested that periodic confirmation or verification of calibration source values be made a part of surveillance procedures.

IN-CONTAINMENT HIGH-RANGE RADIATION MONITORS: NRR recommends that licensees verify monitor design characteristics by requiring type-testing at sufficient points to demonstrate linearity through all scales up to 10^6 R/hr. In addition, licensees should specify that each production detector be tested at 10^3 R/hr to assure satisfactory response to high levels of radiation.

PARTICULATE AND RADIOIODINE SAMPLING FROM EFFLUENT GAS STREAMS: NRR would accept empirical data on sampling line losses based on actual tests of either the installed system or a full-scale mockup in lieu of calculations based on ANSI N13.1-1969 appendices.

NRR recommends OIE revise MC 2515, Inspection Procedure 84710 or consider preparation of a separate inspection procedure or temporary instruction for NUREG-0737 items. The suggested guidance in NUREG-0737 and this memorandum with its attachments should provide the basis to initiate action.

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501, NUREG-0737, Technical Specifications,

Subject codes: 6.4, 7.3, 12.16

Applicability: Reactors

HPPOS-040 **PDR-9111210182**

Title: Effluent Radiation Monitor Calibrations

See the memorandum from R. L. Baer to C. J. Paperiello dated November 13, 1985. Regulatory Guides and ANSI N13.10-1974 do not suggest multipoint calibrations are necessary beyond the initial preoperational testing for effluent monitors. Single point calibration using secondary sources are acceptable where detectors are inherently linear.

After a review of the existing Regulatory Guides (1.21 and 4.15) and ANSI industry standards (ANSI N13.10-1974) that establish relevant guidance, it is believed that these documents do not suggest multipoint calibrations are necessary beyond the initial preoperational acceptance testing for these effluent monitoring systems (sometimes referred to as "primary calibration", as used in ANSI N13.10-1974, Section 5.4.10). Section 5.4.10 further states that the primary "...calibration shall be related to a secondary source or method which will be used for periodic in-plant recalibrations." This suggests that routine re-calibrations can be less rigorous than the one-time, initial primary calibration. These periodic recalibrations should be

viewed as ensuring that the detection system has remained stable over time. Therefore, "single-point" calibrations using secondary sources (e.g., solid sources), should be considered adequate to meet the requirements of standard Technical Specifications where detectors are inherently linear.

Assuming a licensee calibrates at a single point, the licensee should consider selecting that point at or near an alarm or action level. Routinely calibrating near an alarm point, coupled with the ongoing comparison of real-time monitor readings against laboratory analysis of periodic grab samples containing "normal" levels of radioactive effluents, seems to provide an adequate assurance of proper monitoring operability. However, calibration near an alarm point or action level is neither a requirement nor a position in the relevant guides or standards.

Region V provided input pertinent to this discussion which focused on detector saturation problems. They provided documented performance testing by a Region V licensee to determine the potential for saturation problems with the plants' effluent monitors. In general, the licensee found Geiger-Muller (GM) tubes were most seriously affected, NaI scintillator/photo-multiplier (PM) tubes less affected, and plastic scintillator/PM tubes least affected.

Given the overall upgrade in effluent monitoring as a result of the NUREG-0737 requirements, each licensee should already be able to demonstrate adequate effluent monitoring capability at high ranges needed during accidents to provide meaningful information relative to a monitored "accident-type" release stream. The evidence demonstrating monitor operability at high ranges need not be verified by each licensee as primary calibrations since previous guidance provided by NRR for calibration of NUREG-0737 monitors suggests other acceptable alternatives.

In summary, "single-point" routine calibrations are adequate for scintillation monitors, given the monitors inherent stability and a thorough initial primary calibration. The use of single-point, routine calibrations for GM tubes is acceptable, given that the radiation monitor initiates a fail-safe trip function (isolates, or re-directs the effluent to another monitored pathway) below the radiation level where the initial primary calibration began to show appreciable saturation losses. To ensure that control room operators understand GM effluent monitor system limitations, emergency implementing procedures should clearly define these system limitations. For example, in the event of a steam generator tube failure, the procedures should highlight (e.g., caution notes) probable invalid readings from an SJAE GM monitor (down scale response as the detector saturates, in response to a worsening primary-secondary leakage).

Regulatory references: ANSI N13.10-1974, Regulatory Guide 1.21, Regulatory Guide 4.15, Technical Specifications.

Subject codes: 6.4, 7.3

Applicability: Reactors

HPPOS-088 **PDR-9111210244**

Title: Corrections for Sample Conditions for Air and Gas Monitoring

See IE Information Notice No. 82-49 entitled as above and dated December 16, 1982. Calibration of monitoring systems for noble gases, particulates, and iodine must include correction for operation at reduced pressures. Newer systems provide built-in compensation but older analog systems may require the use of manual correction factors.

A problem of pressure differentials in gas monitoring systems was identified by the licensee at the Diablo Canyon nuclear power plant. At Diablo Canyon, the gas monitor takes suction through an isokinetic sampling head about 100 feet up the plant vent stack. In maintaining a flow of 10 cfm, necessary to ensure isokinetic sampling, it was found that the gas monitor chamber pressure was about 12 inches of Hg below atmospheric pressure (30 inches of Hg). This resulted in a reduction in density of the sample chamber by about 40 percent. As a result of this reported sampling deficiency, each NRC Region conducted a survey of selected operating LWRs to determine whether licensees were making the necessary differential corrections for effluent monitoring. Results of these Regional surveys indicated that a generic deficiency does exist. Twenty plants were surveyed and eleven facilities reported they made no pressure differential corrections.

Since calibration of normal range noble gas detectors (sensors) is usually done at atmospheric pressure using Kr-85 gas, it is essential that calibration and opera-

tional readouts be automatically corrected for the reduced pressure conditions encountered in system operation, or procedures specify the application of appropriate correction factors. Particulate and iodine effluent release determinations are also sensitive to sample flow rate which may be affected by system pressure variations. Errors on the order of 10% to 50% in the calculation of particulates and iodine can result if no compensation is provided for measurement of actual gas flow in the sampling system at reduced pressure. Operating variables such as the length of sample run, and variation in the pressure differential across a particulate filter can also affect operating pressure. In addition to long sample runs, another significant factor is the increase in pressure drop across a particulate filter caused by dust loading.

One of the simplest and most commonly used gas flow measurement devices is the variable area flow meter, commonly known as the rotameter. A rotameter calibrated at atmospheric pressure will not read correctly at either higher or lower pressure, unless properly compensated [D. K. Craig, Health Physics 21, 328-332 (1971)]. Pressure correction factors for specific rotameters are available from the various manufacturers as part of the instruction manuals supplied with the equipment. Manufacturers of sampling/monitoring systems are aware of potential discrepancies in flow rate measurements. Current systems provide built-in compensation of air flow rate indication for operation at less-than-atmospheric pressure through the use of pressure and temperature transducers and computer software algorithms. Older analog systems may require application of manual correction factors. Instruction manuals provided to licensees by the vendors of older sampling/monitoring systems should describe the procedures for making the necessary corrections.

Independent verification of the calibration of a flow rate measurement system can be accomplished by placing a calibrated rotameter in series at the sample intake end of the system and comparing readings of the system rotameter under various system pressure conditions with those of the calibrated rotameter. Since the verification rotameter operates at ambient pressure, the only correction needed for the calibration procedure are the correction for ambient pressure (relative to standard) and a small correction for temperature (the latter is only necessary for high precision work - the error in assuming a standard conditions of 70°F is less than 5% for the temperature range of 24°F to 116°F which encompasses most plant effluent streams). Existing NRC regulations require the control of radioactive releases from nuclear facilities and require measurements of radioactive materials in effluents. It is implicit in all requirements for effluent monitoring that these measurements be reasonably accurate. Licensees are expected to review their facility's effluent monitoring program to determine the applicability of the information provided in this notice.

Regulatory references: 10 CFR 20.103, 10 CFR 20.106, 10 CFR 20.201, 10 CFR 20.1204, 10 CFR 20.1302, 10 CFR 20.1501

Subject codes: 6.4, 6.9, 7.2, 7.3

Applicability: All

HPPOS-279 PDR-9306140215

Title: Technical Assistance Request Regarding Electronic Calibration of Survey Instruments

See the memorandum from J. E. Glenn to R. R. Bellamy dated October 30, 1991. This memo responds to a technical assistance request by Region I, dated September 16, 1991, regarding a determination of the acceptability of the survey meter calibration protocol proposed by St. Barnabas Medical Center. The proposed protocol would allow the licensee, St. Barnabas Medical Center, to do calibrations of lower ranges on GM instruments with an electronic pulse generator.

The substitution of an electronic pulse generator for radiation from a calibrated radioactive source to calibrate a radiation detection instrument is not acceptable. Use of the electronic pulse generator will properly calibrate the electronics, but will not determine whether the detector is operating properly. The licensee indicated in the TAR that Ludlum Measurements, Inc., used only electronic means for calibrations on the lower scales. Ludlum Measurements, Inc., was contacted to verify this assertion. A Ludlum representative clarified that they first calibrate the electronics with the electronic pulse generator, then reattach the probe and make measurements in a radiation field to find the conversion factor from counts per minute to millirem per hour.

If the licensee determines that due to the fluctuations of background radiation, precise calibration of the lowest scale of the instrument is not possible, the

licensee may choose to label the lowest scale with the most conservative of three methods. The first possibility is to label the lowest scale by the average correction factor obtained from the radiation measurements. The second possibility is to make a graph from which the correction factor may be deduced. The third possibility is to show that the scale was checked for function but not calibrated, or indicate that the scale is not operative. [NOTE: If this scale is necessary to show compliance with NRC's regulations or the licensee's license, then the instrument will be considered out of calibration and in noncompliance.]

Regulatory references: 10 CFR 20.1501, 10 CFR 35.51

Subject codes: 6.4

Applicability: All

HPPOS-280 **PDR-9306150132**

Title: Technical Assistance Request, Clarification of 10 CFR 35.50(b)(1)

See the memorandum from J.E. Glenn to W. E. Cline dated November 12, 1991. This memo responds to a Region II request for clarification of the performance of dose calibrator consistency checks as described in 10 CFR 35.50(b)(1). Specifically, "is it appropriate for a licensee to preform this test on the cobalt-57 (Co-57) setting although technetium-99m (Tc-99m) is the most frequently used isotope?"

Medical licensees are required to perform a dose calibrator daily constancy check. 10 CFR 35.50(b)(1) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use, and that the test be done on a frequently used setting. Based on numerous nuclear medicine inspections in Region II, the most frequently used setting is Tc-99m, and based on the requirements of 10 CFR 35.51(b)(1), the licensees who use Tc-99m more frequently should perform this test on the Tc-99m setting with a dedicated sealed source (which is usually Co-57). However, some licensees perform this test on the Co-57 setting although Tc-99m is the most frequently used setting.

While this issue is not addressed in the Statements of Consideration for either the proposed or final rule on 10 CFR Part 35, effective April 1, 1987, it is believed that the rule is intended to assure that the licensee determines the consistency of the dose calibrator, on each day of use, under the actual conditions of use. Since most medical licensees use Tc-99m for patient dosage administrations more frequently than any other isotope, such licensees must check the Tc-99m setting, on each day of use, with a dedicated check source. If the licensee frequently uses the Tc-99m setting to measure patient dosages but only does a constancy check on the Co-57 setting, it appears appropriate to cite against 10 CFR 35.50(b)(1) unless the licensee can show that the Co-57 setting is frequently used to measure patient dosages.

It is recommended that Co-57 be used as a standard to measure the constancy of the Tc-99m setting because of the close proximity of its energies. Cobalt-57 has principal energies of 122 and 136 keV and Tc-99m has a principal energy of 140 keV. It is also recommended that dose calibrators having pre-calibrated settings or potentiometers be tested on both the Co-57 and Tc-99m settings because discrepancies or fluctuations have been observed between the two settings when tested for constancy with the same check source. If such discrepancies are observed, it could indicate that there is a problem with one or both of the settings. Inspectors should encourage licensees to do a daily constancy check of all commonly used isotope settings, not only Tc-99m to ensure the accuracy of all administered patient dosages.

Regulatory references: 10 CFR 35.50

Subject codes: 6.4, 6.6

Applicability: Byproduct Materials

HPPOS-223 **PDR-9111220129**

Title: Consideration of Measurement Uncertainty When Measuring Radiation Levels Approaching Regulatory Limits

See the memorandum from J. W. N. Hickey and L. J. Cunningham to M. R. Knapp (and others) dated August 3, 1990. The memo states that as with any regulation, limits must be given as exact, precise values. The method of demonstrating compliance with these limits is usually left to the regulated person. Any method that provides a reasonable demonstration of compliance will be accepted.

The NMSS and NRR Offices became aware of a letter transmitting a notice of violation that appeared to send an incorrect message to licensees. The incorrect message was that licensees must consider inherent uncertainties when measuring radiation levels approaching regulatory limits and must establish procedural limits that are less than the regulatory limits by an amount that equals (or exceeds) the "instrument error." That message is incorrect.

The following statement was made by the NRC in response to a petition for rule making with regard to limits for surface radiation levels of packages prepared for transport (44 FR 22233, April 13, 1979): "As with any regulation, the (safety) limits must be given as exact, precise values. The methods of demonstrating compliance with these limits are usually left to the regulated person. Any method which provides a reasonable demonstration of compliance will be accepted. In most cases, exact measured values are not required." This statement is still valid.

All measurements are inherently imprecise and inaccurate to some degree. Inevitably, there will be cases involving transportation of radioactive materials in which a valid measurement by the shipper shows a radiation level below the limit and a valid measurement by the receiver shows a radiation level above the limit. Without evidence that the shipper's measurement is invalid, there is no reason to assume that the shipper's measurement is incorrect and, consequently, that the shipper had inadequate control over shipping of packages.

The NRC position is that the result of a valid measurement obtained by a method that provides a reasonable demonstration of compliance or of noncompliance should be accepted and that the uncertainty inherent in that measured value need not be considered in determining compliance or non-compliance with a regulatory limit. Thus, only the measured value (and not the sum of the measured value and its uncertainty) need be less than the value of the limit to demonstrate compliance with the limit. Conversely, only the measured value (and not the measured value less its uncertainty) need be greater than the value of the limit to demonstrate non-compliance with the limit.

Regulatory references: None

Subject codes: 6.6, 7.1, 12.7

Applicability: All

HPPOS-229 PDR-9111210328

Title: Relaxation of Definition of Source Check in Reference to Effluent Radiation Monitors

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated December 6, 1990. This memo states that any proposal by a licensee to relax the definition of a source check is not acceptable without compensatory measures to maintain overall effluent control for the proposed relaxation.

A licensee had submitted an amendment request to move the existing procedural details of the current Radiological Effluent Technical Specifications (RETS) to the Offsite Dose Calculation Manual (ODCM). The licensee, as well as twenty-two other facilities, used plastic scintillator/photomultiplier type effluent radiation monitors that contained either a built-in LED light source or a secondary check source that did not expose the primary detector. These alternative source check measurements were used to meet the monthly qualitative source check requirement. The definition of "source check" under the Technical Specifications requires that the channel sensor, including the primary radiation detector, be exposed to a radioactive source.

The licensee's amendment request would not change the definition for source check; however, if the amendment were approved, the licensee would be free to relax the definition for source check under its ODCM, provided they met the criteria that "the over-all level of radiological effluent control is not reduced." A violation of this criteria would be a violation of the licensee's Technical Specification.

The NRR staff have adopted the position that any proposal by a licensee to relax the definition of source check, whether through an amendment request or under its ODCM pursuant to Generic Letter 89-01, is not acceptable without the licensee providing compensatory measures for the proposed relaxation. This is necessary because such changes on measurements can reduce the overall effluent control. Therefore, the following conditions must be met:

1. If the detector of concern is used as the primary means of quantifying radionuclides in effluent streams, the licensee must proved justification on why an alternative and technically more accurate measurement (e.g. taking grab samples) is not available. If an alternative measurement is not available, then detector specific and other effluent-related information should be provided either in the ODCM or other means for the staff to evaluate whether the overall effluent control will be reduced.

2. If the scintillator plastic/photomultiplier type detector is used only for detecting radiation that activates the alarm/trip setpoint, relaxation of the current source check definition should be accompanied by a commitment from the licensee to provide compensatory measures to ensure the overall effluent control not be reduced over time and usage. A commitment by the licensee to Cross-check and Document the detector scaler count-rate with the grab sample result (C&D measurement), where practical, in lieu of the monthly source check measurement, would be acceptable. In those situations where the C&D measurement or other comparable measurements are not practical, the use of the LED light source and/or secondary check source measurements would be acceptable.

Regulatory references: 10 CFR 50, Regulatory Guide 1.21, Regulatory Guide 4.15, Technical Specifications

Subject codes: 6.6, 7.3, 12.12

Applicability: Source

HPPOS-171 PDR-9111220193

Title: Lower Technical Specification Limit of Detection for Liquid Effluents

See the memorandum from L. J. Cunningham to W. D. Shafer dated December 7, 1987. Technical Specification requirements on lower limits of detection in effluents apply to the sampling and analysis systems (equipment and procedures), not individual samples.

It was found that a licensee's procedures were designed to detect cesium-134 at the required level in distilled water, not in a normal effluent sample. This did not meet the intent of the licensee Technical Specifications on lower limits of detection for radioactive liquid effluents. Attempts were made to clarify the requirements on lower limits of detection (NUREG/CR-4007) but these are still ambiguous.

The requirements are on the sampling and analysis system (equipment and procedures) rather than requirements for individual samples. Licensees are required to have equipment and procedures that attain the specified lower limit detection under normal conditions. Therefore, an occasional failure of an analysis to achieve the specified lower limit of detection with an actual sample is not a failure to comply. Repeated failures to achieve the specified lower limit of detection, however, are indicative of a system deficiency and do constitute a violation of the Technical Specifications (TS).

To perform the required measurements, licensees must account for the presence of various nuclides in the samples. This may require measures such as increasing the counting time and/or the use of up-to-date software to resolve peaks with similar energies. This is indicated in the TS by requiring the use of "blank samples as appropriate" for determining the background count rate.

Regulatory references: Technical Specifications

Subject codes: 6.8, 7.3

Applicability: Reactors

HPPOS-221 PDR-9111220112

Title: Lower Limit of Detection (LLD) for Potentially Contaminated Oil

See the memorandum from F. J. Congel to D. M. Collins dated January 30, 1985. For cases in which no release of radioactive material is authorized, the appropriate lower limit of detection (LLD) is the "operational state of the art" value used for laboratory measurements of environmental samples. This is the LLD value given in the standard Radiological Effluent Technical Specifications (RETS) for environmental samples. The health physics position was written in the context of 10 CFR 20.302, but it also applies to "new" 10 CFR 20.2002. HPPOS-071 and HPPOS-072 contain related topics.

Region II requested that licensee guidance be developed for acceptable surveys of potentially contaminated oils and referred to IE Circular No. 81-07 (see

HPPOS-071) as espousing the use of operational state-of-the-art measurements for release of materials. However, IE Circular No. 81-07 does not establish criteria for releasing radioactively contaminated materials from restricted areas for unrestricted use (see HPPOS-072).

The regulations applicable to nuclear power reactor licensees do not provide for the release of materials that are known to be radioactively contaminated at any level. Authorization for disposal of specific radioactively contaminated materials may be requested as specified in 10 CFR 20.302 [or 10 CFR 20.2002]. The intent of the above IE circular was to provide guidance on acceptable limits of detection of portable survey equipment, thus defining "how hard you have to look" for the case in which no release of radioactive material is authorized.

When no release of radioactive material is authorized, the appropriate LLD is the "operational state-of-the-art" value used for laboratory measurements of environmental samples. This is the LLD given in the standard RETS for environmental samples (e.g., 15 pCi/L, or 1.5×10^{-8} μCi/ml for Co-58, Co-60 and Cs-134). 49 FR 36653, PRM-20-15 states that the measured radioactivity for major sources of waste oil at BWRs and PWRs are typically 1×10^{-7} to 1×10^{-6} μCi/ml.

For cases in which disposal of radioactively contaminated oil has been authorized by the NRC pursuant to 10 CFR 20.302 [or 10 CFR 20.2002], the necessary LLD need only be sufficiently low to ensure that the particular limits are not exceeded. Therefore, these LLDs may be substantially above the technical specification environmental LLD if the NRC authorized release limits correspond to radioactivity concentrations substantially above these levels. Since the release limits authorized pursuant to 10 CFR 20.302 [or 10 CFR 20.2002] are established on a case-by-case basis, the corresponding LLDs necessary to ensure that the release limits are not exceeded will vary accordingly.

Regulatory references: 10 CFR 20.302, 10 CFR 20.2002

Subject codes: 3.6, 6.8, 7.6, 12.8

Applicability: All

HPPOS-006 **PDR-9111210091**

Title: Particulate Sampling Line Bend Radii

See the memorandum from L. B. Higginbotham to W. L. Fisher dated March 8, 1977, and the incoming request from W. L. Fisher dated January 24, 1977. Stack and vent sampling lines should have a bend radius equal to or greater than five times the diameter of the sampling line.

During a preoperational inspection of Unit 1 at Davis Besse, several right angle bends were observed in an airborne sample line that lead to a particulate monitor. In response to the deviation for failure to comply with FSAR (Section 11.4.2.1) requirements for representative sampling, the licensee stated that the right angle bends had been replaced with bends of radii equal to five times the line diameters. The licensee further stated that the new line configuration was in conformance with ANSI N13.1-1969.

ANSI N13.1-1969 states: "Elbows in sampling lines should be avoided if at all possible, but when they are required, the bend radius of the elbow should be as long as practicable ..." (Section B5). Although the phrase, "as long as practicable" does not appear to be defined further in the narrative portion of ANSI N13.1-1969, Section A3.4 and Figures A2 and A5 appear to give some credence to the selection of R equal to or greater than 5D for sampling probes, where R is the bend radius of the sampling line and D is the diameter of the sampling line. Section A3.4 does, however, contain the caveat that in "some probe configurations ... deposition may be significant ...."

In examining the installation of stack and vent sampling systems, a bend radius equal to or greater than five times the diameter of the sampling line should be accepted. However, an evaluation must be preformed by the licensee to actually demonstrate that representative samples are being collected. Such an evaluation can be done by collecting special samples at the location of the sample probe and correlating the results with those obtained at the "remote" sample collector.

Regulatory references: ANSI N13.1-1969, Final Safety Analysis Report

Subject codes: 6.9, 7.3, 9.1

Applicability: Reactors

2.9 MONITORING AND SURVEYS

HPPOS-010 **PDR-9111210101**

Title: 10 CFR 20.201(b), "Surveys", Final Rule - Effective November 20, 1981.

See the memorandum from R. H. Wessman to R. T. Carlson (and others) dated November 5, 1981, and the enclosure of the notice on final changes to 10 CFR 20.201(b) from the Federal Register (FR 53647-53648, October 30, 1981). The revision to 10 CFR 20.201(b) is enforceable whenever adequate surveys (evaluations) are not preformed, even though failure to perform adequate surveys did not result is a violation of another NRC radiation protection standard. This health physics position also applies to "new" 10 CFR 20.1501(a).

The revised rule on surveys is based on the assumption that such failure to perform adequate surveys has the potential to cause a violation or a violation could have occurred. In the context of the rule, the principal role of performing surveys or making evaluations necessary to comply with regulations is preventive, rather than to determine if a licensee has satisfied other 10 CFR Part 20 requirements.

It needs to be noted that the revised rule not only requires surveys as may be necessary to comply with regulations, but surveys must be performed that are reasonable under the circumstances to evaluate the extent of the potential radiation hazards. Thus, a survey serves as an effective means in preventing both the occurrence of a violation and the development of conditions in which violations could occur (see Supplementary Information in FR 53647).

While the revised rule on surveys was effective on November 30, 1981, most licensees do not subscribe to the Federal Register, nor are they required to subscribe. Therefore, enforcement actions should not be considered until the rule is published in the Rules and Regulations for which licensees are required to have current copies. This is in keeping with past practices.

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501

Subject codes: 7.1, 7.2, 7.6

Applicability: All

HPPOS-138 **PDR-9111210373**

Title: Interpretation of 10 CFR 20.201(b), "Survey Requirements"

See the memorandum from J. Lieberman to P. F. McKee dated October 23, 1986. Surveys are required to comply with 10 CFR 20. Licensees must also make surveys as are reasonable under the circumstances to evaluated radiation hazards that may be present. Citations are permitted against 10 CFR 20.201(b) when no 10 CFR 20 limit or requirement is violated. This health physics position also applies to "new" 10 CFR 20.1501(a).

A memorandum dated October 2, 1986, requested the views of OGC on the meaning of subparagraph (2) of 10 CFR 20.201(b) which states: "Each licensee shall make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." In addressing the issues raised, OGC consulted the Statements of Consideration which accompanied both the proposed rule amending Section 201(b), 45 FR 45302 (July 3, 1980) and the publication of the final rule which added subparagraph (2), 46 FR 53647 (October 30, 1981). The matter was also discussed with the Rulemaking Division of OGC.

Section 20.201(b) originally provided: "Each licensee shall make or cause to be made such surveys as may be necessary for him to comply with the regulations in this part." The proposed rule would have amended this section to read: "Each licensee shall make or cause to be made such surveys as are reasonably called for by circumstances surrounding the use of source, byproduct, or special nuclear material." The Statements of Consideration which accompanied the publication of the proposed rule stated that the regulation was redrafted "to clarify the intent of the survey requirement to assure that licensees are on notice that the requirement is to make appropriate surveys and that the requirement may be violated even if compli-

ance with some other requirement of Part 20 does not result from the failure to survey...." In the final rule, the text of revised Section 20.201(b) differed from that set out in the proposed rule. The existing text of the section was retained, with the addition of subparagraph (2). As indicated in the Statements of Consideration which accompanied the publication of the final rule, this was done in response to a public comment received on the proposed amendment to the section which questioned whether the proposed language eliminated the goal of preventing overexposures. The commentary explained:

"While there is a significant relationship between the survey and other Part 20 requirements in that information obtained through responsible compliance with 20.201(b) may well prove essential in determining whether a licensee has or has not satisfied other Part 20 requirements, this is not the primary function of the survey requirement. The principal role of the survey is preventive. Adequate survey procedures provide measurable protection for the health and safety of the worker and the public because they provide the information necessary for the establishment of adequate protective measures. The usefulness of this early warning system may be seriously reduced if licensees are not held responsible for failure to conduct any survey or for failure to conduct an adequate survey when violations of other Part 20 requirements have not occurred.... The clarifying phrase provides that when a violation of other Part 20 requirements has not occurred, the Commission will consider in determining whether the 20.201 survey requirement has met the reasonableness of the actions taken in the light of all circumstances to evaluate the extent of the radiation hazards."

Nowhere in the Statements of Consideration is the view expressed that the surveys required are only those which relate to or are necessary to comply with the regulations of Part 20. Indeed, the commentary emphasizes that the determination of whether a licensee has or has not satisfied other Part 20 requirements is not the primary function of the survey requirement. Based on the above, OGC concluded that the correct interpretation of 10 CFR 20.201(b) [or 10 CFR 20.1501(a)] is that surveys are required in accordance with specific Part 20 regulations and also are required as is reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. Consequently, citations are permitted against 10 CFR 20.201(b) [or 10 CFR 20.1501(a)] when no other specific Part 20 limit or requirement is violated.

[Note: 10 CFR 20.1501(a) states: "Each licensee shall make or cause to be made, surveys that - (1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate - (i) the extent of radiation levels; (ii) concentrations or quantities of radioactive materials; and (iii) the potential radiological hazards that could be present."]

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501

Subject codes: 7.1, 7.2, 7.6

Applicability: All

HPPOS-255 PDR-9308020142

Title: Airborne Thorium From Welding Rods

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated June 18, 1993. This memo addresses a question from a corporate health physicist at a nuclear utility that had found airborne thorium in a nuclear power plant. Although this regulatory position is presented quite clearly in 10 CFR Part 40, it is being issued as a health physics position to call attention to an exemption that might otherwise be overlooked by Part 50 licensees.

A response was requested as to whether there are any NRC regulatory requirements that apply to airborne thorium caused by grinding the tips and using welding rods containing thorium. The response stated that 10 CFR 40, "Domestic Licensing of Source Material", in subsection 40.13(c)(1)(iii), provides that any person is exempt from the regulations in Part 40 and from requirements for an NRC license to the extent that the person receives, possesses, uses, or transfers any quantities of thorium contained in welding rods. Therefore, there are no NRC regulatory requirements that apply to airborne thorium caused by grinding and using welding rods that contain thorium.

Additional technical information concerning the considerations for the 10 CFR Part 40 exemption for thoriated welding rods does not include any information on the radiological hazards associated with their use. However, some information on the radiation doses associated with the use of these rods can be found in the following references:

1. NUREG/CR-1039, "Estimated Radiation Doses from Thorium and Daughters Contained in Thoriated Welding Electrodes," December 1979.

2. NUREG/CR-1775, "Environmental Assessment of Consumer Products Containing Radioactive Material," October 1980.

3. NCRP Report No. 95, "Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources," 1987.

4. E. M. Crim and T. D. Bradley, Abstracts of Papers Presented at the Thirty-Eighth Meeting of the Health Physics Society, Atlanta, Georgia, 11-15 July, 1993, *Health Physics*, Vol. 64, Supplement 1, p. S85, June 1993.

Reference 2 includes the following summary statement concerning radiation doses:

> The maximum individual fifty-year dose commitment to bone for welders was estimated at between 55 mrem and 2 rem for a one-year exposure. Welders not engaged in welding at home and occasional welders were estimated to receive a bone dose commitment of 16 to 575 mrem and 1.3 to 115 mrem, respectively. A maximum individual bone dose commitment range between 30 and 230 mrem was estimated for non-welders. External doses for all group members were estimated to be less than 1 mrem.

Reference 4 includes the following statement concerning airborne thorium (Th-232) from welding rods:

> The results for the grinding and welding operations to date, show that all personal and area air samples are below the maximum permissible concentration for Th-232 as well as below the derived air concentration.

Regulatory references: 10 CFR 40.13

Subject codes: 7.2, 8.4

Applicability: Reactors

HPPOS-039 PDR-9111210178

Title: Generic Guidance on Preplanned Alternative Method for High Range Noble Gas Monitoring.

See the memorandum from E. L. Jordan to R. A. Scarano dated October 22, 1985. This memo states that preplanned alternate methods of determining noble gas releases as backups to high range noble gas monitors need not be continuous monitors. Local radiation survey instruments or meters on the effluent line are an acceptable preplanned alternate method.

A request was made for generic guidance during a review of the proposed alternative method (PPAM) for determining noble gas releases proposed by Palo Verde Nuclear Generating Station (PVNGS). The PPAM was required by PVNCS Technical Specifications to be used as a backup for the High Range Noble Gas (HRNG) monitors required by NUREG-0737, Item II.F.1. It was Region V's position that a backup to the HRNG monitors must be a continuous monitor with a comparable range. However, based on discussions with cognizant members of NRR's staff, it was found that the PPAM does not necessarily have to be a continuous monitor.

NRR also stated that the current form of the Technical Specifications began with a memorandum from D. G. Eisenhut to T. E. Murley dated October 20, 1980. This memo proposed that provisions for monitoring noble gas in Standard Technical Specifications be relaxed. Prior to this time, the action statement for an inoperable HRNG monitor required a plant shutdown. No technical basis could be found for the shutdown requirements; therefore, the provision for initiating a PPAM was substituted in the action statement. The intent of the revised action statement was to ensure that the licensee devised a feasible method to monitor noble gases as a backup to the HRNG monitors, but not to require redundant HRNG monitors.

Prior to the issuance of NUREG-0737, interim requirements for monitoring high range noble gases were specified in NUREG-0578. During its review of these interim measures, NRR accepted a method of HRNG monitoring if the licensee could demonstrate that it was adequate to characterize the radioactive release without exceeding the dose limits of GDC-19. Many licensees found that the simplest method was to install a local radiation survey instrument or meter on the effluent line. This method was preferable to grab sampling since it is less dose intensive and easier to

shield. For many plants, the interim system installed to meet the requirements of NUREG-0578 now serves as the PPAM. However, taking the position that this is the only acceptable proposal is a significant deviation from the position established by NRR.

Regulatory references: NUREG-0737, Technical Specifications

Subject codes: 7.3, 9.1, 12.16

Applicability: Reactors

HPPOS-170 **PDR-9111220188**

Title: Sampling Drywell Atmosphere Before a Release

See the memorandum from L. J. Cunningham to R. B. Samworth dated November 3, 1988. Sampling drywell atmosphere is required before each and every purging or venting. Furthermore, methodology and parameters in TS referencing the ODCM, should accurately represent the contents of the ODCM.

Region V requested assistance in interpretation of two current Washington Nuclear Plant - Unit 2 (WNP-2) Technical Specifications (TS): TS 3/4.11.2.1, and TS 3/4.11.2.8. Specifically, Region V asked: "Does TS Section 4.11.21 and Table 4.11.2 require a sample of drywell atmosphere be taken and analyzed prior to each vent and/or purge operation through the Standby Gas Treatment (SGT) system?" Region V also asked: "If prior-to-release samples are required, should this be reflected in the ODCM, along with an appropriate decontamination factor to account for SGT cleanup?"

NRR reviewed the Inspection Report documenting the positions of both the inspector and the licensee in regard to the subject question. NRR agreed with the position expressed by the licensee's Corporate Nuclear Safety Review Board (CNSRB) member at the November 27, 1985 meeting of their Plant Operations Committee (POC) recorded on pages 10 and 11 of the Inspection Report. WPN-2 TS 4.11.2.1.2 with its Table 4.11.2 requires that a grab sample be taken prior to each purge and vent from primary containment. TS 4.11.2.8.3 provides additional requirements for the case of purging or venting through other than the SGTS, but says nothing about when the SGTS is used. The applicability of TS 3/4.11.2.1 is "At all times." Therefore, the answer to the first question of Region V is "yes."

In regard to the second question, TS 3/4.11.2.1.2 ties the sampling and analysis program of Table 4.11.2 to dose rate determinations "in accordance with the methodology and parameters in the ODCM." Thus, statements regarding these determinations should be incorporated in the ODCM.

Regulatory references: Technical Specifications

Subject codes: 7.3

Applicability: Reactors (BWR)

HPPOS-004 **PDR-9111210080**

Title: Definition of Waste Gas Storage Tank Radioactivity Limits

See the memorandum from J. S. Bland to J. P. Stohr dated August 28, 1980, and the incoming request from J. P. Stohr dated July 2, 1980. The wording "equivalent Xe-133" and "considered as Xe-133" in Standard Technical Specifications allow the licensee to use area radiation monitoring readings coupled with a calculational method to approximate inventories in waste gas delay tanks (WGDT).

NUREG-0472, "Radiological Effluent Technical Specifications for PWR's," Section 3.11.2.6 limits the amount of radioactivity in each waste gas storage tank to (x) curies of noble gas. Section 3.11.2.6 further states that the activity shall "be considered as Xe-133." However, the document fails to provide a definition of "considered as Xe-133" or provide a definition of how this determination is to be made. There is also inconsistent wording between NUREG-0472 which presents a "considered as Xe-133" limit and the STS Guidance Document (NUREG-0133) which describes the limit as "Xe-133 equivalent."

The wordings "Xe-133 equivalent" and "considered as Xe-133" were included for the purpose of identifying to licensees the applicable use of area radiation monitor readings in determining an approximate tank radioactivity inventory. The intent of the STS requirement was not to require daily isotopic analysis of the WGDT inventories. Instead, the licensee is allowed to use area radiation monitor readings coupled with a calculational method to approximate tank

inventories. Realizing that isotopic distributions change with increased storage times, licensees must demonstrate the applicability of any calculational method employed for this purpose.

In determining the curie limits during licensing, NRR evaluates the expected radionuclide distribution and conservatively establishes a limit such that under accident conditions (decay tank rupture) offsite dose will be less than 0.5 rem. The limit, as presented, is a cumulative sum of the total radionuclide distribution evaluated during licensing. Therefore, considering the inventory limit as a gross activity limit is consistent with the formulation of the "considered as Xe-133" limit and the STS basis which describes the limit as "Xe-133 equivalent."

Regulatory references: Technical Specifications

Subject codes: 7.3, 9.1

Applicability: Reactors

HPPOS-102 **PDR-9111210230**

Title: Meaning of the Expression "Dose Equivalent Xe-133" in the Technical Specifications

See the memorandum from C. A. Willis to D. M. Montgomery dated March 4, 1985. "Dose equivalent Xe-133" means equivalent in ability to deliver gamma-ray doses to the whole body. Either 0.018 Ci of Kr-89 or 18 Ci of Kr-85 is equivalent to 1 Ci of Xe-133.

Historically, the activity inventory limits for waste gas storage tanks have been expressed in curies (Ci) of dose equivalent Xe-133, specifically "curies noble gas (considered as Xe-133)." In the RETS implementation program, it was suggested that this be clarified by adding a definition to the RETS. This suggestion was rejected on the grounds that the intent was manifest from the "basis" statement. The "basis" statement says that this limit is to ensure the release of a tank's contents will not cause a whole body dose to any individual at the exclusion area boundary of more than 0.5 rem. Questions have indicated that further clarification may be appropriate.

The intent of the LCO is to ensure that the inadvertent release of the contents of a waste storage tank does not cause a gamma-ray dose to the whole body of over 0.5 rem offsite. Thus, the LCO whole body was given in terms of Xe-133 equivalent curies to facilitate implementation. That is, the licensee need never determine the actual radioactivity contents of a tank; instead it may simply determine the dose rate from gamma rays and convert to equivalent curies of Xe-133 based on a calibration with Xe-133.

This approach seems more accurate than the alternative. The alternative is to determine the quantity present of each nuclide and calculate the potential gamma-ray dose to the whole body using the various dose conversion factors.

The problem is more difficult if the detector responds to beta-particles. The dose rate from beta particles is not the quantity of interest and so cannot be used directly. It is necessary to determine the nuclide composition of the gas and relate this to the total activity. The quantities of the various nuclides can be converted to Xe-133 equivalent curies using the dose conversion factors (DFB_i) of Regulatory Guide 1.109, the values for gamma radiation of DOE/TIC-11026, the energy specific values for gamma rays from the "Table of Isotopes" (7th Edition), or other convenient reference. The slight differences in results obtained with the different references is unimportant. Where this approach is used the "dose equivalent Xe-133" concept offers no practical advantages; it is simply another way of saying "potential for delivering a gamma-ray dose to the whole body."

If the inventory is determined by sampling and isotopic measurement by gamma-ray spectrometry, the problem is much the same as with the beta-particle measurements, and involves the weighting by various dose-conversion factors.

Regulatory references: Technical Specifications

Subject codes: 7.3, 9.1

Applicability: Reactors

HPPOS-008 **PDR-9111210096**

Title: Response to Questions Concerning Enforcement of 40 CFR 190, "EPA Uranium Fuel Cycle Standard"

See the memorandum from L. B. Higginbotham to A. F. Gibson dated July 29, 1981, and the incoming request from A. F. Gibson dated May 13, 1981.

Enclosures to these memos include: (1) a NRR letter to All Power Reactor Licensees dated September 17, 1979, and (2) a copy of the Radioactive Effluent Technical Specifications (RETS) 3.11.4. A licensee's commitment to the Radiological Effluent Technical Specifications (RETS) 3.11.4 is acceptable to demonstrate compliance with the EPA Uranium Fuel Cycle Standard, 40 CFR 190.

In a letter dated September 17, 1979, all power reactor licensees were informed of the requirement to comply with 40 CFR 190 as of December 1, 1979. This letter also stated that a licensee commitment to RETS 3.11.4 would be an acceptable method of demonstrating compliance. Licensees were requested to submit that commitment, or an alternative method of compliance. Inspection for compliance with 40 CFR 190 should be made against those commitments for licensees who do not have Technical Specifications covering compliance with 40 CFR 190.

Responses to specific questions concerning inspection for compliance with 10 CFR 40 were as follows:

1. Qualitative guidance on acceptable calculation methods is provided in NUREG-0543, "Methods for Demonstrating LWR Compliance With the EPA Uranium Fuel Cycle Standard (40 CFR 190)," (February 1980). Since there are no special 40 CFR 190 monitoring requirements, no guidance is needed on this subject.

2. No letters or orders will be sent revoking the existing effluent limits. Licensees must comply with 40 CFR 199 in addition to any other "existing limits."

3. Compliance with 40 CFR 190 is not based on calendar quarters. As stated in Section 3.11.4 of the RETS, the 40 CFR 190 annual limits apply to any twelve consecutive months.

4. Licensees are not expected to have difficulty in complying with 40 CFR 190. Proposed enforcement actions for licensees who cannot demonstrate compliance with 40 CFR 190 should be coordinated with the HQ staff. As indicated in RETS 3.11.4, a licensee whose estimates of doses exceeds the 40 CFR 190 limits, from a condition that has not already been corrected, should request a variance in accordance with the provisions of 40 CFR 190, at the time the Special Report on exceeding the 40 CFR 190 limits is submitted. A variance will be granted until staff action on the request is completed by NRR.

5. No additional monitoring equipment is required, and no "grace period" is needed for procurement or installation of such equipment.

6. The use of Regulatory Guides 1.109-1.113 may result in calculated doses that are too conservative for determining compliance with 40 CFR 190. See NUREG-0543 for a discussion of this point.

Regulatory references: 40 CFR 190, Technical Specifications

Subject codes: 7.3, 9.0, 12.12

Applicability: Reactors

HPPOS-212 **PDR-9111220007**

Title: ... Dissolved Noble Gases in Liquid Effluents and Compliance With Technical Specifications 3.11.1

See the memorandum from L. J. Cunningham to F. J. Hebdon (and others) dated July 12, 1987. The TS limit for dissolved or entrained noble gases in liquids is 200 picocurie/ml total activity. This limit is independent of other nuclides. There is no need to include noble gases in the MPC summation formula in Note 1 of Appendix B to 10 CFR Part 20 (§§20.1-20.601). The health physics position was written in the context of 10 CFR 20.106, but it also applies to Section 20.1302 and Appendix B, Note 4, of the "new" 10 CFR Part 20 (§§20.1001-20.2401).

Standard Technical Specification 3.11.1 states: "The concentration of radioactive material released in liquid effluents to UNRESTRICTED AREAS ... shall be limited to the concentrations specified in 10 CFR Part 20, Appendix B, Table II, Column 2 for radionuclides other than dissolved or entrained noble gases. For dissolved or entrained noble gases, the concentration shall be limited to 200 picocurie/ml total activity."

In response to an inquiry from a licensee, RPB said that the staff does not consider Part 20, Appendix B to give limits for noble gases in water. Specifically, the footnotes addressing "nuclides not listed above" do not apply to the noble gases because the noble gases are listed.

RPB also said that the technical specification limit for noble gases is independent of the concentrations of other nuclides. That is, the LCO is satisfied if noble

gas concentration does not exceed 200 picocurie/ml and the concentrations of other nuclides do not add up to more than one MPC equivalent using Note 1 to Appendix B to 10 CFR Part 20 (§§20.1-20.601) [or one DAC equivalent using Note 4 to Appendix B of 10 CFR Part 20 (§§20.2001-20.24010]. Hence, there is no need to include the noble gases in the Part 20 summation formula [i.e., the DAC summation formula in Note 4 of Appendix B to §§20.1001-20.2401].

Regulatory references: 10 CFR 20.106, [10 CFR 20.1302,] Technical Specifications

Subject codes: 7.3, 9.2

Applicability: Reactors

HPPOS-122 PDR-9111210281

Title: Clarification of Regulatory Guide 1.21, Section C.10, "Sensitivity"

See the memorandum from L. K. Cohen to J. T. Sutherland dated October 5, 1977. It clarifies the provision in Regulatory Guide (RG) 1.21 that allows determination of concentrations of certain radionuclides based on measurements of other radionuclides and predetermined ratios.

Provided below are answers to specific questions raised on Section C.10 of RG 1.21 which states: "... it may be more appropriate to calculate releases of such radionuclides to those radionuclides which are routinely identified and measured. Measurements should be made periodically to establish and assure the continued validity of the ratios used. Any reported data determined by this method should be clearly identified."

1. Should the nuclides to be considered include all 10 CFR 20 Table II nuclides?

No. This statement was inserted in RG 1.21 to cover situations during routine analyses, where a particular radionuclide or radionuclides predominated a mixture or had a gamma energy spectrum which interfered with other gamma energies. Under these circumstances, it would be difficult to measure certain radionuclides which are known to be present from more detailed extensive analyses. The techniques depends upon having a data base of detailed, thorough analyses, perhaps performed with better sensitivity and resolution. For example, periodically, the licensee should make a long measurement on a sample with GeLi system. Information from these analyses would be then used to generate ratios and calculate other radionuclides unresolved in the NaI spectrum.

2. Should the nuclides to be ratio'd be based upon the isotopic inventory of a composite batch (weekly, monthly, quarterly, yearly) or single batch (preceding batch, or reference batch to be selected by licensee)?

The makeup of the composite to determine ratios depend upon the variability of the isotope mixture and ratios observed in the past data. If the mixture is stable, then quarterly composited samples may be sufficient, if not, then more extensive sampling and analyses may be necessary.

3. If a reference batch, selected by the licensee, is acceptable - what documentation requirements are necessary?

The licensee must provide documentation to demonstrate that the batch is representative of the effluent streams being analyzed. The licensee must also provide and document a series of analyses over a reasonable length of time to demonstrate the stability of the isotopic mixture.

4. Where should the ratio based sample be obtained (primary coolant, secondary systems)?

The sample should be collected from an effluent stream that assures a representative sample. It is meaningless to calculate ratios from isotopic mixtures of the primary coolant for determining airborne effluents.

Regulatory references: Regulatory Guide 1.21

Subject codes: 7.3, 10.1

Applicability: Reactors

HPPOS-007 PDR-9111210092

Title: Monitoring of Radioactive Release Via Storm Drains

See the memorandum from W. J. Dircks to Commissioner Bradford dated August 28, 1981. This memo states that a blanket requirement for monitoring storm drains (yard drains) from every power

reactor is unwarranted from a safety standpoint. The information was also provided to J. H. Joyner (and others) by L. J. Cunningham in the form of a memorandum dated September 10, 1981.

Based on an unmonitored release of radioactive water on July 30, 1981, at the Northern States Power Company's Monticello Plant and similar occurrences at Millstone, Unit 1 (June 21, 1981) and at the Japanese Tsuruga plant, it was asked if there were technical reasons for not continuously monitoring storm drains for radioactivity.

In the Monticello Plant incident, an unreviewed and improper action by a plant engineer resulted in radioactive water being used in the cement solidification of radioactive wastes at a newly-installed portable solidification system located in the radwaste shipping building. The building was not designed for this purpose and did not have floor drains or curbs to prevent spilled water from escaping. The incident occurred when the responsible engineer improperly and inadvertently used slightly radioactive water from the reactor's condensate storage tank by connecting a rubber hose secured by a hose clamp to the piping of the concrete mixing system. The hose came loose and an estimated 2,000 gallons of radioactive water spilled onto the concrete floor of the radwaste storage building. The water ran down the sloping floor, under two closed overhead garage-type doors, and into the storm drain system.

An estimated 100 gallons of water, contaminated with 4.5×10^{-7} μCi/ml I-131 and 1.4×10^{-6} μCi/ml I-133, entered the Mississippi River at the storm drain outfall. At the point of release, the isotope concentrations were approximately 300% of the "maximum permissible concentration" described in 10 CFR 20 (§§20.1-20.601), Appendix B, Table II, Column 2, but dilution and dispersion by the Mississippi River was assumed to have resulted in essentially instantaneous reduction to non-detectable concentrations with essentially zero environmental radiation-dose impact. The remainder of the water entered the soil or was trapped in the storm drain ditches.

NRR replied that no insurmountable technical reasons existed with regard to the monitoring of storm drains for radioactivity. However, practical difficulties in the automatic sampling or extraction of material for radioactivity analysis, as well as practical problems of volumetric measurements from the highly variable stream flow rates would need to be resolved if the total release were to be determined. In addition, if it is assumed that each nuclear power plant is serviced by a single storm drain system (also called yard drains), the initial cost of the installation of monitoring equipment per plant would be approximately 200 to 500 thousand dollars and that the annual operation and maintenance costs would be 20 to 50 thousand dollars.

Because of the difficulties in monitoring radioactive discharge into storm sewer drains, the associated costs for installation and operation, the general knowledge of past experiences with this particular type of unmonitored release from reactor operations, and the small potential effect on public health, it was the opinion of the EDO that requirements for monitoring storm sewer drains were unwarranted.

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501, Technical Specifications

Subject codes: 7.3, 7.4, 9.2

Applicability: Reactors

HPPOS-009 **PDR-9111210097**

Title: Request for NRR Follow-Up on Environmental Samples with Levels Greater Than FES Estimates

See the memorandum from L. B. Higginbotham to J. Sutherland dated April 15, 1976. The memo states that the concentrations of radioactive materials in environmental samples higher than those estimated in the Final Environmental Statement are not, by themselves, cause for concern.

An "Evaluation of the Results of Oconee Environmental Survey" was forwarded to NRR. Concern was expressed over what significance should be placed on observed environmental radioactive levels found to be greater than the estimated levels in the Final Environmental Statement (FES). The submitted evaluation stated that the concentrations of radioactivity detected by the South Carolina Department of Health in environmental samples were well below the South Carolina drinking water standards and the inspection of Oconee's liquid radwaste control program did not identify any noncompliance with the Technical Specifications. The doses to the public calculated using NRC models by Duke Power Company were below the numerical guides of 10 CFR 50, Appendix I.

NRR stated that the values of anticipated annual releases of radioactive material in liquid effluents and the corresponding anticipated concentrations in the tailrace as presented in the Oconee FES were exactly what they were claimed to be - anticipated or estimated values. FES values are estimates of long-term averages for the 40 year life of the plant and these estimates may vary from the observed value for any specific year. In this situation, regulatory limits were not exceeded; there was no information that was previously unknown to NRR; and there was no information contrary to that assumed by NRR in its issuance of the license. Therefore, based on this criteria, the significance of levels in the environment greater than estimated levels in the FES is minimal and that concentrations of radioactive materials in environmental samples higher than those estimated in the FES are not, by themselves, cause for concern.

The regional response to such incidences should be to provide the SEP Branch with a brief summary of the findings and these will be forwarded to Licensing for information. The Regional response need not involve an evaluation of the data nor a modification of the inspection schedule to inspect the subject area.

Regulatory references: Technical Specifications, Final Environmental Statement

Subject codes: 7.4

Applicability: Reactors

HPPOS-071 **PDR-9111210163**

Title: Control of Radioactively Contaminated Material

See IE Circular No. 81-07 entitled as above and dated May 14, 1981. This document specifies that the monitoring of items and materials removed from a restricted area should be done with instruments and techniques capable of detecting 5000 dpm/100 cm^2 total and 1000 dpm/100 cm^2 removable beta/gamma contamination.

IE Information Notice No. 80-22 described events at nuclear power reactor facilities regarding the release of radioactive contamination to unrestricted areas by trash disposal and the sale of scrap material. These releases were caused by a breakdown in the contamination control program including inadequate survey techniques, untrained personnel performing surveys, and inappropriate material release limits.

The recurring problems associated with minute levels of contamination indicated that specific guidance was needed by NRC nuclear power reactor licensees for evaluating potential radioactive contamination and determining appropriate methods of control. Thus, IE Circular No. 81-07 provides guidance on the control of radioactive contamination. Because of the limitations of the technical analysis supporting this guidance, it is only applicable to nuclear power reactor facilities.

Contaminated or radioactive items and materials must be controlled, contained, handled, used, and transferred in accordance with applicable regulations. Items and materials should not be removed from restricted areas until they have been surveyed or evaluated for radioactive contamination by a qualified individual. (A qualified individual is defined as a person meeting the radiation protection technician qualifications of RG 1.8, Rev. 1.) The only exceptions are hand-carried personal effects (e.g., notebooks and flashlights) that are subject to the same survey requirements as the individual possessing them.

Contamination monitoring with portable survey instruments or laboratory measurements should be performed with instruments and techniques (survey scanning speed, counting times, background radiation levels) that are capable of detecting 5000 dpm/100 cm^2 total and 1000 dpm/100 cm^2 removable beta/gamma contamination. Instruments should be calibrated with radiation sources that have energy spectrum and instrument response characteristics consistent with the radionuclides being measured. If alpha contamination is suspected, appropriate surveys and/or laboratory measurements capable of detecting 100 dpm/100 cm^2 fixed and 20 dpm/100 cm^2 removable alpha activity should be performed.

In evaluating the radioactivity of inaccessible surfaces (e.g., pipes, drain lines, etc.), measurements at accessible points may be used. However, this method can be used only if the contamination at accessible points is representative of contamination at inaccessible locations. If this can not be demonstrated, the items should not be released for unrestricted use.

Draft ANSI Standard 13.12 provides useful guidance for evaluating radioactive contamination and should be considered when establishing a contamination control and radiation survey program. [Draft ANSI Standard

13.12 was never issued in final form and it is no longer considered to be a source of useful guidance.]

Regulatory references: 10 CFR 20.201, 10 CFR 20.301, 10 CFR 20.1501, 10 CFR 20.2001

Subject codes: 7.6, 9.7

Applicability: Reactors

HPPOS-072 **PDR-9111210170**

Title: Guide on "How Hard You Have to Look" as Part of Radioactive Contamination Control Program

See the letter from R. C. DeYoung to E. D. Swartz (Commonwealth Edison Company) dated May 18, 1982. The intent of IE Circular No. 81-07 (IEC-81-07) was to give guidance on "how hard you have to look" for radioactivity when the use of portable survey equipment is necessary as part of a radioactive materials control program. The detection limits in IE Circular No. 81-07 (IEC-81-07) are not release limits. The health physics position was written in the context of 10 CFR 20.201, 20.301, and 20.302, but it also applies to the "new" 10 CFR Part 20, Sections 20.1501, 20.2001, and 20.2002. HPPOS-071 and HPPOS-73 contain related topics.

The intent of IEC-81-07 (see HPPOS-071) was to provide guidance on acceptable limits of detection of portable survey equipment; thus, defining "how hard you have to look" for radioactivity when the use of portable survey equipment is necessitated as part of a radioactive materials control program. Low background, fixed laboratory counting equipment can readily detect levels of radioactivity several orders of magnitude less than the detection levels discussed in the circular. However, the use of laboratory counting equipment is not always practical for all situations and portable survey equipment may need to be employed.

The circular did not establish criteria for releasing radioactivity contaminated materials from restricted areas for unrestricted use. The regulations applicable to nuclear power reactor licensees do not provide for release of materials for unrestricted use that are known to be radioactively contaminated at any level. Authorization for disposal of specific radioactively contaminated materials may be requested as specified in 10 CFR 20.302 [or 10 CFR 20.2002]. The Commission recognizes the need for "de minimis" classification of wastes and has initiated work to define "de minimis" levels on a specific waste basis. This work is continuing. [Note: The statement concerning "de minimis" classification of wastes is related to the below regulatory concern (BRC) policy, which has now been withdrawn.]

With regards to your request for concurrence with release criteria in your "Radiation Protection Standards," we cannot concur since the regulations do not contain release criteria provisions as described above. The method available to you for obtaining authorized release limits is to submit to the Office of Nuclear Reactor Regulation (NRR) a request for license amendment that addresses specific release limits. Although we have sent a copy of your letter to NRR for information, the excerpt you provided from your "Radiation Protection Standards" lacks specifics which would support a request for specific release limits for radioactively contaminated materials.

If you desire a specific authorization for disposal or a license amendment for specific release limits, please direct your request to the Office of Nuclear Reactor Regulation.

Regulatory references: 10 CFR 20.201, 10 CFR 20.301, 10 CFR 20.302, 10 CFR 20.1501, 10 CFR 20.2001, 10 CFR 20.2002

Subject codes: 7.6, 9.7

Applicability: Reactors

HPPOS-073 **PDR-9111210176**

Title: Surveys of Wastes from Nuclear Reactor Facilities Before Disposal

See IE Information Notice 85-92 entitled as above and dated December 2, 1985. This document supplements IE Circular 81-07 (IEC-81-07) as it applies to surveys of solid wastes before disposal from nuclear reactor facilities. It also discusses typical surveys that could be made to preclude unintentional release of radioactive materials. The health physics position was written in the context of 10 CFR 20.201 and 20.301, but it also applies to the "new" 10 CFR Part 20, Sections 20.1501 and 20.2001. HPPOS-071 and HPPOS-072 contain related topics.

IEC-81-07 was issued by NRC in 1981 (see HPPOS-071) and provided guidance on the control of radioactively contaminated material and identified the extent licensees should survey for contamination (see HPPOS-072). The criteria in IEC-81-07 addressed surface contamination levels based on the best information available at the time and were related to the detection capability of portable survey instruments equipped with thin-window "pancake" Geiger-Mueller (GM) probes responding primarily to beta radiation. The monitoring of aggregated, packaged material was not addressed. There was no major emphasis on segregating waste from designated contamination areas in 1981. As a result, large volumes of monitored wastes were not being released for unrestricted disposal. However, because of the recent emphasis on minimizing the volume of radioactive waste, current practices at many nuclear power facilities results in large volumes of segregated, monitored wastes with large total surface areas being released as "clean" waste.

When scanning surfaces with hand-held pancake probes, there is a chance that some contamination will not be detected or the total surface area will not be completely scanned. [See papers by J. F. Sommers, "Sensitivity of Portable Beta-Gamma Survey Instruments," Nuclear Safety 16(4), pp. 452-457 (1975), and "Sensitivity of GM and Ion-Chamber Beta-Gamma Survey Instruments," Health Physics 28(6), pp. 775-761 (1975).] Thus, when numerous items of "clean" material are combined, the accumulation of small amounts of contamination that escaped pancake probe detection may be detected using detectors sensitive to gamma radiation (e.g., by using a sensitive scintillation detector in a low-background area). Such measurements of packaged clean waste before disposal can reduce the likelihood that contaminated waste will be disposed of as clean waste.

To avoid the unintentional release of radioactive materials from nuclear reactor facilities, a good monitoring program that includes the following is recommended.

1. Surveys made with methods for detecting very low levels of radioactivity to discriminate between materials that are contaminated and those that can be disposed of as clean waste. The survey methods should provide licensees with reasonable assurance that licensed material is not released from their control.

2. Surveys using portable survey instruments with small pancake GM probes should be done only on small items and small areas. Because these instruments and probes lose detection sensitivity when moved and because of the difficulties in completely scanning large areas, this method of survey should be supplemented with other techniques for larger items.

3. Final measurements on each package of aggregated wastes should be done to ensure that an accumulation of licensed material resulting from the buildup of multiple, nondetectable quantities has not occurred (e.g., final measurements using sensitive scintillation detectors in low-background areas).

Regulatory references: 10 CFR 20.201, 10 CFR 20.301, 10 CFR 20.1501, 10 CFR 20.2001

Subject codes: 7.1, 7.6, 9.7

Applicability: Reactors

HPPOS-250 **PDR-9206260127**

Title: Monitoring at Nuclear Power Plants for Contamination by Radionuclides that Decay by Electron Capture

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated May 28, 1992. The memorandum contains an enclosure with three attachments providing information concerning monitoring contamination from electron-capture emitters. HPPOS-071 contains a related topic.

Information provided by the NRC Regions did not suggest a generic health and safety problem with monitoring electron-capture emitters among nuclear power plants, but did indicate a wide range in contaminating activity. Many licensees recognized that conventional detectors used in hand frisking for beta-emitter contamination, particularly "pancake" GM detectors, have a low counting efficiency for x-rays and gamma rays emitted by electron-capture nuclides. Some licensees have or were considering obtaining more efficient detectors (such as proportional counters filled with argon-methane) for monitoring electron-capture nuclides. However, some licensees appeared to be making improper applications of the numerical criteria in IE Circular 81-07 (see HPPOS-071) to monitoring for electron-capture nuclides and to automated personnel contamination monitors. There-

fore, the enclosure to the memorandum includes the following discussion of previous NRC guidance on monitoring for contamination at nuclear power plants.

IE Circular 81-07 (IEC-81-07) provides guidance on monitoring for surface contamination by "beta-gamma" and alpha emitters. As indicated in that circular an in IE Information Notice 85-92, the numerical criteria included in that circular (e.g., a detection capability of 5000 dpm/100 cm^2 for total "beta-gamma" contamination) are based on considerations of hand frisking with portable survey instruments equipped with thin-window (relatively small area) "pancake" GM detectors that respond primarily to beta radiation and that are relatively insensitive to x-rays and gamma rays. Thus, the numerical criteria were not intended for, and are not appropriate for, surveys for contamination by radionuclides (or mixtures of radionuclides) that emit photons but that emit little or no beta radiation. The staff does not plan to develop new criteria for detection of photons, whether x-rays or gamma rays, in contamination surveys. The qualitative guidance in Circular 81-07 and Information Notice 85-92 is applicable to all surveys for contamination of materials before release to unrestricted areas. However, the guidance in Circular 81-07 and Information Notice 85-92, for the detection of contamination of materials, is not intended to be applied to automated personnel contamination monitors used for detection of contamination of workers. The numerical criteria of IE-81-07, which are expressed in terms of activity per unit area, are not applicable to measurements of the total activity of the contamination on materials or workers.

The NRC, as noted in "NRC Staff Perspective" included with the enclosures, is concerned with the potential for unauthorized release of detectable contamination from licensed material. Licensees should be aware of changes in contamination detection capabilities resulting from changes in radionuclide composition.

Regulatory references: 10 CFR 20.1501

Subject codes: 6.1, 6.3, 7.6, 7.7, 8.3, 8.4, 9.7

Applicability: Reactors

HPPOS-149 **PDR-9111220081**

Title: Allowable Contamination Limit for Thorium-natural

See the memorandum written for files by R. G. Page and dated August 27, 1982. This memo concerned a telephone conversation with Mark Whittaker of Chem. Nuclear, Inc. The memorandum states that the allowable contamination limit in the Guidelines for Decontamination of Facilities for Unrestricted Use or Termination of Licenses for Byproduct, Source or Special Nuclear Material for "thorium-nat" is the total radioactivity present from thorium radionuclides plus all daughters.

Regulatory references: 10 CFR 30.3, 10 CFR 40.3, 10 CFR 70.3

Subject codes: 3.6, 5.0, 7.6, 12.4

Applicability: Source Material

HPPOS-183 **PDR-9111210288**

Title: Decontamination Limits for Americium-241

See the memorandum from R. E. Cunningham to H. D. Thornburg dated September 15, 1981. This memo provides appropriate surface and soil decontamination limits for Am-241. Based on the total dose from inhalation and ingestion, the soil concentration limit for Am-241 is calculated to be 30 picocuries per gram (pCi/g) in order not to exceed the 3 millirad per year recommended by the EPA.

Acceptable surface contamination levels for Am-241 are specified in "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material." The maximum and average levels of fixed Am-241 contamination permitted on surfaces released for unrestricted use is 300 and 100 disintegration per minute per 100 square centimeters (dpm/100 cm^2), respectively. Removable contamination should not exceed 20 dpm/100 cm^2.

With respect to soil decontamination limits, the EPA recommended on November 30, 1977, radiation dose guidelines for transuranium elements such that no individual will receive a radiation dose in excess of 1 millirad per year to the lung and 3 millirad per year

to the bone from exposure to the contaminated soil (42 FR 60956-60959). In this case, the solubility classification of Am-241 is a W compound (see ICRP Publication 30) and its existence in soil will contribute to the inhalation and ingestion pathways through resuspension of soil in air and uptake from plants. The critical organ is the bone. Based on the total dose from inhalation and ingestion, the soil concentration limit for Am-241 is calculated to be 30 pCi/g in order not to exceed the 3 millirad per year limit.

Regulatory references: None

Subject codes: 3.6, 7.6, 8.4, 12.4

Applicability: All

2.10 OCCUPATIONAL EXPOSURE AND DOSE

HPPOS-186 **PDR-9111210292**

Title: Determination of Radiation Exposure from Dosimeters

See the memorandum from W. P. Ellis to G. L. Snyder (and others) dated March 25, 1977. When both a direct reading dosimeter (DRD) and a film or TLD badge are worn, the film or TLD reading is normally considered the dose of record. If a film or TLD badge is exposed when not worn, it may be appropriate to use a DRD reading.

The purpose of the badge dosimeter is to measure the radiation dose received by the individual who wears it. For example, if a badge dosimeter shows a reading of 3.5 rem for a month or quarter, the nuclear industry and NRC have historically accepted this as proof that the individual received a radiation dose of 3.5 rem if one cannot show that the exposure to the badge most likely occurred when the employee was not wearing it.

Although all facts surrounding an overexposure should be established, the inspector does not need to establish additional proof that a radiation exposure occurred. However, if there is cause to believe that the individual was not exposed, it is incumbent on the licensee to demonstrate or provide evidence that the exposure to the badge dosimeter did not constitute a valid exposure to its user. NRC does not take the position that badge readings are not accepted as valid exposures of personnel if there is not other positive proof to support the finding; rather, in the interest of safety, we must accept the badge readings as valid radiation exposures of personnel unless the licensee can provide reasonable evidence to the contrary.

A second point of concern is the consideration of DRD values versus the film or TLD badge in establishing an individual's radiation dose. Generally, the DRD has not been accepted by the nuclear industry or NRC as the dosimeter of record. It is true that on some occasions when a film or TLD badge was inadvertently exposed while not used by the designated user, the DRD has been used as the best evidence of the individual's exposure. However, there are too many variables involved to use the DRD in lieu of the film or TLD badge. Therefore, the DRD is considered

to be a control device (i.e., only an indicator of the estimated dose). The DRD as a general rule is highly energy dependent. Many such dosimeters are made of metal or other materials with high atomic numbers which absorb many of the low energy photons. Consequently, we find that the film or TLD readings are higher than the DRD for the same exposure to multi-energy photons. The DRD may show a lower radiation exposure than the film or TLD because of the error in numerous readings at the start and end of each work period. On the other hand, the exposures estimated from DRDs could also establish error on the high side, dosimeters can drift or discharge when bumped and are not considered reliable even to the extent of their limited ranges. When exposure data is collected for an individual by both DRD and either film or TLD badge, the dose as determined from the film or TLD should be accepted as the individual's exposure of record.

Often a licensee will explain that the DRD readings were 2.5 rem (at the control point) and the film or TLD readings was 3.3 rem or some similar value. The latter reading is the most representative of the individual's exposure to radiation if all other factors are equal. This is frequently the source of failure to make adequate survey or evaluation of the radiation levels which results in exposure to individuals in excess of the regulatory limits. We cannot accept the licensee's explanation of error in calculations of the estimated dose from DRDs as reasons to forgive failure to make proper evaluations of such potential exposures.

Finally, questions concerning exposures that resulted from licensed byproduct material and other unlicensed sources of ionizing radiation such as x-ray or radium were answered. If any part of an individual's exposure results from licensed byproduct materials, the NRC has jurisdiction for taking enforcement actions for the total exposure. If an individual were to receive 3 rem from x rays and 0.3 rem from gamma rays emitted by cobalt-60 for a total of 3.3 rem in a single quarter, the NRC would issue a citation for a radiation dose of 3.3 rems and indicate that it exceeds the permissible quarterly limit.

[Note: The "new" 10 CFR Part 20 does not have quarterly or other limits covering periods of less than a year. In order to maintain compatibility with ICRP recommendations for dose limitation, the quarterly limit has not been kept and only annual dose limits are stated in 10 CFR 20.1201(a). The annual limit for the whole body is 5 rem (0.05 Sv). If an individual were to receive a "deep-dose equivalent" of 5 rem from x rays and 0.3 rem from gamma rays emitted by cobalt-60 for a total of 5.3 rem in a calendar year, the NRC would issue a citation for a dose equivalent to the whole body of 5.3 rems and indicate that it exceeds the permissible annual limit.]

Regulatory references: 10 CFR 20.101, 10 CFR 20.201, 10 CFR 20.1201, 10 CFR 20.1501

Subject codes: 8.1, 8.3

Applicability: All

HPPOS-273 PDR-9306100107

Title: Technical Assistance Request, Evaluation of Comments on NRC Information Notice for Ophthalmic Applicators (NRC IN 90-59)

See the memorandum from J. E. Glenn to D. M. Collins dated February 20, 1992. As requested in a Region II memorandum from William Cline to J. E. Glenn, dated March 13, 1991 (Enclosure 1), the staff has reviewed the comments presented by the Navy Radiation Safety Committee (Enclosure 2) concerning NRC Information Notice 90-58, "Improper Handling of Ophthalmic Strontium-90 Beta Radiation Applicators" (Enclosure 3). The following comments were offered in response to the Navy Radiation Safety Committee's concerns as denoted by NRC Region II (Enclosure 1).

Comment 2a: Issue of holding the eye open with tape during the procedure.

NRC consultants tell us that tape is not an optimal means of securing a patient's eyelid. The current medical practice calls for the use of eyelid retractors. In order to prevent Bremsstrahlung radiation, retractors made of low atomic weight materials are preferred.

Comment 2b: Number of treatments per year versus use of fingertips.

The number of treatments stated in case 2 was used as an example and should not become the focus of the illustration. The case emphasizes that a physician using his/her fingers to secure the eyelid while administering the treatment is improper procedure.

Regardless of the number of treatment applications, attention surrounding the illustration should be directed towards ALARA guidelines and the use of passive restraints such as eyelid retractors to immobilize the eyelid.

Comment 2c: Interpretation of "extremity" limits.

Contrary to the Navy's criticism, contact with the source tip of the applicator could indeed result in a radiation dose in excess of NRC limits. We do not agree with the concept that exposure with the Sr-90 eye applicator source is tantamount to "hot particle" exposure because of differences in geometry and dosimetry. In particular, the area irradiated by a "hot particle" is substantially less than one square centimeter, whereas the area irradiated by a strontium-90 (Sr-90) eye applicator is greater than one square centimeter. As defined in 10 CFR 20.1003, the shallow-dose equivalent for skin or extremities applies to tissue at a depth of 0.007 centimeters averaged over an area of one square centimeter. Therefore this criteria applies to Sr-90 eye applicators.

Comment 2d: Rules requiring personnel monitors.

The requirements for personal dosimeters discussed in the information notice are in keeping with minimally accepted ALARA guidelines.

The Navy's data indicates that their exposures do not approach 10 CFR Part 20 minimum requirements for personnel monitoring devices. However, it would be prudent health physics practice to wear personal dosimeters because of unanticipated exposures as well as planned exposures. Once an individual has demonstrated sufficient knowledge and skill using an applicator, exceptions might be considered.

If a licensee can clearly demonstrate that (1) the radioactive material used is limited to the Sr-90 eye applicator and (2) the resulting exposures did not reach the limits set forth in 20.202 or 20.1502(a), NRC would consider licensee procedures without requirements for the use of personal dosimeter devices on a case-by-case basis.

Comment 2e: Sterilizing agents.

Further review of the sterilization processes revealed that the typical manufacturer's directions for sterilizing the device are inconsistent with the Centers for Disease Control's (CDC) recommendations. While this may be an important point, the information provided in Item 1 of the typical manufacturer's instructions was designed to call the licensee's attention to the need for sterilization of the Sr-90 eye applicators. The manufacturers may ultimately modify their sterilization procedures to coincide with those of the CDC.

Comments 2f and 2g: Corrosion and Calibration.

The information of concern in comments 2f and 2g was not discussed in NRC IN 90-58. We are currently planning to develop an information notice covering both the calibration and possible corrosion of the device.

Comment 2h: Seventy years of use without an incident.

The three uses cited in the information notice represent examples of significant potential exposures and, as such, warrant notification of the licensees.

Regulatory references: 10 CFR 20.1, 10 CFR 20.202, 10 CFR 20.1101, 10 CFR 20.1502

Subject codes: 8.1, 8.3, 8.5

Applicability: Byproduct Material

HPPOS-224 **PDR-9111220133**

Title: Blind Spiking of Personnel Dosimeters and the Inspection Program

See the memorandum from J. E. Wigginton to L. R. Greger dated June 27, 1989. Blind spiking of personnel dosimeter has never been included explicitly in an inspection procedure for reactors. However, there may be reason to cover this topic on a case-by-case basis. Under the NVLAP program and the ANI/MAELU inspection of personnel dosimeters, nuclear power plants are expected to do blind spiking. The health physics position was written in the context of 10 CFR 20.202, but it also applies to "new" 10 CFR 20.1501.

It was asked whether, considering that 10 CFR 20.202(c) [or 10 CFR 20.1501(c)] requires NVLAP accreditation for personnel dosimeters, inspectors should continue to inspect for blind spiking of personnel dosimeters by nuclear power reactor

licensees. The answer is that given the coverage of personnel dosimetry QA/QC in the NVLAP program and in the ANI/MAELU inspections, there is no need for all NRC inspections of personnel dosimetry to cover blind spiking of dosimeters. However, there may be reasons to cover this topic on a case-by-case basis. The answer is based in part on the following information.

Blind spiking of personnel dosimeters has never been included explicitly in an inspection procedure for power reactors; however, such spiking falls within the more general item of "quality assurance for dosimeter processing" (Inspection Procedure 83524, Section 3.03 a) and "quality assurance of personal dosimetry measurements" (Core Inspection Procedure No. 83750, Section 3.05 a.7). Apparently inspectors in Region III, and possibly other regions, have looked to see if licensees are spiking badges. At least one region (Region I) has done NRC spiking of licensee personnel dosimeters using the Radiological and Environmental Research Laboratory to do the spiking.

To be accredited by NVLAP, a dosimetry processor must pass the proficiency test(s) and must satisfy documented NVLAP criteria. The NVLAP criteria for accreditation include general requirements for a quality assurance program but no specific requirement for dosimeter spiking. However, conformance to the NVLAP criteria is checked during onsite assessments by NVLAP assessors and the quality assurance checklist provided to the assessor (to "guide" the assessor) includes "#107. The processor's quality assurance program includes processing checks such as ... blind audit dosimeters unknown to the technician ...."

The ANI/MAELU inspection procedure on personnel dosimetry (dated October 1986) includes the requirement (Number 8.4.4.3): "There should be a continuing program of blind spiking TLD's or film badges. 1. Spiked badges should be included in each processing cycle. 2. A reasonable range of exposures for gamma and beta radiation energies should be included in the spiking program." Thus, ANI/MAELU clearly expects nuclear power plants to do blind spiking.

Regulatory references: 10 CFR 20.202, 10 CFR 20.1501

Subject codes: 8.1, 12.7, 12.15

Applicability: Reactors

HPPOS-268 **PDR-9306090293**

Title: Technical Assistance Request, BP International Limited Request for an Exemption from 10 CFR 20.202(c).

See the memorandum from J. E. Glenn to R. J. Pate dated October 8, 1991. An exemption for the regulations pursuant to 10 CFR 20.203(c) was granted by license amendment at the request of BP International, a British firm, on the behalf of BP Exploration Company, Anchorage, Alaska. 10 CFR 20.203(c) requires that dosimetry processors to be accredited by the National Voluntary Accredition Program (NVLAP). The exemption states: "Notwithstanding the requirements of 10 CFR 20.202(c), the licensee may use personnel dosimetry processed by the United Kingdom National Radiological Protection Board." This health physics position also applies to "new" 10 CFR 20.1501(c).

Regulatory references: 10 CFR 20.203, 10 CFR 20.1501

Subject codes: 8.1, 12.19

Applicability: All

HPPOS-002 **PDR-9111210075**

Title: Overexposure of Diver During Work in Fuel Storage Pool

See IE Information Notice No. 82-31 entitled as above and dated July 28, 1982. This notice cautions power reactor licensees about radiation hazards to divers working in spent fuel storage pools.

On June 1, 1982, while installing fuel rack support plates in the storage pool at Indian Point Unit No.2, a diver received a dose equivalent of 8.7 rem to the head. Upon exiting the pool the diver's 500-mR and 5-R pocket ionization chambers (worn on the head) were off-scale. The licensee suspended all diving operations and read the multiple TLDs worn on other body locations. A second diver received a total body dose of 1.6 rem. The fuel storage pool modifications had been ongoing for three months, with daily averages for dose equivalent to total body of about 50 mrem per diver.

A review of the incident by the licensee and NRC found several factors that contributed to the overexposure:

1. An irradiated fuel assembly was mistakenly transferred to a location within two to four feet of the diver's work area. A poor-quality copy of the fuel transfer procedures was apparently a factor in the improper fuel transfer. Limited visibility caused by cloudy water and a lack of underwater lighting may have prevented visual detection of the misplaced fuel assembly. No QA reviews were required or conducted of the irradiated fuel assemblies between fuel movement and the exposure incident.

2. A prior-to-work radiation survey of the pool was performed with an underwater ionization chamber connected by a long cable to the detector. The survey failed to detect the misplaced fuel assembly and exposure rate of several hundred R/hr within two feet of the diver's work area. Intermittent, erratic behavior of the survey meter had been observed during previous dives, and the licensee attributed the erratic behavior to a buildup of moisture in the housing for the underwater ionization chamber.

3. The radiation monitoring devices used during the underwater operations failed to function properly. Alarming dosimeters, mounted inside the diver's helmet, failed to alarm at the 200-mR set point. These dosimeters were under the control of the diving contractor and were not checked with a source on the day of the incident. The licensee monitored the dive with the same ionization chamber instrument used for the predive survey and failed to detect exposure rates in excess of 1 R/hr in the diver's work area.

The licensee increased senior management oversight for the spent fuel pool project and implemented the following corrective actions:

1. Whenever fuel movement occurs, QA personnel will independently witness and verify the new locations. Other irradiated objects with exposure rates of more than 1 R/hr at contact will be controlled in a similar manner. After any movement of either fuel or irradiated components (more than 1 R/hr at contact), an underwater radiation survey will be conducted before diving operations will resume.

2. Daily, before any diving operation, a radiation survey of the diving pool will be made. Such surveys will be performed with two independent monitoring devices. A survey map of the pool will be updated to reflect current status of the ongoing fuel rack modification

3. Each diver will wear a calibrated, alarming dosimeter that will be checked daily before any diving operations, and a remote-readout detector that will be monitored continuously by health physics technicians. Divers will also surface periodically and their pocket ionization chambers will be read. Any significant deviation from expected work patterns or radiation levels will be grounds for dive termination.

4. Pool clarity and underwater lighting acceptance criteria have been established to help insure adequate visibility is maintained at all times.

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501, Regulatory Guide 8.38

Subject codes: 6.5, 7.1, 8.1

Applicability: Reactors

HPPOS-233 **PDR-9111210342**

Title: Applicability of Regulatory Position 1.3 of Regulatory Guide 8.32 to Nuclear Reactor Facilities

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated February 6, 1991. The memo states that although there are relatively few workers at nuclear reactor facilities who meet the criteria of Regulatory Position 1.3, those employees who can come into skin contact, ingest or absorb water or other substances with concentrations of tritium greater than 0.01 mCi/kg must be identified.

The purpose of this memorandum was to respond to a question as to whether or not Regulatory Position 1.3 of Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program," applies to nuclear reactor facilities. As discussed below, Regulatory Position 1.3 does apply to nuclear reactor facilities (and other facilities); however, there are a relatively small number of workers, if any, at nuclear reactor facilities who meet the criteria of Regulatory Position 1.3 and, therefore, a relatively small number of workers, if any, at nuclear reactor facilities for which bioassay is recommended as a result of Regulatory Position 1.3.

Table 1 of Regulatory Guide 8.32 has two columns listing quantities of tritium and a third (right-hand) column listing concentrations of tritium in water. Regulatory Position 1.1 refers to the first two (tritium quantity) columns of Table 1 and does not apply to nuclear reactor facilities. Regulatory Position 1.2 refers to the third (tritium concentration) column of Table 1, and applies to nuclear reactor facilities; however, nothing in Position 1.2 or elsewhere in the guide indicates that Position 1.2 is the only position that applies to nuclear reactor facilities. Regulatory Positions 1.1 and 1.2 are based on considerations of intakes of tritium, as a gas or vapor, from the air. Regulatory Position 1.3 supplements Positions 1.1 and 1.2 and is based on considerations of intakes of tritium in the form of tritiated liquids that pass through the skin. Regulatory Position 1.3 is applicable to all licensed facilities, including nuclear reactor facilities, for the situation described in that position.

Regulatory Position 1.3 is as follows: "1.3. Bioassays should also be performed when an employee can come into skin contact with, ingest, or absorb into the body through cuts, abrasions, or accidental (hypodermic) injection, water or any other substance with concentrations of tritium greater than or equal to 0.01 mCi/kg (0.01 μCi/cc) such as may be common in laboratory applications."

The stipulation "... when an employee can ..." should be interpreted reasonably. We understand the intended meaning of this statement to be much nearer to "... when an employee can reasonably be expected to ..." than it is to "... when there is even a remote possibility that an employee can ...." Thus, there are relatively few workers at nuclear reactor facilities that meet the criteria of Position 1.3 and those that do meet the criteria must be identified by radiation protection professionals, based on considerations of the circumstances of the particular duties of the workers in a particular plant.

Examples of workers who may meet the criteria of Position 1.3 include, but are not necessarily limited to, (1) divers in pools of water with tritium concentrations greater than or equal to 0.01 μCi/cc, and (2) workers who routinely sample, and may be sprayed with, or otherwise come into contact with, water with tritium concentrations greater than or equal to 0.01 μCi/cc.

Regulatory references: Regulatory Guide 8.32

Subject codes: 8.2

Applicability: Reactors

HPPOS-246 **PDR-9111220096**

Title: Enforcement Policy For Hot Particle Exposure - Answers to Three Questions

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated November 3, 1990. This memo notes that IE Information Notice No. 90-48 states what NRC will do, not what licensees are required to do, in assessing the dose from hot particle exposures. The enforcement policy does not require any licensee to change any procedure, and the existing flexibility in determining compliance with dose limits in 10 CFR 20 has not been eliminated as a result of this policy. The dose to be recorded on NRC Form 5 (or equivalent) is the dose calculated to determine compliance with the relevant Part 20 limit. The health physics position was written in the context of 10 CFR 20.101, but it also applies to "new" 10 CFR 20.1201.

IE Information Notice 90-48, "Enforcement Policy for Hot Particle Exposures," dated August 2, 1990, was sent to all power reactor licensees. Since that time, nearly everyone who has telephoned the NRR technical contacts about this policy has asked if licensees are required to change any of their procedures as a result of this policy. Also, attendees at the Edison Electric Institute (EEI) Health Physics Group meeting in Long Beach asked if, as a result of this policy, existing flexibility in determining compliance with the Part 20 limits has been eliminated.

The answer to the first question is no; the enforcement policy does not require any licensee to change any procedure. The enforcement policy states what the NRC will do, not what licensees are required to do. This question arose primarily because of the statement in the policy that "In determining whether a hot particle exposure has exceeded the limits of 10 CFR 20.101 [or 10 CFR 20.1201], ... hot particle exposures will not be added to skin doses from sources other than hot particles...." Licensees, who have been adding hot particle exposures to other skin doses asked if they needed to change their procedures for recording skin doses. They were assured that they did not need to change, but that the NRC would follow this policy in

determining whether an overexposure had occurred. However, because of this statement in the policy, any licensee who chooses to change record-keeping procedures and not add hot particle exposures to other exposures is free to do so.

The answer to the second question is also no; existing flexibility in determining compliance with the Part 20 dose limits has not been eliminated as a result of the policy. This question arose primarily as a result of the statement in the policy, taken from NCRP Report No. 106, that "... the hot particle will be assumed to have been in contact with the skin." However, the statement applies to use of the policy after it has been determined that there has been an overexposure. It does not have to be applied in the determination of compliance or non-compliance with the dose limits of 10 CFR 20.101 [or 10 CFR 20.1201]. However, once the NRC staff has been informed that there has been an overexposure, the staff is to use the assumptions required by the policy to determine whether a notice of violation will be issued and, if so, what the severity level should be.

The following example may help clarify the issue. Assume a hot particle has been found on the inside of an inner garment of a worker. In determining the skin dose [or shallow dose equivalent] for comparison with the Part 20 dose limit [see 10 CFR 20.1201], the licensee and the NRC staff need not assume that the particle was on the skin during the period of the exposure. As in the past, the particle may be assumed to have been on the clothing where it was found and the dose to the skin may be determined using reasonable time and motion studies that take into account the movement of the garment and particle relative to the skin. If the dose determined using these assumptions is below the Part 20 limit [see 10 CFR 20.1201], the enforcement policy need not be considered. But if the dose exceeds the limit, the enforcement policy based on NCRP Report No. 10 must be applied by the NRC staff. In applying this policy to this example, it is assumed that the particle was on the skin during the entire period of the exposure, because it cannot be shown that the particle was never on the skin.

The above example also raises the question of what dose should be recorded on NRC Form 5 (or equivalent). Since Part 20 requirements are not changed by the enforcement policy, the dose to be recorded is the dose calculated to determine compliance with the relevant Part 20 limit. However, licensees may, add supplemental information concerning methods and values used by NRC staff in enforcement actions.

Regulatory references: 10 CFR 20.101, 10 CFR 20.1201

Subject codes: 2.1, 8.3, 12.7

Applicability: Reactors

2.11 RESPIRATORY PROTECTION

HPPOS-117 PDR-9111220025

Title: Medical Surveillance for Respirator Users

See the open letter from R. B. Minogue dated March 14, 1978. This letter states that the NRC does not require complete physical examinations of each respirator user, only an initial medical examination and annual reviews of medical status. Licensees can obtain proof from contractors that determinations of medical status were made on contractor employees. The health physics position was written in the context of 10 CFR 20.103, but it also applies to "new" 10 CFR 20.1703. HPPOS-061 and HPPOS-103 contain related discussions.

NRC Regulation 10 CFR 20.103(c) [or 10 CFR 20.1703(a)] permits licensees to make allowance for the use of respirators provided that the equipment is used as stipulated in Regulatory Guide (RG) 8.15. Licensees who make allowance for respirators are required by RG 8.15 to determine:

> "... prior to assignment of any individual to tasks requiring the use of respirators that such an individual is physically able to perform the work and use the respiratory protective equipment. A physician is to determine what health and physical conditions are pertinent. The medical status of each respirator user is to be reviewed at least annually."

The purpose of the requirement is to protect the health of workers who might have to use respirators. It must be noted, however, that the NRC does not require a complete physical examination of each respirator user, only an initial medical examination and an annual review of medical status. The physician might or might not require a physical examination as part of his health assessment.

It is not necessary that the licensees' physician determine the medical status for the employees of contractors at the licensee's sites. Licensees can meet the requirement for making the determinations by obtaining proof from their contractors that the required examinations of medical status have been made. Currently, there is no standard method for medical surveillance of this type. [Note: ANSI Z88.6-1984 was developed to provide guidance and information for physicians and other professionals to determine the suitability of personnel for respirators.] NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials," offers suggestions that a licensee's physician may wish to follow.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, Regulatory Guide 8.15

Subject codes: 8.10

Applicability: All

HPPOS-061 PDR-9111210245

Title: Guidance Regarding Physicians' Determination of Physical Qualification of Respiratory Equipment Users

See the memorandum from W. L. Fisher to R. E. Hall dated February 1, 1984. This memo states that physicians must make final determinations of fitness for each respiratory equipment user. The health physics position was written in the context of 10 CFR 20.103(c)(2), but it also applies to "new" 10 CFR 20.1703(a)(3).

Although physicians need not administer each test personally, it is not acceptable for a physician to establish criteria and have the licensee (or any other designee) use these criteria to make the determination that the individual is or is not qualified. The physician may use a medical designee (such as an office nurse) for signing the medical approval/denial form for the physician, as long as the designee's signature is clearly for administrative convenience and the physician has not relinquished any responsibility for the fitness determination.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, Regulatory Guide 8.15, NUREG-0041

Subject codes: 8.10

Applicability: All

HPPOS-219 PDR-9111220025

Title: Intervals Between Physical Examinations for Respirator Users

See the letter from M. C. Thadani to H. W. Keiser (Senior Vice President-Nuclear, Pennsylvania Power and Light Company) dated May 30, 1989. This letter states that physical examinations for respirator users are prescribed every 12 months by 10 CFR 20.103(c)(2). However, a physical examination conducted every 9-15 months, provided that three consecutive exams do not exceed 39 months, is consistent with NRC staff interpretations of interval requirements. This health physics position also applies to "new" 10 CFR 20.1703(a)(3)(v).

A written request was made for exemption from the requirement of 10 CFR 20.103(c)(2) regarding the 12 month time interval for physical examinations to assure an individual is physically able to use respiratory protective equipment. Specifically, Pennsylvania Power and Light Company requested an exemption to permit physical examinations every 9-15 months, providing that the total time of the three consecutive physical examinations does not exceed 39 months.

It was determined that the request was consistent with the NRC staff's position on implementation of the time interval requirements of 10 CFR 20.103(c)(2), and therefore, an exemption was not needed.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703

Subject codes: 1.1, 8.10

Applicability: All

HPPOS-103 PDR-9111210235

Title: Request for Clarification of Guidance Regarding Physicians Determination for Physical Qualification of Respiratory Equipment Users

See the memorandum from D. A. Allison to M. M. Shanbaky dated July 19, 1985. This memo states that physicians need not sign all forms regarding physical fitness. But, the physician should be involved in the supervision of the fitness program, the review of overall results and individual cases that fall outside certain physical parameters, and the supervision of personnel performing the tests. Simply establishing the program with no further involvement is not adequate. The health physics position was written in the context of 10 CFR 20.103, but it also applies to "new" 10 CFR 20.1703. HPPOS-061 contains a related topic.

In regards to determining compliance with the 10 CFR 20.103(c)(2) requirement of who physically signs "fitness" forms, the intent is to have physicians screen individuals for health problems prior to respirator use. An acceptable compliance situation, however, could involve a trained nurse who physically administers medical testing and documents and signs the required forms. This situation is acceptable provided the results of the tests are within a range established and approved by a physician, and the physician agrees to retain full responsibility. If the results of the physical tests fall outside the acceptable range, the individual's case should be referred to the physician for more direct attention and testing. [Note: The above 10 CFR 20.103(c)(2) requirement is now found in 10 CFR 20.1703(a)(3).]

Each form does not necessarily need to be signed by a physician; however, the physician should be involved in the supervision of the fitness determination program. Physician supervision of the program is indicated by the review of overall results, the review of individual cases that fall outside established ranges, and the general supervision of personnel actually performing the physical assessments. Simply establishing acceptable ranges for the tests, with no further involvement, is not adequate.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, Regulatory Guide 8.15, NUREG-004

Subject codes: 8.10

Applicability: All

HPPOS-116 PDR-9111210272

Title: OSHA Interpretation: Beards and Tight-Fitting Respirators

See the memorandum from R. L. Baer to R. R. Bellamy (and others) dated November 2, 1984. OSHA's position is that no bearded individual can achieve a consistent and satisfactory fit when any tight-fitting respirator is worn. Qualitative fit tests are highly subjective and errors with this type of testing

are generally high. HPPOS-094 contains a related topic.

In response to a request by Region III for technical assistance in April 1983, OIE issued a memorandum providing a broad technical basis to support the position for prohibiting bearded users from wearing SCBA's. However, at that time, a strict legal reading of NRC regulations led to the conclusion that as long as no respirator protection factor was assumed, a bearded individual could not be prohibited from wearing a respirator.

The controversy over bearded fire brigade members at a Region III facility continued and an OSHA written interpretation on the subject surfaced (see enclosures to memorandum). This OSHA interpretation is clear and direct - OSHA's 29 CFR 1910.134(e)(5)(i) prohibits facial hair in the seal area. It is also OSHA's position that:

1. The employer is in violation of the standard if employees are allowed to wear respirators over facial hair at the sealing surface of the respirator.

2. Qualitative fit tests are highly subjective and the errors associated with this type of testing are generally high.

3. Based on the information available, no bearded individual can achieve a consistent and satisfactory fit when any tight-fitting respirator is worn.

OIE recommends that if recalcitrant licensees continue to allow bearded Emergency Response/fire brigade individuals to wear tight-fitting respirators after being informed of OSHA's interpretation and position, the region should refer this nonradiological respiratory problem to the appropriate OSHA authorities, in accordance with Chapter 1007 of the IE Manual (Interfacing Activities Between Regional Offices and OSHA).

By separate correspondence to RES, we plan to recommend RES change the regulations to expressly forbid facial hair in the seal area of tight-fitting respirators.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703

Subject codes: 8.10, 12.13

Applicability: All

HPPOS-162 **PDR-9111220148**

Title: Use of Contact Lenses with Respirators

See the memorandum from F. J. Congel and R. E. Cunningham to M. R. Knapp (and others) dated June 5, 1989. Contact lenses may be worn will full face respirators under specified conditions. This permission is a policy change.

a. Lawrence Livermore National Laboratory report of August 16, 1985 (DE86001775, UCRL-53653) by R. A. da Rosa and C. Weaver, "Is It Safe to Wear Contact Lenses with a Full-Facepiece Respirator?"

b. U.S. Department of Energy, Memorandum from M. L. Walker dated September 23, 1986, Subject: Amendment of the Occupational Safety and Health Administration (OSHA) Prohibition on Wearing Contact Lenses in Contaminated Atmospheres with Full-Face Respirators.

c. U.S. Department of Labor, Occupational Safety and Health Administration, Memorandum from T. Shepick dated February 8, 1988, Subject: Contact Lenses Used with Respirators (29 CFR 1910.34(e)(5)(ii)).

d. Draft ANSI Z88.2-1989, American National Standard Practices for Respiratory Protection.

References (a) and (b) accompanied the June 3, 1986 memorandum from R. L. Baer to the Regional Branch Chiefs of the Emergency Preparedness and Radiological Protection of the Division of Radiation Safety and Safeguards. These references shed new light on the NRC policy on the use of prescriptive lenses with respirators. As referenced in RG 8.15 and stated in NUREG-0041, the policy states: "Contact lenses shall not be worn with full face respirators. These devices present a distinct hazard to the individual owing to the possibility of the lenses slipping because of pressure on the outside corners of the eyes from a full face mask or a speck of dirt getting under them while the respirator is being worn. Corrective action would

entail removing the respirator, which would mean that the individual would either have to leave the contaminated atmosphere or run the risk of exposure if he removed the respirator in the contaminated area."

On the basis of references (a) and (b), the June 3, 1986 memorandum contemplated a policy change that would permit NRC licensees to use contact lenses with respirators. However, at the time, OSHA prohibited the use of contact lenses with respirators in nonradioactive environments. The NRC staff postponed the contemplated policy change rather than implementing different policies and regulations for radioactive and nonradioactive environments. Subsequently, OSHA revisited this subject.

Reference (c) modified OSHA enforcement procedures so that, among others, violations involving the use of gas permeable and soft contact lenses shall be documented but citations shall not be issued. In view of this modified enforcement procedure of OSHA, the previously contemplated NRC policy change to permit the use of contact lenses with respirators was reconsidered. The staff continues to believe that the use of contact lenses with respirators will enhance overall worker safety by improving vision of those persons who regularly wear contact lenses and who are required to use respirators in the course of their jobs.

In response to requests from NRR, the Office of Nuclear Regulatory Research has budgeted for comprehensive revisions of 10 CFR Part 20 and RG 8.15. These revisions will incorporate updated standards including those developed by ANSI Committee Z88.2. Specifically, reference (d) states: "6.5.3.3. Use of contact lenses is permitted with respirator wear provided the individual has previously demonstrated that he or she has had successful experience wearing contact lenses. The contact lens wearer shall be required to have practice wearing the respirator while wearing the contact lenses." Accordingly, the NRC staff position is changed to permit the use of contact lenses with respirators in accordance with the above citation from ANSI Z88.2-1989.

Regulatory references: Regulatory Guide 8.15

Subject codes: 5.6, 8.10, 12.19

Applicability: All

HPPOS-147 **PDR-9111220069**

Title: Respirator User's Notice - Use of Unapproved Subassemblies

See the above entitled notice issued by J. B. Moran on November 6, 1984. This notice states that NIOSH/MSHA approves only complete respirator assemblies and not subassemblies such as cylinders or air supply hoses. Users of approved respirators must not interchange subassemblies or make unapproved modifications to respiratory protection devices.

The National Institute for Occupational Safety and Health (NIOSH) had received many questions and complaints in regard to the interchangeability of respirator subassemblies and unapproved modifications to NIOSH/MSHA certified respirators. Further, some problems reported to NIOSH had, upon investigation, been found to have been caused by user's modifying certified respirators that resulted in the modified respirator failing to perform as anticipated, thus jeopardizing the respirator user.

NIOSH/MSHA respirator certification regulations, Title 30 Code of Federal Regulations Part 11 (30 CFR 11), state that approved respirators "are maintained in an approved condition and are the same in all respects as those respirators for which a certificate has been issued." [30 CFR 11, 11.2(b)] In addition, the regulations permit NIOSH/MSHA to approve only complete respirator assemblies and prohibit the approval of respirator subassemblies such as cylinders or air supply hoses. These requirements are intended to ensure that one manufacturer has overall control and responsibility for the integrity of the approved respirator.

In some cases even minor modifications to respirators may make significant changes in the performance of the respirator. Manufacturers who modify certified respirators must test the modification to determine if the respirator continues to meet the minimum requirements of 30 CFR 11, and must submit the modifications to NIOSH. A user who modifies a certified respirator may not be able to determine whether a change will decrease respiratory protection. Several cases have been reported to NIOSH where unapproved modifications or use of an unapproved subassembly have resulted in respirator failures. Therefore, users of NIOSH/MSHA approved respirators are cautioned against interchanging subassemblies or making unapproved modifications to their respiratory protective devices.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703

Subject codes: 8.10

Applicability: All

HPPOS-037 **PDR-9111210173**

Title: Farley 1 & 2 - 10 CFR Part 20 Exemption Request, MSA GMR-I Canister (Part No. 466220) Radioiodine Protection Factor

See the memorandum from D. R. Muller to G. C. Lainas dated June 28, 1984. It recommended an exemption to allow licensees to use MSA GMR-I canisters for protection against iodine gases and vapors with certain restrictions. This action set a precedent. The health physics position was written in the context of 10 CFR 20.103, but it also applies to "new" 10 CFR 20.1703.

The Radiological Assessment Branch (RAB) reviewed a licensee's application for an exemption to 10 CFR Part 20, Appendix A, Footnote d.2(c) to allow the use of MSA GMR-I Canisters. Although the action established a precedent, the RAB recommended, in accordance with the provisions of 10 CFR 20.103(e) [or 10 CFR 20.1703(a)(2)], that the exemption be approved with restrictions.

The restrictions were enumerated by the NRC staff in their Safety Evaluation Report and are summarized as follows:

1. A protection factor of 50 for radioiodine gases and vapors was to be used.

2. The MSA GMR-I Canisters were to be discarded after a maximum of 8 hours continuous use time.

3. The MSA GMR-I Canisters were not to be used in the presence of organic solvent vapors.

4. The MSA GMR-I Canisters were to be stored in sealed, humidity barrier packaging in cool, dry environments.

5. The service life of the MSA GMR-I Canisters were to be calculated from the time of unsealing, including periods of non-exposure.

6. The MSA GMR-I Canisters were to be used with a full facepiece capable of providing protection factors greater than 100.

7. The MSA GMR-I Canisters were not to be used in total challenge concentrations of organic iodines and other halogenated compounds greater than 1 ppm, including nonradioactive compounds.

8. The MSA GMR-I Canisters were not to be used in environments with temperatures greater than 110°F.

The above exemptions are subject to amendment by the NRC staff and will remain in effect until rescinded by NRC staff or superseded by regulation.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, NUREG/CR-3403

Subject Code: 8.4, 8.10

Applicability: Reactors

HPPOS-094 **PDR-9111210195**

Title: Guidance Concerning 10 CFR 20.103 and Use of Pressure Demand SCBA's

See the memorandum from L. J. Cunningham to L. R. Greger dated September 8, 1983. Personnel having any condition, including facial hair, that prevents a leak-tight seal and proper operation, should not be qualified respirator wearers. For emergency entries, a licensee can use post-work whole body counts to show compliance with 10 CFR Part 20 intake limits. The health physics position was written in the context of 10 CFR 20.103, but it also applies to "new" 10 CFR 20.1703. HPPOS-116 contains a related topic.

Guidance was requested concerning 10 CFR 20.103 [or 10 CFR 20.1703] and the use of pressure demand SCBA's. A Region III licensee's proposed respiratory protection plan to allow bearded personnel to use pressure demand SCBA's was discussed with RES and NIOSH. Region III objected to the licensee's proposal but could find no clear regulatory basis for the objection. IE supported the objection and felt there was a strong technical basis for that objection.

IE found several technical flaws in the licensee's proposal to deviate from the normal industry practice

of requiring clean-shaven faces in the seal area of tight fitting respirators. One serious problem is the potential to "overbreathe" (e.g., a person working under heavy physical stress, such as fire fighting efforts, can exceed the SCBA's air supply capacity). When a beard-caused leak exists in the seal area, the additional "makeup" air is drawn from the outside atmosphere through the leak area. Another problem is the beards interference with the operation of the facepiece's exhaust (exhalation) valve. A beard can hold this valve open, and on a deep breath, could allow outside, contaminated air to enter the facepiece. Also, on a normal volume inhalation an open exhaust valve could allow loss of air, thereby reducing the user's service time.

A major problem with the licensee's proposal centers on the high probability for increased outward leakage caused by beard interference with the seal. The Industrial Hygiene Support Group at Lawrence Livermore National Laboratory (LLNL) has noted during testing of bearded personnel that the SCBA advertised 30-minute air supply (which normally lasts about 20 minutes) ran out in 10 to 12 minutes at a moderate work load. As reported in an article, "Facial Hair and Breathing Protection" (The International Fire Chief, December 1980): "It must be emphasized again that facial hair characteristics change daily, so any test of facepiece fit or how long the breathing air cylinder will last on one day will be different on succeeding days." IE and NIOSH believe that a daily quantitative fit test would probably be required to ensure adequate air supply service time for bearded users who have facial hair in the seal area. The administrative costs and problems with such a program seem to be tremendous.

IE also addressed a specific question on whether 10 CFR 20.103(a)(3) [or 10 CFR 20.1204(a)] permits the use of post-exposure whole body counts to determine compliance with Part 20 intakes. The regulations allow licensees who choose not to fully implement the respiratory protection program of 10 CFR 20.103(c)(2) [or 10 CFR 20.1703(a)(3)] to use respirators, but does not allow them to take any credit for protection factors [see 10 CFR 20.1204(b)]. IE feels this is a reasonable position from the perspective of providing workers protection during routine, planned operations in airborne radioactivity areas. For these operations, the degree of hazard can be pre-determined by air sampling, and licensees can then assume no protection factors and limit the stay time such that administrative intake "overexposures" should not occur. However, the case for fire fighters differs drastically.

Prompt emergency response does not lend itself to pre-work assessment of airborne hazards. In emergency situations, it is clearly illogical to take a "no-protection" assumption for entry into IDLH areas of unknown hazards. In the case of fire fighters, exposure to radioactive materials is generally of secondary importance, and toxic fumes/gases are the principal hazard. However, a strict legal reading of the regulations leads us to conclude that nothing prohibits using post-work whole body counts for demonstrating compliance with Part 20 limits. From a routine radiological perspective, IE is comfortable with this reading; however, in the case of unqualified respirator wearers performing emergency response actions in high risk areas with the attendant unknown level of protection, IE strongly believes the regulations should require high quality respiratory protection.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1204, 10 CFR 20.1703

Subject codes: 8.2, 8.4, 8.10

Applicability: All

HPPOS-118 **PDR-9111210275**

Title: Airflow Measurement and Control for Supplied-Air Respirators

See the memorandum from J. E. Wigginton to J. H. Joyner (and others) dated August 5, 1982. It provides guidance on assuring that the required minimum airflow is being provided to each individual respirator user when several users are sharing a single air regulator manifold supply.

In response to a Regional inspector's request, the Los Alamos National Laboratory (LANL) was asked how IE can be assured that required minimum airflow is being provided to each individual respirator user when several users are sharing a standard air regulator manifold supply. This discussion is limited to continuous-flow Type C respirators. The airflow requirements of regulator-controlled airline respirators (such as pressure-demand) are so much less than continuous-flow devices, that adequate airflow is not usually a problem.

There appears to be a misunderstanding on what flow measurement is appropriate when adjusting the air pressure on an airline. It is the airflow about the head and face of the respirator wearer that largely determines the protection provided by the device. Therefore, one needs to be concerned only with the airflow at ambient conditions. Furthermore, the temperature and pressure at most actual working conditions are sufficiently close to standard conditions that either may be used for the calculations. An exception would be for work at high altitude, such as above 6000 ft at Los Alamos, where the atmospheric pressure is less than 80% of sea level, requiring corrections for the difference in flow.

Manufacturers of airline respirators include instructions specifying a range of air pressure required to produce the needed flow rates based on both the lengths of hose used and the number of sections connected together. Concern with the latter is because of the considerable pressure drop in the quick-connect fittings between each section of hose. If the appropriate pressure for the total length of hose is used, ample flow should be available.

Problems may develop when more than one user is connected to an air manifold with a single regulator and pressure gauge. If each user has different hose lengths or respirators with different air pressure requirements, this manifold arrangement should not be used. In this case, it is difficult to determine if each user is receiving the required airflow. A much better approach would be a system where individual control is provided with a separate regulatory and pressure gauge for each user.

In addition, the user has the option of measuring the airflow at the respirator. This is most easily done during the set up of the system before work begins. The lengths of hose required for the job should be connected. In most systems, there is a belt-mounted valve or regulator. The high-pressure air hose plugs into this valve, and a low-pressure breathing tube runs to the facepiece or hood. The end of the breathing tube is the best point at which to take the flow measurements. Disconnect the tube from the facepiece and insert into a calibrated rotameter or other airflow measuring instrument, and then, the line pressure may be adjusted to obtain the desired airflow. It is recommended that any air supply system be designed to deliver greater than the minimum required (4 cfm for tight fitting facepieces and 6 cfm for hoods), but the flow should be adjusted so as not to be so high as to be uncomfortable for the wearer. If the pressure required for each configuration of hose and respirator combination is recorded, future respirator set up of this type will be made considerably easier. Any questions as to the adequacy of airflow can be easily answered by actually measuring it.

One final important point must be made about the use of appropriate hose fittings. It is extremely important in a work place using a variety of different piped fluids, that the fitting used for breathing air be different and incompatible with any other in the plant. Supplied air respirators may be ordered with one of several different quick-connect fittings, and, if any one of these is not in use in the plant, there is no problem. However, in the event that all of the hose fittings available for the respirator manufacturer are already in use, then a different, unique fitting will have to be selected for breathing air. The user organization must then replace all of the fittings on the valves and hoses with the special fitting. Since the resistance of the new fitting may not be known, the airflow to respirator with various hose lengths should be measured as discussed above.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, Regulatory Guide 8.15

Subject codes: 8.10

Applicability: All

HPPOS-146 **PDR-9111210387**

Title: Updated Guidance on Fit Testing of Biopak 60-P Respirator Users

See the memorandum from L. J. Cunningham to J. N. Grace (and others) dated August 19, 1984. It is acceptable to check the fit of the Biopak 60-P while the user is wearing just the facepiece equipped with a high efficiency filter supplied by the manufacturer of the device. A fit factor of 1000 is reasonable in the negative pressure air-purifying mode. This memo supersedes an earlier one from L. J. Cunningham to L. R. Greger dated August 8, 1983.

Licensees and inspectors had inquired as to what constitutes an acceptable method for performing quantitative fitting of the wearers of this apparatus as required in footnote 1, to Appendix A of Part 20. Specifically, was it acceptable to check the fit of the device (the

face to facepiece sealing capability) by testing the user while the user was wearing just the facepiece equipped with a high efficiency filter supplied by the manufacturer of the device?

Previous guidance stated that the wearer must don the entire unit for fit testing since it was felt that fitting the facepiece with a high efficiency filter that is capable of allowing no more than 0.03% leakage would preclude measurement of the required 0.02% leakage or less through the face to facepiece sealing area. However, the 0.03% leakage allowed for high efficiency filters is determined with a more penetrating aerosol (monodispersed) than used in fit testing. Therefore, it is possible to measure the 0.02% leakage accurately with the facepiece equipped with a high efficiency filter (0.02% leakage corresponds to a fit factor of 5000).

Requiring a fit factor of 5000 in the negative pressure air-purifying mode is too restrictive. This approach to fit testing allows no credit for protection provided by the positive pressure inside the facepiece generated by the device in its normal mode of operation. Positive pressure inside the facepiece can compensate for inward leakage of contaminants to some extent by ensuring air circulating through the device is leaked outward instead of leaking contaminants into the worker's breathing zone. However, with this device, protection is obtained at a large cost if the fit is poor and outward leakage is substantial because reduced service life results as outward leakage of air is made up from the small volume of oxygen carried by the user. The volume carried is sufficient to exchange the volume of carbon dioxide released in respiration with compressed oxygen. Carbon dioxide is removed from the circulating air by the sorbent scrubber.

A hard and fast number that delineates good from poorly fitting respirators is not available. In the opinion of many experts in the field of respiratory protection, a fit factor of 1000 seems reasonable for distinguishing between good and poorly fitting respirators. It is recommended that licensees use this number as a guide for determining if an acceptable fit has been achieved with this device.

For those persons who are unable to attain a fit factor of 1000 with just the facepiece in negative pressure mode, participation in emergency, potentially IDLH situations should be restricted. This person may experience drastically reduced service time which reduces emergency response capability as well as hindering escape from a potentially life threatening situation.

The intent of the previous guidance was not to verify proper functioning of the entire unit. The operability of the assembled unit is checked after maintenance and before each use. In addition, fit testing of workers wearing the assembled unit in the case of this apparatus was presenting other problems due to the low makeup volume and leakage detection interference from background water vapor droplets and particulates from the carbon dioxide scrubber system.

Based on the interference problem that has been reported and reevaluation of the previous guidance, it is recommended that fit testing of wearers of the BioPak 60-P be performed with just the facepiece equipped with a high efficiency filter and that a factor of 1000 be considered an acceptable fit. A recommendation will be made to RES to update Appendix A to include the intent of this interpretation in the next rule change.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, Regulatory Guide 8.15

Subject codes: 7.2, 8.10

Applicability: All

HPPOS-175 **PDR-9111210266**

Title: Acceptability of New Technology Respirator Fit Testing Devices

See the memorandum from R. L. Pedersen to M. M. Shanbaky (and others) dated April 10, 1989. The memo states that new technology devices can be used to conduct quantitative fit testing of respirators provided the device can be shown to be technically adequate, satisfies regulatory commitments, and meets the intent of the regulatory requirements.

The Radiation Protection Branch was queried on the acceptability of new respirator fit testing devices that were on the market. When determining that a method is technically adequate, an inspector should keep in mind that:

1. Fit Factors determined by any quantitative fit test are not Protection Factors and can not be used as such.

2. Acceptance criteria for Fit Factors should be set at least ten times the Protection Factor of the mask being fit (i.e., to show a proper fit on a mask with a protection factor of 50, a Fit Factor of at least 500 should be measured).

3. Testing methods should reasonably simulate use conditions.

4. An adequate base for correlating the parameter being measured (aerosol concentration, pressure drop, etc.) to a Fit Factor, should be established.

It has been reported that one device on the market, QUANTAFIT, requires the subject to be absolutely still with no facial movement. Apparently momentary breaks in the face seal, caused by facial movement, fail the test. This type of leakage is well known even in a good fitting respirator and it is a major contributor to the overall leakage (or fit) of the mask. If this information is correct, it is difficult to see how this method can adequately measure the respirator fit.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703

Subject codes: 5.6, 8.10

Applicability: All

HPPOS-225 **PDR-9111220136**

Title: Footnote g of Appendix A to 10 CFR 20 Concerning Protection Factor for Respirators

See the letter from L. J. Cunningham to J. A. Kvikstat (3M Occupational Health and Environmental Safety Division) dated July 25, 1990. The protection factor assigned in 10 CFR 20 Appendix A (§§20.1001-20.2401) was established for half mask elastomeric face pieces and is not applicable to non-elastomeric disposable respirators. Half-mask disposable respirators capable of providing a good seal are a recent innovation. Licensees can apply for protection factors under 10 CFR 20.103(d). This health physics position also applies to Paragraph 20.1703(a)(2) and to Footnote g in Appendix A of the "new" 10 CFR Part 20 (§§20.1001-20.2401).

Guidance was requested on whether a disposable high efficiency respirator manufactured by the 3M Company met the description of a half-mask respirator in Footnote g of Appendix A to 10 CFR 20 and could be afforded a protection factor (PF) of 10. NRC stated that PFs were derived from performance testing and then assigned to classes of respirators. The PF assigned in Appendix A was established for half mask elastomeric face pieces and was not applicable to non-elastomeric disposable respirators. The "under-chin" specification in Footnote g is intended to distinguish between 1/2 and 1/4 mask elastomeric face pieces; the latter not providing an acceptable seal.

Disposable half-mask respirators that provide a good seal are recent innovations. NRC is currently considering amending 10 CFR 20 to add a disposable respirator classification to Appendix A; however, the PF to be assigned to this class has not been established. Until Part 20 is amended to add a disposable respirator classification, NRC licensees wishing to use 3M respirators can apply to the Commission for authorization under paragraph 10 CFR 20.103(d) [or 10 CFR 20.1703(a)(2)].

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703

Subject codes: 8.10

Applicability: All

HPPOS-226 **PDR-9111220140**

Title: Intent of the QA Testing of Respirator HEPA Filters, as Discussed in NUREG-0041

See the letter from L. J. Cunningham to S. K. Herweyer (TSI Incorporated) dated February 27, 1990. Aerosol penetration testing of filters or canisters should be performed with a testing protocol that is capable of detecting significant filter damage or deterioration. It is not necessary, nor is it required, to recertify the filter as HEPA prior to use. The health physics position was written in the context of 10 CFR 20.103, but it also applies to "new" 10 CFR 20.1703

Confirmation was asked whether the intent of the Quality Assurance Testing of respirator high efficiency particulate (HEPA) filters discussed in NUREG-0041 was that they be tested to meet the NIOSH certification protocols. The NRC does not require the recertification of HEPA filters prior to use.

10 CFR 20.103(c) requires that "when respirator protective equipment is used to limit the inhalation of airborne radioactive material ... the licensee shall use equipment that is certified or had certification extended by ... NIOSH/MSHA." [Note: 10 CFR 20.1703(a) requires that "the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by ... NIOSH/MSHA."] This requirement is echoed in Appendix A, Footnote (b) to 10 CFR 20 [and Footnote d.2(b) of Appendix A to 10 CFR Part 20 (§§20.1001-20.2401)] which indicates that the protection factors listed for air-purifying respirators are valid only when the "high efficiency particulate filters (above 99.97% removal efficiency by thermally generated 0.3 μm dioctyl phthalate [DOP] test or equivalent)" are used. Use of non HEPA filters would be outside the NIOSH/MSHA certification.

Respirator filter manufacturers have quality assurance (QA) and quality control (QC) programs approved by NIOSH to ensure their HEPA filters or cartridges meet certification criteria referred to in the Appendix A footnote. The QA program discussed in NUREG-0041 is provided to assure that this certification has not been voided by deterioration or damage. Aerosol penetration testing of filters prior to their reuse is necessary to detect damage, incurred by prior use, that may not be evident with a visual or pressure drop test.

In 1983, responding to a question regarding the acceptance criteria for filter QA testing by our licensees, the NRC Office of Research (RES) took the position that respirator filters had to be tested with a 0.3 micron, thermally generated DOP aerosol. This defaulting to the HEPA filter certification criteria was a conservative position taken due to a lack of data on other test methods. Since that time, however, filter testing protocols with other aerosol media and/or generating techniques has been shown to provide adequate sensitivity to detect damage to a filter which would void its HEPA characteristics. Therefore, it is the current position that aerosol penetration testing of filters and canisters by licensees should be performed with a testing protocol capable of detecting significant filter damage or deterioration. It is not necessary, nor is it required, to recertify the filter as HEPA prior to use.

Regulatory references: 10 CFR 20.103, 10 CFR 20.1703, NUREG-0041

Subject codes: 8.10

Applicability: All

2.12 RADIOACTIVE WASTE

HPPOS-081 **PDR-9111210220**

Title: Low-Level Radioactive Waste Scaling Factors, 10 CFR Part 61

See IE Information Notice No. 86-20 entitled as above and dated March 28, 1986. Attachment 1 to this Information Notice is entitled "Discussion of Scaling Factor Methodology Problem." These documents alert licensees that scaling factors derived from generic data and applied to specific plant data have caused radionuclide concentration underestimates by factors as high as 10,000 from actual facility samples. Guidance is provided on the appropriate use of scaling factors. The health physics position was written in the context of 10 CFR 20.311, but it also applies to "new" 10 CFR 20.2006. HPPOS-290 and HPPOS-291 contain related topics.

NRC inspections have identified a poor correlation between generic radionuclide concentration data, used to classify waste, and actual radionuclide sample data at some nuclear power plants. These inspections determined that some plants with multiple waste streams had been using one set of scaling factors to classify waste from all their waste streams, despite significant differences in radionuclide concentrations. Such practices may have led to a significant under-estimation of certain radionuclides, directly affecting health and safety, as well as significant over estimates that led to limited disposal capacity and increased costs.

Any licensee who transfers radioactive waste to a land disposal facility or to a licensed waste collector or processor is required by 10 CFR 20.311(d)(1) [or 10 CFR 20.2006(d)] to classify the waste according to 10 CFR 61.55. The three LLW classes (A, B, and C) defined in 10 CFR 61.55(a)(2)-(a)(7) describe how the classification is computed, based on concentrations of certain radionuclides within the waste. Because some of these radionuclides may be difficult to routinely measure using counting equipment normally found at power reactor facilities, 10 CFR 61.55(a)(8) permits use of indirect methods such as scaling factors. Indirect methods can be used to determine concentrations of difficult-to-measure radionuclides provided the measurements correlate with actual measurements.

On May 11, 1983, the NRC's Division of Waste Management forwarded a technical position (TP) paper on waste classification to all licensees that described acceptable procedures for determining the presence and concentration of radionuclides listed in 10 CFR 61.55. The TP states that scaling factors should be developed on a facility and waste-stream specific basis. It also stated that the NRC staff recommended the estimated radionuclide concentration derived from scaling methods and that actually measured be precise to within a factor of 10. Scaling factors based on a single set of detailed sample analysis results were acceptable provided assurances were given that they were representative of all samples. [Note: The May 1983 Technical Position on Waste Classification has been revised. See HPPOS-290 and HPPOS-291.]

The use of generic data (derived from similar waste streams from several other facilities) combined with actual plant sample data to derive facility scaling factors offers a limited number of facility waste stream samples. Difficulties arise when scaling factors derived from the mix of generic and facility-specific data are under-conservative and differ from the actual facility samples by factors greater than 10. Use of scaling factors that produce estimates of radionuclide concentrations differing from the most recent actual measurement by factors greater than 10 may constitute noncompliance with 10 CFR 61.55(a)(8) because the reasonable assurance of the correlation standard can not be met. When these discrepancies are observed, either the scaling factors need to be adjusted to agree with the most recent analysis of that waste stream, or the waste stream needs to be resampled.

As histories of sample analysis facility waste streams are compiled, licensees may determine new scaling factors based on the most recent sample analysis or refine currently used scaling factors by combining the latest analysis with those previously obtained. Licensees may also benefit by identifying individual facility waste streams and determining unique scaling factors for each. Facilities that have more than one operating unit will need separate scaling factors for each waste stream unique to the unit. One set of scaling factors would be appropriate for wastes produced by systems shared by two or more units.

Regulatory references: 10 CFR 20.311, 10 CFR 61.55, 10 CFR 20.2006

Subject codes: 9.0, 9.4, 9.6

Applicability: Reactors

HPPOS-290 **PDR-9306210270**

Title: Waste Form Technical Position, Revision 1

See the letter from P. H. Lohaus to Commission Licensees dated January 24, 1991. Included with is the extensive document, "Waste Form Technical Position, Revision 1", which must be reviewed in its entirety for proper interpretation. The document was written in the context of 10 CFR 20.311, but it also applies to the "new" 10 CFR Part 20, Section 20.2006 and Appendix F to §§20.1001-20.2401. HPPOS-289 and HPPOS-291 contain related topics.

The regulation "Licensing Requirements for Land Disposal of Radioactive Waste," 10 CFR Part 61, establishes a waste classification system based on the radionuclide concentrations in the wastes. Class B and C waste are required to be stabilized. Class A wastes have lower concentrations and may be segregated without stabilization. Class A wastes may also be stabilized and disposed of with class B and C wastes. All Class A liquid wastes, however, require solidification or absorption to meet the free liquid requirements. Structural stability is intended to ensure that the waste does not degrade and (a) promote slumping, collapse, or other failure of the cap or cover over a near-surface disposal unit and thereby lead to water infiltration, or (b) impart a substantial increase in surface area of the waste form that could lead to an increase in leach rate. Stability is also a factor in limiting exposure to an inadvertent intruder since it provides greater assurance that the waste form will be recognizable and nondispersable during its hazardous lifetime. Structural stability of a waste form can be provided by the waste form itself (as with activated stainless steel components), by processing the waste to a stable form (e.g., solidification), or by emplacing the waste in a container or structure that provides stability (e.g., high integrity container or engineered structure).

This technical position on waste form was initially developed in 1983 to provide guidance to both fuel-cycle and non-fuel-cycle waste generators on waste form test methods and results acceptable to the NRC

staff for implementing the 10 CFR Part 61 waste form requirements. It has been used as an acceptable approach for demonstrating compliance with the 10 CFR Part 61 waste stability criteria. This position includes guidance on (1) the processing of wastes into an acceptable, stable waste form, (2) the design of acceptable high integrity containers, (3) the packaging of filter cartridges, and (4) minimization of radiation effects on organic ion-exchange resins. The regulation, 10 CFR 20.311 (d)(1) [or, at present, 10 CFR 20.2006(d) and Section III.A.1 of Appendix F to §§20.2001-2401], requires waste generators and processors to prepare wastes that meet the waste characteristics requirements of Part 61 (including the requirements for structural stability). The recommendations and guidance provided in this technical position are an acceptable method to demonstrate waste stability. One way of demonstrating conformance with the general recommendations contained in this technical position is to reference an approved Topical Report, because such reports are reviewed and approved by the acceptance criteria contained in this technical position. However, additional actions (e.g., plant-specific process control procedures) by waste generators will be needed to demonstrate that a stabilized plant-specific waste stream satisfies Part 61 waste form requirements.

Since the initial issuance of the Technical Position, it has been the intent of the NRC staff to provide additional guidance on waste form as it became necessary to address other pertinent waste form issues. One such issue involves the use of cement to stabilize low level wastes. Field experience and laboratory testing of cement solidified low-level radioactive waste has shown that some unique chemical and physical interactions can occur between the cement constituents and the chemicals and compounds that can exist in the waste materials. Therefore, an appendix (Appendix "A") dealing with the qualification testing, performance confirmation and reporting of mishaps involving cement-stabilized waste forms has been included in this revision to the Technical Position.

To provide more comprehensive guidance and cement stabilization of low-level radioactive waste, Appendix A addressed several areas of concern that were not considered in the May 1983, version of this Technical Position. Thus, information and guidance on cement waste form specimen preparation, statistical sampling and analysis, waste characterization, process control program (PCP) specimen preparation and examination, surveillance specimens and reporting of mishaps are provided in Appendix A. The guidance provided in Appendix A is the culmination of an extended period of study and information gathering and exchange between NRC staff and representatives of various organizations, including government laboratories, the Advisory Committee on Nuclear Waste (ACNW), cement processing vendors, other waste form vendors, nuclear utilities, and state regulatory agencies. Especially useful in the development of the guidance in Appendix A was the information exchanged in the Workshop on Cement Stabilization of Low-Level Radioactive Waste held in June, 1989. The workshop proceedings have been published as an NRC report, NUREG/CP-0103, which is available from either the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082, or National Technical Information Service, Springfield, Virginia 22161.

Regulatory References: 10 CFR 20.311, 10 CFR 20.2006, 10 CFR 61.55, 10 CFR 61.56

Subject codes: 9.0

Applicability: All

HPPOS-289 **PDR-9306180280**

Title: Mixed Nuclide Classification

See the letter from P. H. Lohaus to S. Arnold (Westinghouse Hanford Co.) dated January 4, 1993. A request was made for NRC interpretation of the regulatory requirements in 10 CFR Part 61 paragraph 61.55(a)(5) regarding the classification of wastes containing mixtures of long- and short-lived radionuclides. The question specifically requested clarification on whether radionuclides from both tables of 10 CFR 61.55 should be considered independently. Table 1 of 10 CFR 61.55 contains limits for long-lived radionuclides and Table 2 contains limits for short-lived radionuclides.

The staff position was that the waste generator should calculate the classification of the waste using the sum-of-the-fractions rule separately for the Table 1 isotopes. The following is an acceptable approach to classification of wastes containing both long- and short-lived radionuclides. First, the sum-of-the-fractions for the Table 1 isotopes should be calculated, and then, the sum-of-the-fractions for the Table 2 isotopes should be calculated. If the Table 1 sum does

not exceed 0.1, the classification is determined by using Table 2 only. If the Table 1 sum is between 0.1 and 1, and the Table 2 sum is less than 1 for the Column 3 limits, the waste is Class C. In both cases the sums-of-the-fractions are calculated separately for the Table 1 isotopes and the Table 2 isotopes.

Regulatory references: 10 CFR 61.55

Subject codes: 9.0, 9.4

Applicability: All

HPPOS-042 **PDR-9111210190**

Title: Contaminated Soil at Big Rock Point

See the memorandum from F. J. Congel to C. J. Paperiello dated April 11, 1985. Contaminated soil cannot be left in place without NRC approval pursuant to 10 CFR 20.302. 10 CFR 30.14 on "Exempt Concentrations" is not applicable. The health physics position was written in the context of 10 CFR 20.105, 20.106, and 20.302, but it also applies to the "new" 10 CFR Part 20, Sections 20.1301, 20.1302, and 20.2002.

NRR reviewed the matter of contaminated soil with regard to the need for the licensee to request permission under 10 CFR 20.302 [or 10 CFR 20.2002] to dispose of the material by leaving it in place. NRC considered the information provided and made the following conclusions:

1. The licensee has licensed byproduct material in a location and form where it is not secure (e.g., against the weather). Even though the NRC might find, after review of the circumstances, that leaving the material in place is satisfactory with regard to the public health and safety and with regard to environmental impacts, the licensee cannot unilaterally make such a determination. The licensee must do something about the disposition of the material; the choices are either to excavate the material, package it and ship it to a licensed burial ground or to request, pursuant to 10 CFR 20.302 [or 10 CFR 20.2002], approval of a procedure to dispose of it in some other manner (e.g., by leaving it in place).

2. Including the estimated total quantity of radioactivity as released effluent in their second half 1984 effluent report does not relieve the licensee of the responsibility for the proper disposition of the licensed material, the majority of which remains in place in the soil. Even though weathering and leaching may deliver some of the radioactivity to Lake Michigan within seven years, some will remain in the soil at the location of the leak; it continues to be licensed byproduct material for which the licensee is responsible.

3. For purposes of determining compliance with 10 CFR 20.105 and 20.106 [or 10 CFR 20.1302 and 20.1301, respectively], the licensee is responsible for accounting for release of radionuclides to the environment (e.g., to Lake Michigan, in the time periods in which they actually occur).

4. 10 CFR 30.14, "Exempt Concentrations," is not applicable to these circumstances; the licensee was not given specific authorization to introduce the byproduct into the soil. Applicable regulations, 10 CFR Part 20, do not provide lower limits to concentrations and quantities for which licensees are responsible.

Regulatory references: 10 CFR 30.14, 10 CFR 20.105, 10 CFR 20.106, 10 CFR 20.302, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.2002

Subject codes: 9.0, 9.3, 9.7

Applicability: Reactors

HPPOS-043 **PDR-9111210193**

Title: Disposal of Exempt Quantities of Radioactive Material

See the memorandum from J. M. Gutierrez to J. H. Joyner dated April 13, 1983, and the incoming request from J. H. Joyner dated March 22, 1983. It is an OELD opinion that radioactive material held under license can only be disposed of pursuant to 10 CFR Part 20, even when the quantity disposed is less than that listed in 10 CFR 30.71, Schedule B. The document clarifies the scope and purpose behind 10 CFR Parts 20 and 30. The health physics position was written in the context of 10 CFR 20.301, 20.303, and 20.306, but it also applies to the "new" 10 CFR Part 20, Sections 20.2001, 20.2003, and 20.2005. HPPOS-190 contains a related topic.

In an incident considered for enforcement action, a janitor employed by a licensee removed a five gallon drum containing one to two microcuries of tritium. The drum was subsequently sent to a landfill before

the licensee discovered the loss. Neither 10 CFR Part 20 nor the terms of the materials license in question would authorize disposal of one to two microcuries of tritium in a landfill. Specifically, although 10 CFR 20.303 and 20.306 [or 10 CFR 20.2003 and 20.2005] permit the disposal of small quantities of tritium (hydrogen-3) by a means other than to an authorized recipient, neither regulation section is applicable to the facts of this situation.

The opinion of OELD was sought because the incident raised the question of whether a licensee should be cited for an act with so little public health and safety consequence. In addition, it was suggested that certain regulations appear to authorize disposal of licensed material in individual quantities that do not exceed those listed in 10 CFR 30.71, Schedule B by transfer to any recipient, including garbage collectors and sanitary landfills.

10 CFR Part 30, specifically Section 30.71, Schedule B, establishes quantities of potentially licensable material that are sufficiently small so as not to warrant licensing. In contrast to the threshold determination of what quantities should be licensed, 10 CFR Part 20 governs the waste disposal process for material determined to be licensable, regardless of the quantities being considered for disposal.

As guidance, a general rule of statutory construction is that when two regulations are in apparent contradiction, the specific governs the general. Thus, although 10 CFR 30.18(a) does authorize the receipt, possession, use, transfer, ownership or acquisition of potentially licensable material in quantities below that listed in Schedule B of 10 CFR 30.71, the governing regulation for purposes of waste disposal is 10 CFR 20.301 [or 10 CFR 20.2001]. Therefore, once a license is issued, the terms of that license and Part 20 govern with respect to waste disposal. Schedule B is irrelevant to that question, but it rather goes to the issue of whether a quantity of a particular substance in the first instance should be licensed.

Therefore, when the licensee inadvertently disposed of one to two microcuries of tritium, it was in violation of both the terms of its license and the regulations of 10 CFR 20.301(a) [or 10 CFR 20.2001(a)(1)]. From an enforcement perspective, the fact that the amount disposed would not in itself be licensable is irrelevant.

Regulatory references: 10 CFR 20.301, 10 CFR 20.2001, 10 CFR 30.18, 10 CFR 30.71

Subject codes: 9.0, 9.7, 11.2, 12.7

Applicability: All

HPPOS-150 **PDR-9111220094**

Title: Disposal Requirements for Specific and Exempt Licensed Smoke Detectors

See the letter from J. W. N. Hickey to D. L. Tremblay (Simplex Time Recorder Company) dated October 5, 1981. Imported smoke detectors possessed under a specific license must be returned to the manufacturer. A licensee who possesses detectors distributed as exempt items is exempt from regulatory requirements regarding the smoke detectors, and they may be disposed of as ordinary trash.

Your letter to General Counsel dated September 8, 1981 has been referred to the Division of Fuel Cycle and Material Safety. In our telephone conversion, you explained that your company possesses two types of smoke detectors: those imported, possessed, and distributed in accordance with NRC License Nos. 20-17584-01 and 20-17584-02E, and those obtained from an American manufacturer as exempt units.

We agreed that the imported detectors must be returned to the manufacturer in accordance with your licenses, and that your letter concerns the domestic units. To the extent that you possess domestic smoke detectors distributed as exempt units, you are exempt from any regulatory requirements. Therefore, you may dispose of these units as ordinary trash.

Regulatory references: 10 CFR 30.20, 10 CFR 32.26

Subject codes: 3.3, 9.0

Applicability: Byproduct material

HPPOS-034 **PDR-9111210157**

Title: Applicability of 10 CFR 20.303(d) to Disposable Diapers Contaminated with Tc-99m.

See the memorandum from J. R. Mapes to J. R. Metzger dated January 6, 1979, the memorandum from

J. R. Metzer to A. B. Davis dated January 18, 1979, and the incoming request of A. B. Davis dated December 13, 1978. It is an OELD opinion that the exemption in 10 CFR Part 20.303(d) for excreta applies only to excreta discharged to a sanitary sewer and does not apply to excreta remaining on disposable diapers placed in trash cans or disposed of otherwise. The health physics position was written in the context of 10 CFR 20.301 and 20.303, but it also applies to the "new" 10 CFR Part 20, Sections 20.2001 and 20.2003.

During a Region III inspection of a children's hospital, an inspector found an infant's disposable diaper contaminated with Tc-99m in a trash can that was not labeled to indicate the presence of radioactive material and that in fact was a normal cold trash can. The hospital had given diagnostic doses of Tc-99m to infants. Diapers soiled with feces were rinsed in the toilet and then placed in the cold trash (i.e., non-radioactive trash).

In response to citations for failure to survey diapers prior to disposal, and disposal of radioactive material by a means not authorized by 10 CFR 20.301 [or 10 CFR 20.2001], the licensee stated they called several children's hospitals across the country and determined that they all use the same method of diaper handling. They also point out that 10 CFR 20.303(d) [or 10 CFR 20.2003(b)] states that "excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section," and that this should exempt their diapers.

Region I was contacted and they stated that they have never looked into diaper disposal at medical institutions. Several HPs in both Regions I and III who have worked at medical institutions have stated that persons receiving diagnostic doses of radioactive material are not considered radioactive and are not segregated from other patients and no special handling is given to their bed clothes, bed pans, or excreta. Special handling is reserved for patients under therapy.

Diapers from children and excreta from incontinent adults undergoing nuclear diagnosis would be considered not radioactive. On the other hand, 10 CFR 20.303 [or 10 CFR 20.2003] addresses disposal by release into the sanitary sewer. The exception in 10 CFR 20.303(d) [10 CFR 20.2003(b)] applies to excreta that enters the sewer where it is held and diluted before release to an unrestricted area. The citation was not for the feces washed into the sewer but for material remaining on the diapers in normal cold trash that was disposed of by normal trash methods. There appears to be no exemption for material excreted and not disposed via the sanitary sewer.

The OELD opinion agrees with the Region III opinion (i.e., diapers are not exempt from the requirements of 10 CFR 20.303 [or 10 CFR 20.2003] because they contain excreta residue, and therefore, must be labeled as contaminated waste). The exemption only applies to material actually released to the sanitary sewer. Hospitals ordinarily hold contaminated waste for about seven half lives or until there is no detectable contamination and then dispose the material via normal trash channels. This would be particularly simple for Tc-99m with a half life of 6 hr. Of course, waste destined for normal trash disposal must be placed in a suitable holding area as contaminated waste until the radioactivity has decayed to nondetectable levels.

Regulatory references: 10 CFR 20.303, 10 CFR 20.2003

Subject codes: 9.0, 9.3, 9.7

Applicability: Byproduct material

HPPOS-035 **PDR-9111210162**

Title: Scope of Exemption in 10 CFR 20.303(d) for Disposal of Patient Excreta in Sanitary Sewers

See the memorandum from W. J. Olmstead to H. E. Book dated October 13, 1982, and the incoming request from H. E. Book dated August 31, 1982. It is an OELD opinion that the exemption in 10 CFR 20.303(d) applies even when disposals of patient excreta do not follow direct routes from patient to sewer (e.g., urine samples sent to a laboratory for analysis). Thus, records need not be kept per 10 CFR 20.401(b). The health physics position was written in the context of 10 CFR 20.6, 20.303, and 20.401, but it also applies to the "new" 10 CFR Part 20, Sections 20.1006, 20.2003, and 20.2108.

During an inspection in a nuclear medicine laboratory, a Region V inspector asked a medical technologist if any I-131 waste was disposed to the sanitary sewer. When the answer was affirmative, the inspector asked to see the record of such disposals required by 10 CFR 20.401(b) [10 CFR 20.2108(a)]. He was told that no records were kept. On the basis of that informa-

tion, a Notice of Violation was issued, including a citation for noncompliance with 10 CFR 30.51(a) and 20.401(b) [or 10 CFR 20.2108(a)], both of which require records of disposal.

The licensee responded that urine collected during uptake studies and containing I-131 was disposed to the sanitary sewer after being held for some decay. While some records were maintained, they did not include the quantity of I-131 in the urine at the time of disposal. The physician stated, as part of his corrective action, the quantity of I-131 in microcuries would be recorded for each disposal. Region V told the licensee they would request an interpretation of the regulations. It was suggested to the licensee that he continue to maintain records of the disposals, but that he would be informed the contents of the interpretation when received.

10 CFR 20.303 [or 10 CFR 20.2003] specifies the conditions under which licensees may dispose of licensed material by release into a sanitary sewer system and provides only one exception to these conditions. That exception is contained in 10 CFR 20.303(d) [or 10 CFR 20.2003(b)] which states in part:

"Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section."

It is an OELD opinion that as long as two basic conditions of the exemption are satisfied, licensees are permitted to discharge patient excreta into sanitary sewers without limitation. The two conditions for exemption that must be satisfied are: (1) the matter to be disposed of must be excreta, and (2) the excreta must be obtained from individuals undergoing medical diagnosis or therapy with radioactive materials. OELD also expressed the opinion that exempt disposals of patient excreta should not be subject to the recordkeeping requirements contained in 10 CFR 20.401(b) [or 10 CFR 20.2108(a)].

In must be noted that in accordance with 10 CFR 20.6 [or 10 CFR 20.1006], the opinions expressed by OELD do not constitute an interpretation which will be recognized as binding upon the Commission.

Regulatory references: 10 CFR 20.303, 10 CFR 20.401, 10 CFR 20.2003, 10 CFR 20.2108

Subject codes: 2.1, 9.0, 9.7

Applicability: Byproduct Material

HPPOS-319 **PDR-9307060010**

Title: Technical Assistance Request, Medical College of Virginia, Richmond, VA; Policy Guidance Concerning Use of Xenon-133 in Saline

See the memorandum from J. E. Glenn to D. M. Collins dated June 25, 1993. This memo responds to a technical assistance request from Region I, dated May 29, 1992, concerning a request from the Medical College of Virginia for policy guidance. The licensee requested clarification whether xenon-133 (Xe-133) in saline should be considered a gas and the subsequent applicability requirements of 10 CFR 35.205. The licensee intended to administer Xe-133 in saline intravenously to patients for cerebral blood flow studies. These patients cannot be moved into a room at negative pressure for the studies without creating a potential health risk.

Xe-133 dissolved in saline is technically not a gas. Therefore, the licensee does not need to adhere to the requirement to administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms as stipulated in 10 CFR 35.205(b). However, in case of a spill of the saline solution before administration, the xenon will be released from the suspension as a gas. The licensee should indicate if the xenon is dissolved in saline under pressure. If so, additional precautions may be necessary if the vial containing the Xe-133 is inadvertently punctured. The rebreathing system should recapture all exhaled xenon. It will be essential for the licensee to post spilled gas clearance times and have adequate safety precautions to ensure minimal exposure of personnel and patients in the Neuroscience Intensive Care Unit.

Therefore, the requirements of 10 CFR 35.205(a), (c), (d), and (e), that stipulate air concentrations be within 10 CFR Part 20 limits, calculation and posting of spilled gas clearance times, monthly checks of the operation of the reusable collection systems, and measurement of ventilation rates in the area each six month, should be instituted as part of the licensee's

protocol for use of Xe-133 in cerebral blood flow studies.

Regulatory references: 10 CFR 35.205

Subject codes: 9.1, 11.2, 11.3, 12.19

Applicability: Byproduct Material

HPPOS-291 PDR-9306210267

Title: Waste Volume Reporting Requirements of RG 1.21 and the Need for Waste Classification Documentation

See the memorandum from S. Bahadur and L. J. Cunningham to J. H. Joyner (and others) dated December 7, 1992. The minutes of the April 1992 Reactor Health Physics Counterpart meeting identified two items needing resolution. The first item was a question regarding volumes and activity of low-level waste sent off-site for processing that should be reported per Regulatory Guide 1.21 in the reactor licensees' semi-annual (now annual) effluent release reports (i.e., per 50.36a). This question arose again from a contractor involved in decommissioning activities at the Shoreham plant. The second item involved the need for a licensee to provide waste classification documentation for radioactive material shipped to a processor for segregation before subsequent offsite disposal. HPPOS-081 and HPPOS-290 contain related topics.

With respect to the first item, the solid waste information reported in the annual report should be the volume and activity of the low-level waste leaving the reactor site that the licensee believes will be sent directly, or via a processor or collector, to a licensed disposal site. Consistent with this response, and Regulatory Guide 1.21, Table 3, the report should identify the type of waste, the number of shipments, mode of transportation, and destination of the waste shipments leaving the licensee's facility. If it is known by the licensee that waste shipped to a processor is to be received back following processing, the volume and activity of the processed waste would not be included in the annual reports until the waste again leaves the site for disposal.

With respect to the second item, the current regulations [10 CFR 20.311(d) or, at present, 10 CFR 20.2006(d) and Section III.A in Appendix F to 10 CFR Part 20 (§§20.1001-20.2401] require the preparation of a manifest for transfers of radioactive waste to a land disposal facility, a licensed waste collector, or a licensed waste processor (see HPPOS-081). The term "radioactive waste," as used above, applies to the transfer of any radioactive material for which no further use by the license is foreseen (e.g., material sent for compaction prior to disposal is waste; contaminated tools transferred for decontamination before intended reuse is not waste).

On the follow-on question, the regulations do not require a generator to classify waste being sent to a processor. Classification is only required if the generator is shipping low-level waste to a collector or directly to the disposal site. Note that the May 1983 Technical Position on Radioactive Waste Classification incorrectly states that transfer of waste to a processor require licensees to classify the waste. A pending revision to this Technical Position incorporates the needed correction (see HPPOS-290).

Regulatory references: 10 CFR 20.311, 10 CFR 20.2006, Regulatory Guide 1.21

Subject codes: 3.5, 9.3, 9.4, 9.6

Applicability: All

HPPOS-220 PDR-9111220108

Title: 10 CFR 20.311, "Transfer for Disposal and Manifests"

See NRC Information Notice No. 88-16 entitled as above and dated April 22, 1988. The manifest accompanying low-level waste shipments must provide enough information to allow traceability to the original generator. One acceptable approach would be to provide, for each container, a simple generator code (e.g., A, B, C), and refer to an attached list for the name, address, and telephone number of the generator corresponding to the code. The health physics position was written in the context of 10 CFR 20.311, but it also applies to "new" 10 CFR 20.2006.

10 CFR 20.311 [or 10 CFR 20.2006] states that each shipment of radioactive waste to a land disposal facility must be accompanied by a manifest that describes the waste shipment. Among other requirements, this description must include the name, address, and telephone number of the waste generator. The purpose of

identifying the waste generator is twofold. It provides a source of information about the waste if questions or problems arise, and it enables development of a representative data base showing factors such as actual generators, type of licensee, and state where generated, rather than data skewed by large volumes from brokers or waste collectors.

For waste collector licensees who handle only packaged waste, Paragraph 20.311(e) [or Paragraph 20.2006(d) and Section III.B in Appendix F to 10 CFR Part 20 (§§20.1001-20.2401)] provides two options for shipment manifest preparation. The first option allows the waste collector to prepare a new manifest to reflect consolidated shipments. The new manifest serves as a listing or an index for the detailed generator manifests, which must be attached to the new manifest. The second option allows the waste collector to prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information contained in 10 CFR 20.311(b) [or Section I in Appendix F to 10 CFR Part 20 (§§20.1001-20.1401)]. Licensed waste processors who treat or repackage waste are considered in Paragraph 20.311(f) [or Section III.C in Appendix F to 10 CFR Part 20 (§§20.1001-20.2401)] to be the waste generators. Waste processors must prepare a new manifest reflecting this responsibility.

Contrary to Paragraph 20.311(e)(2) [or Section III.B.2 in Appendix F to 10 CFR Part 20 (§§20.1001-20.2401)], waste collectors who prepare new manifests for shipping prepackaged low-level waste to land disposal facilities have sometimes failed to either consistently identify the original waste generators or consistently provide sufficient information to maintain the identity of the waste generators for each specific waste container. The intent of 10 CFR 20.311 [or 10 CFR 20.2006] is to ensure that each waste container delivered to a land disposal facility is traceable to a specific waste generator. Waste collector licensees should ensure that disposal facility shipment manifests identify, for each container of prepackaged waste, the name, address, and telephone number of the person generating the waste. Similarly, land disposal operators accepting prepackaged waste from collectors should ensure that container-specific waste generator information is included.

One acceptable approach would be to provide for each container a simple generator code (e.g., A, B, C), and refer to an attached list for the name, address, and telephone number of the generator corresponding to the code. Another acceptable approach would be to print the names, addresses, and telephone numbers of the generators directly on the manifest continuation sheets. Other approaches are acceptable provided the required waste generator information corresponds to individual waste containers.

Regulatory references: 10 CFR 20.311, 10 CFR 20.2006

Subject codes: 2.1, 3.5, 9.6

Applicability: All

HPPOS-169 **PDR-9111220186**

Title: Disposal of Byproduct Material Used for Certain *In Vitro* Clinical or Laboratory Testing

See the memorandum from J. D. Kinneman to Materials Inspectors dated December 15, 1980. Most waste generated from use of *in vitro* test kits under the general license of 10 CFR 31.11 can be disposed in non-radioactive trash. However, mock iodine-125 sources listed in 31.11(a)(7) must be disposed of as required by 10 CFR 20.301. This health physics position also applies to "new" 10 CFR 20.2001.

Licensees performing certain *in vitro* tests that contain byproduct materials are authorized to dispose of the waste in non-radioactive trash. Under the provisions of 10 CFR 31.11, a general license may be issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use certain byproduct materials in prepackaged form for *in vitro* clinical or laboratory testing. The provisions of this paragraph exempt most byproduct materials used pursuant to the general license from the requirements of 10 CFR Parts 19, 20, and 21. Because of the exemption from the provisions of 10 CFR 20, most radioactive wastes generated in the use of these *in vitro* tests may be disposed of as ordinary waste (i.e., non-radioactive trash). Before these materials can be discarded in the trash, all radiation labels should be removed and destroyed. [Note: Mock iodine-125 sources listed in 10 CFR 31.11(a)(7) must be disposed of as required by 10 CFR 20.301 and 10 CFR 20.2001.]

Regulatory references: 10 CFR 20.301, 10 CFR 20.2001, 10 CFR 31.11

Subject codes: 9.0, 9.7

Applicability: Byproduct material

HPPOS-300 **PDR-9306220335**

Title: Letter Dated May 20, 1992, Regarding Alternative Method of Disposal for Contaminated Plastic Test Tubes

See the letter from R. E. Cunningham to K. B. Asarch (Diagnostic Products Corporation) dated June 26, 1992. The letter responds to a request that the NRC provide a written position on: (1) the licensee's proposed method for decontamination and disposal of radioactively contaminated test tubes; and (2) whether there is a specific requirement for NRC licensees to obtain NRC approval of this disposal method pursuant to 10 CFR 20.302 [or, at present, 10 CFR 20.2003].

It is the NRC's position that each licensee must make an adequate survey of trash prior to disposal as required by 10 CFR 20.201(b) [or, at present, 10 CFR 20.1501(a)(2)]. If the trash is not known to contain radioactive material and its radiation exposure levels are not distinguishable from background, it may be disposed without regard to radioactive material disposal procedures (i.e., ordinary or non-radioactive trash). This would be the case with test tubes that are decontaminated (such as washed with bleach) and surveyed prior to disposal. This does not apply for decay-in-storage wastes as it is already known to contain radioactive material. Decay-in-storage waste must be held for the length of time specified in the license condition or in the regulations (generally 10 half-lives).

Licensees are required by 10 CFR 20.201(b) [or 10 CFR 20.1501(a)(2)] to make surveys that are "reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." A licensee must be able to demonstrate to NRC inspectors that the method of survey used is capable of detecting the presence of radioactive material in the test tubes. If a licensee survey bulk groups of random samples of the test tubes rather than each single test tube, then the licensee must be able to demonstrate that their survey method is sufficient to detect all radioactive material prior to disposal. Preferably, licensees will document their tests to demonstrate survey adequacy.

Licensees are currently allowed to dispose of liquid effluents pursuant to 10 CFR 20.303 [or 10 CFR 20.2003], and if the test tubes are no longer contaminated, there are no controls on their disposal. Therefore, regarding the second request, it would not be necessary to obtain NRC approval for a practice specifically allowed by the regulations.

On January 1, 1994, the revised 10 CFR Part 20 becomes effective for all licensees. At that time, 10 CFR 20.2003 will limit disposal of licensed material into the sanitary sewer system. The limiting value for monthly average concentrations is 2×10^{-5} microcuries per milliliter for iodine-125, assuming that iodine-125 is the only radionuclide released into the sanitary sewers. The comparable limit is 4×10^{-5} microcuries per milliliter for release of soluble iodine-125 in the current Part 20. When a licensee implements the revised Part 20, the allowable release concentration drops by a factor of two. Regardless of how the test tubes are disposed, any releases of licensed material into the sanitary sewer system must meet the requirements of the current 10 CFR 20.303 or 10 CFR 20.2003 after implementation of the revised 10 CFR Part 20.

Regulatory references: 10 CFR 20.201, 10 CFR 20.303, 10 CFR 20.1501, 10 CFR 20.2003

Subject codes: 9.0, 9.2, 9.7

Applicability: Byproduct Material

HPPOS-030 **PDR-9111210152**

Title: Burial of Patients With Permanent Implants

See the memorandum from L. B. Higginbotham to A. B. Davis dated April 3, 1980. It references NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," regarding burial of patients with permanent implants. This NCRP report gives levels of radioactivity below which no precautions are needed.

A hospital requested guidance on the disposition of a deceased patient with a permanent implant of 20 mCi of I-125 seeds. They were advised by IE:HQ that, since there were no regulatory requirements, the con-

servative approach would be to remove the implants, if practicable. It was also suggested that a policy might be needed on this issue to provide guidance.

As a general rule, any licensee who requests guidance should be told that he is obligated to adhere to all regulatory requirements, and if no regulatory requirements exist, he may take any action he deems appropriate. Regional offices may inform licensees where to obtain guidance by suggesting generally accepted documents such as NCRP reports, ICRP committee reports, regulatory guides, and ANSI standards.

If the licensee requests more specificity and doesn't have certain reports and time is essential, regional personnel may summarize applicable guidance sections (if available in the region) for the licensee, making it clear that the licensee is not obligated to use regional suggestions to prevent the licensee from believing that NRC is imposing new requirements on him.

In this particular case, the implants would not have to be removed since permanent implants are not intended to be removed. The guidance in NCRP Report No. 37 that deals with management of patients with therapeutic amounts of radionuclides establishes levels of radioactivity below which no precautions are necessary. The deceased patient also contained materials below precautionary concerns, and NCRP reports are generally accepted as appropriate guidance for use in the absence of regulatory requirements.

For patients who die, there are precautions in NCRP Report No. 37 to be taken for physicians performing autopsies and precautions for handling the deceased when no autopsies are performed. There are also precautions for cremating, including total millicurie amounts per year that can be handled safely by a single crematorium, with some exceptions for Ta-182 and Ir-192 that have been shown to significantly contaminate crematoriums. There appears to be no restrictions or precautions on burial except in preparing the deceased for burial.

The guidance in NCRP Report No. 37 is considered to cover this situation adequately, and it is not believed a policy statement is needed on this issue.

Regulatory references: NCRP Report No. 37

Subject codes: 9.0, 9.4, 12.8

Applicability: Byproduct Material

HPPOS-258 **PDR-9306070112**

Title: Policy and Guidance Directive FC 86-10, "Onsite Burial by Material Licensees"

See the memorandum from R. E. Cunningham to Regional Administrators (and Branch Chiefs, Division of Fuel Cycle and Material Safety) dated October 9, 1986, and the enclosed memorandum from V. Stello, Jr., to Addressees dated September 23, 1986. Policy and Guidance Directive FC 86-10 provides updated guidance for reviewing applications requesting authorization for licensees to bury their own radioactive waste onsite. Applications for such authorizations are made pursuant to 10 CFR 20.302. This health physics position also applies to "new" 10 CFR Part 20.2002.

Since the deletion of 10 CFR 20.304, "Disposal by Burial in Soil" (January 28, 1981), and the issuance of IEIN 83-05, "Obtaining Approval for Disposal of Very-Low-Level Radioactive Waste - 10 CFR 20.302" (February 24, 1983), a number of medical, academic, industrial, and reactor licensees have applied to the NRC for approval pursuant to 10 CFR 20.302 to dispose of licensed material by onsite burial or disposal in offsite landfills or hazardous waste disposal sites. The number of such licensee requests has increased in the past few years, and because of waste volume limitations imposed on existing sites by the recently enacted Low-Level Radioactive Waste Policy Amendments Act of 1985, the NRC anticipates a continuation of this tend over the next five years.

Several Divisions within more than one office at NRC Headquarters, as well as the Regional Offices and the Agreement States, have within their respective regulatory purview the responsibility for performing reviews and technical evaluations of proposed waste disposal activities by licensees. Consequently, it is important that a centralized cognizance within the NRC for waste disposal actions under 10 CFR 20.302 [or 10 CFR 20.2002] be maintained and that NRC reviews and decisions relative to these activities be internally consistent and uniformly applied. Examples of areas where agency policy and action should be consistent are as follows: the disposal of wastes which are both

radioactive and chemically hazardous, the notification of State and local authorities of licensee-proposed burials, the authorization of disposal of low-activity waste offsite in the public domain, and the authorization of disposal of potentially recyclable materials contaminated with radioactivity.

To ensure consistency and uniformity in NRC reviews and evaluations, the Division of Waste Management, NMSS, is assigned responsibility to monitor all 10 CFR 20.302 [or 10 CFR 20.2002] actions. Discussions and coordination between offices should take place for the purpose of developing consistent criteria for acceptable waste disposal practices. Recent guidance to non-reactor licensees seeking authorizations pursuant to this regulation has been published in NUREG-1101, Vol. 1. Additional guidance for other applications which are not covered in NUREG-1101 will be completed in the near future. Guidance for reviews of applications from utilities for disposal of reactor-generated waste, pursuant to 10 CFR 20.302 [or 10 CFR 20.2002], is in preparation for incorporation into the Standard Review Plan (NUREG-0800).

NUREG-1101, Vol. 1, "Onsite Disposal of Radioactive Waste," March 1986, provides guidance for non-commercial disposal by subsurface burial. It specifies information to be provided by the licensee so that an adequate evaluation of the application can be performed by NRC staff. In addition, this guidance provides site parameters, radionuclide limits, and disposal methods normally acceptable to the NRC staff. Limiting conditions are described for different categories of radionuclides with respect to total radioactivity, waste packaging, burial frequency, and other conditions normally acceptable for burial.

Licensees applying for onsite burial authorization should be referred to NUREG-1101 for guidance in preparing their requests. If an application meets the guidelines of NUREG-1101, the appropriate Region can issue an amendment without referring the request to NRC Headquarters. A copy of the final licensing actions plus any assessment of the burial request should be sent to the Director, Division of Waste Management. Any questions or special cases should be referred directly to the Director, Division of Waste Management.

Policy and Guidance Directive FC 84-12, Rev. 1, is being revised to reflect the fact that burial cases do not always need to be referred to Headquarters. Policy and Guidance Directive FC 84-7, Rev. 1, pertaining to management of sites containing material already buried pursuant to 10 CFR 20.304, remains unchanged.

Regulatory references: 10 CFR 20.302, 10 CFR 20.2002, NUREG-1101

Subject codes: 9.0, 9.4, 9.7

Applicability: All

HPPOS-031 **PDR-9111210155**

Title: Exemption of H-3 or C-14 Contaminated Scintillation Media or Animal Tissues Under 10 CFR 20.306

See the letter from D. A. Nussbaumer to J. D. Dunkleberger (New York State Energy Office) dated September 8, 1981. The letter states that H-3 or C-14 contaminated scintillation media or animal tissue that qualifies for disposal under 10 CFR 20.306 is exempt from further regulation. If it is transferred to an Agreement State without comparable regulation, the waste is subject to regulation by that State. This health physics position also applies to "new" 10 CFR 20.2005.

Representatives of New York State's radioactive material control agencies had met and reviewed NRC's rule (FR, Vol. 47, No. 47, pp. 16230-16234, March 11, 1981) on the disposal of certain H-3 and C-14 contaminated wastes. In considering the NRC rule, questions concerning the exemption, jurisdiction, recycling and importation of wastes arose that needed to be resolved or clarified before the State of New York could formally adopt comparable provisions.

In response to the exemption question, NRR replied that upon determination by a licensee that H-3 or C-14 contaminated scintillation media or animal tissue qualified for disposal as non-radioactive waste under 10 CFR 20.306 [or 10 CFR 20.2005] or equivalent Agreement State provisions, the material is exempt from further regulation as radioactive material.

In response to the jurisdictional question, NRR replied that if radioactive wastes were exempt from regulations under 10 CFR 20.306 [or 10 CFR 20.2005] in one jurisdiction and subsequently transferred into the jurisdiction of an Agreement State that has not

adopted comparable regulations, the waste is subject to regulation and licensing by the Agreement State.

In response to the recycling question, NRR stated that 10 CFR 20.306 [or 10 CFR 20.2005] pertains to the disposal of specific wastes and that these wastes are garbage or trash-material without value. In the context used, the term "disposal" means the removal of waste from the public and dispersing it to the environment through incineration, landfill burial, etc., and that all disposal techniques decrease the concentration of waste material. Any process, such as reclamation or recycling, that increases the volume concentration of the waste byproduct is not an appropriate disposal technique and is subject to licensing.

On the question of the importation of H-3 or C-14 contaminated scintillation media or animal tissue, NRR replied that the likelihood of this situation is remote. However, because scintillation media or animal tissue wastes originating outside the U.S. were not disposed of by "any [USNRC] licensee," 10 CFR 20.306 [or 10 CFR 20.2005] does not apply. Pursuant to 10 CFR 110.11, an NRC or Agreement State licensee, such as a waste broker, is exempt from an import license to the extent it imports byproduct material that it is authorized to possess under an exemption from licensing requirements or a specific or general license issued by the Commission or an Agreement State.

Regulatory references: 10 CFR 20.306, 10 CFR 20.2005

Subject codes: 9.0, 9.7, 12.9

Applicability: All

HPPOS-295 **PDR-9306220067**

Title: Disposal of Solid Scintillation Media

See the memorandum from J. E. Glenn to R. R. Bellamy (and others) date January 29, 1991. The memo concerns the disposal of solid scintillation media that are available from Beckman Corporation under the trade names Ready-Cap and Ready-Filter. The health physics position was written in the context of 10 CFR 20.306, but it also applies to "new" 10 CFR 20.2005.

Recently, Region I informed NRC Headquarters of the use of solid scintillation media, available from Beckman Corporation under the trade names Ready-Cap and Ready-Filter, for counting samples in liquid scintillation counters. The media consists of urethane silicate with a CRT phosphor. 10 CFR 20.306(a) [or 10 CFR 20.2005(a)(1)] allows for the disposal of liquid scintillation media containing 0.05 microcuries or less of tritium (H-3) or carbon-14 (C-14) per gram of medium without regard to its radioactivity. The media noted above are used for liquid scintillation counting; therefore, 10 CFR 20.306(a) [or 10 CFR 20.2005 (a)(1)] also applies to them.

According to the manufacturer, the volume of mass required for the counting of samples is approximately 100 times less than the mass normally required in the use of liquid scintillation media, and under normal use, the specific activity of the samples would exceed 0.05 microcuries per gram of medium. Therefore, the manufacturer suggest that the samples normally be disposed of as dry waste in a low level radioactive burial site. However, if the samples meet the specific activity requirements of 10 CFR 20.306(a), the samples may be disposed of without regard to their radioactivity.

Regulatory references: 10 CFR 20.306, 10 CFR 20.2005

Subject codes: 9.0, 9.2, 9.3, 9.7

Applicability: All

HPPOS-158 **PDR-9111220137**

Title: 10 CFR 20.303(d) - Disposal by Release Into Sanitary Sewerage Systems

See the excerpt from IE Manual entitled as above and dated February 26, 1973. Under 10 CFR 20.303(d), a licensee may release up to one curie per year into any one sewerage system. If a licensee maintains facilities in several cities, each facility could release up to one curie per year provided that separate sewerage systems are involved. This health physics position also applies to "new" 10 CFR 20.2003(a)(4).

A literal interpretation of 10 CFR 20.303(d) appears to indicate that the maximum quantity of radioactive material that a licensee may release to a sanitary sewer is one curie per year. While this is essentially true,

this also implies that the sum total for all geographical sites under one license may not exceed the above limit, even if a licensee has 10 or 100 facilities spread throughout the country. OGC advised that the words in the regulation, "... radioactive material released into the sewerage system may not exceed ..." could be construed to mean that no more than one curie may be released into any one sewerage system by a licensee. [Note: 10 CFR 20.2003(a)(4) states similarly: "The total quantity of licensed and other radioactive material that the licensee releases in the sanitary sewage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37GBq) of carbon-14, and 1 curie (37 Gbq) of all other radioactive materials combined."]

"Sewerage systems" are generally local (e.g., city) so that if a licensee maintains facilities in several cities, each facility could release up to one curie per year, provided separate sewerage systems are involved. OGC also advised that this interpretation is consistent with the intent of the regulations, i.e., to maintain releases at a minimum to a sewerage system in the interest of precluding any significant health problems. By contrast, a much worse situation could be conceived where a thousand licensees use the same sewerage system, which is perfectly legal under the present regulations, but would appear to be of greater significance than the above considerations.

Regulatory references: 10 CFR 20.303, 10 CFR 20.2003

Subject codes: 9.2, 9.7

Applicability: All

HPPOS-106 **PDR-9111210246**

Title: Use of Hydro Nuclear Service Dry Active Waste Disposal

See the memorandum from J. G. Partlow to J. A. Hind dated June 14, 1985, and the enclosed memorandum from L. J. Cunningham to L. R. Greger dated May 17, 1985. If the equipment performs per Hydro Nuclear's description and is operated according to their instructions, there appears to be no problem with licensee use for sorting of dry active waste. The health physics position was written in the context of 10 CFR 20.201, 20.301, and 20.302, but it also applies to the "new" 10 CFR Part 20, Sections 20.1501, 20.2001, and 20.2002.

In response to the Region III memorandum dated May 21, 1985, OIE needs to point out one clarification. That is, the NRC staff has not yet formally evaluated the Hydro Nuclear System. Our understanding is that Hydro Nuclear will submit a topical report to NRC for review in the near future. Upon completion of this review, we will send you a copy of the staff's review.

In the meantime, our position is that if the equipment performs according to Hydro Nuclear's description and is operated according to their instructions, we see no problem with licensee use. However, the licensee should contact NRR if it plans to dispose of any waste containing detectable amount of radioactivity pursuant to 10 CFR 20.302 [or 10 CFR 20.2002].

In other words, we have no objections to the use of this equipment provided that it is properly operated, as intended by Hydro Nuclear, and that all waste determined to contain detectable licensed material is disposed of as radioactive waste in accordance with the provisions of 10 CFR 20.301 [or 10 CFR 20.2001]; thus, meeting the intent of IE Circular No. 81.07.

Regulatory references: 10 CFR 20.201, 10 CFR 20.1501

Subject codes: 9.3, 9.7

Applicability: Reactors

HPPOS-127 **PDR-9111210299**

Title: Transfer and/or Disposal of Spent Generators

See IE Information Notice No. 81-32 entitled as above and dated October 23, 1981. This notice states that spent radiopharmaceutical generators may be stored for decay to background and, after surveys, disposed of in any manner. Spent generators with residual activity may be transferred only to a person licensed to receive the material. The health physics position was written in the context of 10 CFR 20.201 and 20.207, but it also applies to the "new" 10 CFR Part 20, Sections 20.1301, 20.1801, and 20.1902. HPPOS-045 contains a related topic.

It was reported to NRC that drivers of transporting companies with contracts from suppliers to deliver new generators and to pick up spent generators from medical institutions were storing the generators at their residence and/or removing the generator lead shielding for resale. In one incidence, police found eleven used Mo-99/Tc-99m generators from a major radiopharmaceutical supplier inside a box labeled radioactive materials in the driveway of a driver. The average exposure rates measured from these generators were approximately 25 mR/hr at contact and 2 mR/hr at 3 feet; sufficient to deliver a dose of 25 mrem to the hands during dismantling.

NRC licenses contain specific procedures for the disposal of spent generators (e.g., return to supplier, etc.). In a letter dated June 4, 1981, the NRC Material Licensing Branch stated the conditions for authorizing decay-in-storage of certain radioactive materials, including generators. (A copy is enclosed with this document.) These conditions would be automatically added to new licenses or to existing licenses upon request. The proper way to store spent generators for decay and subsequent disposal is to segregate the generator columns and monitor them separately prior to disposal. There are no special requirements on disposal except for appropriate surveys to verify total decay, records of the surveys, and defacing or removal of labels on the devices. Any surveys should include the lead shielding. The generators may be disposed in non-radioactive trash when the activity has decayed to background levels. When spent generators are stored for decay, the requirements of 10 CFR 20.105 (permissible levels of radiation in unrestricted areas), 10 CFR 20.207 (storage and control of licensed materials in unrestricted areas), and 10 CFR 20.203 (posting and labeling requirements) must be complied with. [Note: The equivalent requirements are now found in 10 CFR 20.1301 (dose limits for individuals members of the public), 10 CFR 20.1801 (security of stored material), and 10 CFR 20.1902 (posting of areas or rooms in which licensed material is used or stored).]

Until surveys indicate that no radioactivity remains, the generators must be treated as licensed material. None of the exemptions of Part 30 apply. Any person possessing these items (e.g., for lead recovery or waste disposal) is required to have an NRC license. The only exception would be the delivery of properly packaged and labeled items to a common or contract carrier for transport to an authorized recipient.

10 CFR 30.41(b)(5) requires that licensed material be transferred only to a person who is licensed by NRC or one of the Agreement States. Therefore, when transferring spent generators back to the supplier, the common or contract carrier transporting the generators should be made fully aware that any operations with or use of the material, other than the actual transport or storage, is not authorized. Following delivery of the generators to the carrier, licensees are urged to provide specific instructions on the shipping papers indicating that the generators are to be delivered to the consignee without any unnecessary delay or unauthorized storage, and that the generators are not to be disassembled. It would be judicious to establish a routine point-of-contact with the supplier to inform him of the carriers being used, and to ask for the supplier's cooperation in reporting any instances of improper actions.

The generator supplier may have provided instructions in package inserts regarding proper, safe and legal packaging and transport of generators. If licensees do not have these instructions or are unfamiliar with them, they are urged to contact the supplier.

Regulatory references: 10 CFR 20.201, 10 CFR 20.207, 10 CFR 20.1301, 10 CFR 20.1801, 10 CFR 20.1902, 10 CFR 30.41

Subject codes: 3.4, 3.5, 9.7

Applicability: Byproduct Material

HPPOS-190 **PDR-9111210300**

Title: Disposal of Exempt Quantities of Byproduct Material

See the memorandum from L. J. Cunningham to M. M. Shanbaky (and others) dated February 12, 1987, and the memorandum from R. L. Fonner to J. C. Partlow dated January 30, 1987. Sections 20.301, 30.14, 30.18, and 40.13(a) of CFR Title 10 do not authorize waste disposal by transfer of exempt quantities of byproduct and/or source materials to persons who do not hold a specific NRC license authorizing them to receive it. The health physics position was written in the context of 10 CFR 20.301, but it also applies to "new" 10 CFR 20.2001.

In your memorandum of January 7, 1987, you ask if OGC had any legal objection to OIE continuing to

view 10 CFR 30.18 as not authorizing disposal of exempt quantities of byproduct materials. Your question was prompted by an internal OELD memorandum that noted an ambiguity in 10 CFR 30.18 that should be corrected in order to present a rock solid basis on which to take issue with a licensee's reliance on that provision to justify disposal of small amounts of radioactive wastes.

The issue in this office was precipitated by a memorandum from the Region II for a legal reading of the regulation in question. Material submitted with your memorandum of January 7, also demonstrates the confusion surrounding the citation of 10 CFR 30.18 and the need to clarify the application of the regulation to disposal of exempt quantities of materials. You agree with the need for clarification but propose in essence that the agency proceed with enforcement prior to such clarification on the view that 10 CFR 30.18 does not authorize disposal or transfer for disposal of the exempt quantities.

There is no objection to adhering to that view. A case can be made for it based upon a long term agency understanding that 10 CFR 30.18 does not authorize disposal or transfer for disposal (see, for example, the note from Eric Jakel to Leo Wade dated June 10, 1975). Because there is some confusion in the record, however, it is not risk free. Therefore, we continue to urge prompt initiation of a clarifying rule.

Regulatory references: 10 CFR 20.301, 10 CFR 20.2001, 10 CFR 30.14, 10 CFR 30.18, 10 CFR 40.13

Subject codes: 3.5, 9.7, 12.10

Applicability: All

2.13 CHEMISTRY

HPPOS-062 **PDR-9111210248**

Title: Chemistry Technician Training and Qualifications

See the memorandum from B. Murray to W. Fisher dated January 31, 1984, and the incoming request from W. Fisher dated January 31, 1984. It discusses chemistry technicians in responsible positions. New hires cannot fill responsible positions unless they have two years experience. Experience may be gained in either a radiochemical or secondary laboratory, and experience may also be gained preoperationally. HPPOS-096, a letter from J. T. Enos (Arkansas Power & Light Company) to E. H. Johnson dated September 6, 1985, contains a related topic.

During inspections of a licensee's chemistry programs, the interpretation of ANSI N18.1-1971 in regard to chemistry technician (or Chem Tech) qualifications was questioned. The Region IV position had been that all Chem Techs must meet the ANSI N18.1-1971 education and qualifications before issuance of an operating license at preoperational facilities, and at licensed facilities, all newly hired Chem Techs must meet the ANSI qualifications. Region IV had also taken the position that if a technician was assigned responsibilities in a radiochemical laboratory, the technician must have 2 years experience in a radiochemical laboratory and the equivalent requirements applied to technicians assigned responsibilities in a secondary laboratory. This issue has generic implications at many plants and in other departments besides chemistry, therefore, guidance was sought of NRR so as to have consistent enforcement throughout the industry. It should be noted that inspection Procedure 83523 requires preoperational inspections in two areas that relate closely to ANSI N18.1-1971.

Inspection Procedure 83523-02.01b relates closely to N18.1 Section 5. The inspector should determine whether the licensee has or will have a training program in accordance with Section 5.1 and 5.3 and whether that training program ensures Chem Techs are trained in one or more of the three ways described in Section 5.3.4.

Inspection Procedure 83523-02.02a relates closely to N18.1 sections 4.1 and 4.5.2. The inspector should

determine whether the sampled Chem Techs have received or will have received experience and education in accordance with Section 4.5.2, so that the objectives of Section 4.1 may be reached. Section 4.5.2 requires two years of "working experience in their specialty." Both years of experience could be at the plant before OL (Section 2.2.4). One of the two years could be on-the-job training (Sections 2.2.7 and 4.1). Besides the required experience, Section 4.5.2 recommends one year of related technical training, which could be obtained at the plant or elsewhere (Section 2.2.6).

If technical specifications will require compliance with ANSI N18.1-1971, the licensee is expected to comply by OL issuance. Chem Techs in responsible positions must have 2 years of experience, both of which could have been obtained at the plant as discussed above. "Chemistry technicians in responsible positions" are those whose decisions and actions during normal and abnormal conditions may affect the safety of the plant (see N18.1 Section 4.1). Unless the licensee makes an acceptable case to the contrary, all Chem Techs who perform radiochemistry or coolant chemistry and who are not in on-the-job training should be considered to hold "responsible positions."

New hires at operating facilities also should be treated as above. That is, unless they have 2 years of experience, they may not fill "responsible positions."

ANSI N18.1-1971 clearly requires that technician experience be gained in the specialty (e.g., chemistry). Whether experience was gained in one kind of a laboratory or another is irrelevant. The important consideration is the applicability of the experience. The licensee must determine the applicability.

ANSI N18.1-1971 does not discriminate against preoperational experience. As above, the important consideration is the applicability of the experience. If the preoperational experience helped prepare the person to work in a "responsible position, " it should be counted. Again, the licensee must determine that applicability.

Regulatory references: ANSI/ANS 3.1-1981, ANSI N18.1-1971, Technical Specifications

Subject codes: 1.1, 1.2, 10.1

Applicability: Reactors

HPPOS-096 **PDR-9111210202**

Title: ANO - Units 1 & 2 - Radiochemistry Personnel Qualifications

See the letter from J. T. Enos (Arkansas Power & Light Company) to E. H. Johnson dated September 6, 1985. Attachment 2 of the letter is a final interpretation provided by the ANS-3 Committee. Technicians in responsible positions are capable of performing all tasks in the discipline. Less qualified technicians can perform specifically defined tasks (e.g., sample taking, preparation, or analysis). Academic training is not a substitute for experience.

AP&L's initial correspondence with the ANS-3 Committee dated May 28, 1984, stating the company's and NRC Region IV's positions in this matter, and the final interpretation of the ANS-3 Committee dated October 30, 1984, are included as attachments to this letter. The ANS-3 Committee is responsible for ANSI N18.1 and ANS 3.1 standards on personnel qualifications for nuclear power plants. Although the ANS-3 Committee did not support AP&L's position that academic training (specifically four year science degrees) should not be allowable substitute for much of the experience requirement for radiochemistry technicians specified by ANSI-N18.1-1971, the Standards Committee did emphasize that the current revision of ANSI/ANS 3.1-1981, addresses the qualification requirements for technicians more specifically and that not all technicians must meet the experience requirements for the "responsible" technician.

Two excerpts from the October 30, 1984, ANS-3 interpretation elaborating on these provisions are repeated below:

1. "Other lesser qualified technicians within the group can perform other specifically defined tasks such as sample taking, preparation, and analysis.

2. "Individuals in training or apprentice positions are not considered technicians or maintenance personnel for purposes of defining qualifications in Section 4, Qualifications, but are permitted to perform work in the job classification for which qualification has been demonstrated.

These individuals may perform work without the direction and observation of qualified individuals if they have previously demonstrated their ability to perform these specific tacks."

AP&L considers this to be representative of the duties of on-shift radiochemists and chemists at ANO, and that lesser qualified individuals, performing with direct supervision and observation, are acceptable, provided that they have demonstrated their ability to accomplish the required tasks. It is noted that the second statement above is a direct quotation from ANSI/ANS 3.1-1981. Adoption of this position was in effect the recommendation of the ANS-3 Committee since they felt that the 1981 standard had already addressed the specific problem raised herein. Although the committee did not agree with the position relative to the qualification of a "responsible" technician, they did provide clarification of which job functions require a "responsible" (and therefore fully qualified) technician.

An agreement was reached which appears to be acceptable to both AP&L and NRC. One individual qualified either under provisions of paragraphs 4.4.3 or 4.5.2 of ANSI N18.1-1971 will be on each shift for the radiochemistry and chemistry disciplines. The ANSI qualification can, therefore, be met by either a professional-technical background (minimum 4 year of related technical or academic training and one year of related experience) or a technician background (minimum two years working experience in the specialty). AP&L was in compliance with ANSI N18.1-1971 when applied in the above discussed manner. There was some uncertainty in the ability to maintain compliance over the next few months. However, due to more personnel becoming qualified in December 1985, AP&L was able to commit to maintaining compliance beginning January 1, 1986. Further, as a compensatory action, AP&L was committed to provide an ANSI qualified individual on-call in the event of an unavoidable temporary interruption in full qualified shift coverage due to future personnel turnover problems.

Regulatory references: ANSI N18.1-1971, ANSI/ANS 3.1-1981, Technical Specifications

Subject codes: 1.1, 1.2, 10.1

Applicability: Reactors

HPPOS-299 PDR-9306220283

Title: Technical Assistance Request, SteriGenics International, Authorization to Increase the Limit on Pool Water Conductivity

See the memorandum from J. E. Glenn to J. A. Grobe dated October 13, 1992. This memo responds to a technical assistance request from Region III, dated May 20, 1992, regarding the request of SteriGenics International (formerly, Radiation Sterilizers, Inc.) to increase the limit on pool water conductivity from 10 to 20 microsiemens per centimeter (mS/cm). By memorandum dated June 20, 1992 (Enclosure 1), NMSS asked the Office of Nuclear Regulatory Research (RES) for its recommendation. We discussed the issue of pool water conductivity during drafting of the final version of the proposed 10 CFR Part 36. The guidance provided below reflects these discussions; SECY-92-323, "Final Rule on "Licenses and Radiation Safety Requirements for Irradiators" (Enclosure 2); and RES' reply to our June 20, 1992 memorandum (Enclosure 3).

The 10-mS/cm value that is recommended by the American National Standards Institute (ANSI), is also the value in the proposed 10 CFR Part 36, and is a current condition of the SteriGenics license. Region III asked the licensee to justify its request. The licensee's response includes the following points:

1. Conductivity greater than 10 mS/cm will not cause long-term or accelerated corrosion of stainless steel used to fabricate cobalt sources.

2. The 10-mS/cm values was chosen based on the level of conductivity attainable with Atomic Energy of Canada (AECL) water purification systems.

3. The are occasions when the 10-mS/cm value may be exceeded; e.g., during source loading.

4. The license previously used the 20-mS/cm value.

It is important to maintain good water quality in a pool-type irradiator. The water must be clear in order for the operator to see the position and location of the sources, to identify source serial numbers, and to find objects which may be dropped into the pool. The water quality must be such that it does not accelerate corrosion of the radioactive sources and does not damage the pool structure.

As indicated in Enclosure 3, the RES metallurgist endorsed the use of 20 mS/cm as an upper limit on conductivity under normal circumstances for 316L or 321 stainless steel, provided that there are no crevices on the source or between the source and the source holder. He expressed concern that localized areas in crevices on the sources or between the source and source holder could contain water with very much higher conductivity values that could accelerate corrosion.

With regard to SteriGenics' request concerning pool conductivity, Region III may amend the SteriGenics license to require the following:

1. Pool water purification system must be run sufficiently to maintain conductivity of the pool water below 20 mS/cm under ordinary circumstances;

2. If pool water conductivity rises above 20 mS/cm, the licensee shall take prompt corrective actions to lower the pool water conductivity and shall take corrective actions to prevent recurrences;

3. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 mS/cm [Note: The licensee may use trend analysis or other similar statistical methods to demonstrate that "conductivity remains below 20 microsiemens per centimeter"];

4. The conductivity meter must be calibrated at least annually;

5. Records of conductivity measurements and calibration of conductivity meters must be maintained for three years from the date of the measurement or calibration;

PROVIDED THAT:

6. SteriGenics' sources are encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance; AND

7. SteriGenics verifies that there are no crevices on the sources or between the source and source holder that would promote corrosion on a critical area of the source.

Regulatory references: License Conditions

Subject codes: 5.0, 10.2

Applicability: Source Material

HPPOS-213 **PDR-9111220010**

Title: Applicability of 10 CFR 50 Appendix B to Chemicals and Reagents

See Interpretative Guide from the IE Manual entitled as above and dated April 1, 1977. The document states that Appendix B to 10 CFR 50 applies to chemicals and reagents used in primary and secondary systems water chemistry control and analysis. Appropriate controls include testing prior to initial use, and labeling and dating to assure proper shelf-life control.

The purpose of this document was to identify specific criteria that should be used by Inspection and Enforcement personnel for the review and evaluation of licensee management control systems for chemicals and reagents used in primary and secondary system water chemistry control and analysis. 10 CFR 50.34(b)(6) requires licensees to describe in the Final Safety Analysis Report (FSAR) information relating to managerial and administrative controls to be used to assure safe operation.

In complying with these requirements, most licensees document an FSAR commitment to the requirements of ANSI N18.7. Section 5.3.7 of ANSI 18.7-1972 and Section 5.3.8 of ANSI 18.7-1976 provide general guidance concerning chemical and radiochemical control activities.

The criteria of 10 CFR 50 Appendix B delineate the need for appropriate controls of certain materials. These materials include chemicals and reagents used in primary and secondary system water chemistry control and analysis. These controls may be in the form of administrative procedures which include provisions for storage and use of laboratory and bulk chemicals used in primary and secondary water chemistry control and analysis. Examples of the type of controls deemed appropriate include:

1. Testing of purchased and lab-prepared chemicals and reagents prior to initial use to ensure that physical and chemical properties are consistent with purchase specifications or other technical requirements.

2. Labeling and dating to assure proper shelf life control plus any special environmental considerations that must be maintained during storage.

Regulatory references: 10 CFR 50, Regulatory Guide 1.33

Subject codes: 10.2, 10.4

Applicability: Reactors

2.14 LICENSING

HPPOS-135 **PDR-9111210361**

Title: 10 CFR 40.14 is Not to be Used for Issuing Exemption Licenses

See the letter from G. H. Cunningham to R. N. Fleck (Assistant Counsel, Union Oil Company of California) dated June 18, 1981. The letter expresses the OELD opinion that as a matter of policy, the NRC will not use 10 CFR 40.14 to authorize exemptions from requirements to obtain a license. 10 CFR 40.14 has never been used to exempt from classification as source material rare earth mixtures in excess of 0.25% by weight thorium.

The NRC was asked how the limit used as the basis for the exemption "0.25 percent by weight thorium, uranium, or any combination of these, ..." was obtained. The exemption in the regulations was based on the statutory exemption for unimportant quantities of source material contained in Section 62 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2092) which reads in part as follows: "Unless authorized by a general or specific license issued by the Commission, which the Commission is hereby authorized to issue, no person may transfer or receive in interstate commerce, transfer, deliver, receive possession of or title to, or import into or export from the United States any source material after removal from its place of deposit in nature, except that licenses shall not be required for quantities of source material which, in the opinion of the commission, are unimportant." In carrying out its regulatory responsibilities, the NRC, like its predecessor the AEC, has consistently followed the practice of implementing the licensing requirements imposed by the Atomic Energy Act, including any statutory exemptions from those requirements, by promulgating regulations. The statutory exemption for unimportant quantities of source materials was implemented in 10 CFR 40.13 of the Commission's regulations.

The exemption for certain rare earth metals and compounds, mixtures, and products was originally established by the AEC on March 31, 1947, when the Commission's regulations on the "Control of Source Material" became effective. At that time, the basis for the exemption was that the quantity of source material present in the exempted materials was not of signif-

icance to the common defense and security. In response to a petition by American Potash and Chemical Corporation, the AEC reconsidered the exemption in March, 1961. At that time, the AEC was aware that rare earth fluorides and rare earth oxides containing approximately 0.2% thorium were used in the manufacture of arc carbons. The AEC was also aware that the rare earth material appearing in consumer products was on the order of 0.19% thorium by weight. On the basis of this and other information, the AEC concluded that the rare earth exemption, with the value of 0.25% by weight thorium, uranium, or any combination of the two, involved unimportant quantities of source material within the meaning of Section 62 of the Atomic Energy Act and should be re-established in the regulations.

The NRC was also asked whether the Commission had ever exercised its discretion under 10 CFR 40.14 to exempt from classification as source materials any rare earth mixtures that contained somewhat in excess of 0.25% by weight thorium. Both the Commission and its predecessor, the AEC, have taken the position that, as a matter of policy, 10 CFR 40.14 procedures will not be used to authorize exemptions from the basic requirement to obtain a license. Under the Commission's present regulations, a source material license is required whenever a rare earth metal, compound, mixture, or product contains 0.25% or more by weight thorium, uranium or any combination of these. There have been no instances in which 10 CFR 40.14 has been used to specifically exempt from classification as source material any rare earth mixture containing thorium in excess of 0.25% by weight.

Regulatory references: 10 CFR 40.13, 10 CFR 40.14

Subject codes: 3.3, 11.1, 12.19

Applicability: Source Material

HPPOS-201 **PDR-9111210341**

Title: Import of Cigarette Plates Containing Source Material

See the memorandum from V. L. Miller to J. D. LaFleur dated October 20, 1982. This memo states that the incorporation of source material into a consumer product, such as cigarette plates, constitutes processing, and therefore, the product does not qualify for any exemption in 10 CFR 40.13. Only specific or general licensees may possess this type of product.

An opinion was sought on whether a consumer product called "Nicotine Alkaloid Control Plate" qualified for any exemption under 10 CFR 40.13. The product, to be imported from Japan, consisted of a light metal plate on which was glued a layer of finely ground thorium containing monazite sand and covered by thin tissue paper. It was estimated that the plate was composed of 50% monazite sand containing 4% thorium. On being placed with the sand side next to a package of cigarettes, the alpha particles emitted by the thorium were to denature and reduce nicotine, tar, and harmful gases.

The NRC opinion was that incorporation of source material into a consumer product constitutes processing, and therefore, the product did not qualify for any exemption from 10 CFR 40.13. As a result, only specific or general licensees may posses the product. No apparent legal purpose for possession in the U.S. exists because of the products sole personal use by cigarette smokers.

Regulatory references: 10 CFR 40.13

Subject codes: 11.1, 11.6

Applicability: Source Material

HPPOS-206 **PDR-9111210356**

Title: Boeing Company Request Concerning Depleted Uranium Counterweights

See the letter from G. H. Cunningham to W. E. Morgan dated April 14, 1983, and the incoming requests from W. E. Morgan (Boeing Company) dated March 18, 1983 and January 6, 1983. The Boeing Company's proposal to apply a corrosive preventive compound to depleted uranium (DU) counterweights was not considered "... chemical, physical, or metallurgical treatment or process ..." and was appropriate for exemption under 10 CFR 40.13(c)(5).

The 747 airplane program utilized DU weights for mass balance of outboard elevator and upper rudder assemblies on the first 550 aircraft built. This equates to approximately 12,000 cast parts and a total mass of DU in excess of 200 tons. Depending upon the model, each aircraft had either 21 or 31 weights. At

each major aircraft overhaul (about 4 to 5 years), it was anticipated that over 20% of these weights would be corroded to where they required reprocessing. This condition was considered to present an unnecessary maintenance burden on the 747 operators. Aside from the high corrosion rate, the weights were extremely difficult to transport with only one recognized reprocessing source in the world.

In a letter dated January 6, 1983, the Boeing Company proposed originally to apply an additional protective coating of Cosmoline (MIL-C-11796) over the protective coating of undamaged DU weights. They intended to require that the weights be (1) corrosion free, (2) properly nickel and cadmium plated and painted, (3) heated to 150-160°F, (4) dipped in MIL-C-11796 at the same temperature, and (5) cooled to ambient temperature. The weights in question were exempt items manufactured by NL Industries of Albany, New York. When the weights were reinstalled on the airplane, they intended to fill the attachment holes with MIL-G-23827 grease. Cautionary marking on the weights would be kept free of corrosion preventative compounds. They asked if these additional processes in any way violated the conditions of 10 CFR 40 of the NRC rules and regulations.

It was NRC staff's view that the above processing falls within the prohibition of 10 CFR 40.13(c)(5)(iv). That provision states clearly that the exemption from licensing in 10 CFR 40.13(c)(5) for DU weights does not authorize any treatment or processing of the counterweights except for repair or restoration of any existing plating or covering. This has been the regulatory position for over 20 years [see 25 FR 6427]. The above proposal involved the processing of the DU weights to add a new coating of a different material. If the work was performed at the Washington plant, Boeing would need (1) a license from the State of Washington authorizing the procedure for coating the DU weights in its possession, and (2) a license from the NRC to distribute the weights to exempt persons (i.e., the operators of the aircraft) after being coated [see 10 CFR 40.13(c)(5)(i) and 150.15(a)(6)].

In a second letter dated March 18, 1983, the Boeing Company proposed the application of corrosion preventative compound MIL-C-16173 to DU weights in service. This procedure would be accomplished during operators scheduled maintenance programs. It would be required that the weights be corrosion free and finished per drawing (nickel and cadmium plus primer) prior to brush application of MIL-C-16173. Both MIL-C-16173 and weights would be at ambient temperatures during application. Attachment holes would be filled with grease (MIL-G-23827) to eliminate water traps and cautionary markings on the weights would be kept legible. No chemical interactions would occur between the corrosive preventative compound (MIL-C-16173) or the grease (MIL-G-23827) and the plating or paint because these compounds do not contain solvents or other agents which might soften paint. The Boeing Company believed that this process, while not as effective in preventing corrosion as their previous proposal, would be a significant improvement and did not violate the intentions of 10 CFR Part 40 of the NRC rules and regulations.

It was NRC staff view that the second proposal was not considered as "... chemical, physical, or metallurgical treatment or process ..." and was appropriate for exemption under 10 CFR 40.13(c)(5).

Regulatory references: 10 CFR 40.13

Subject codes: 11.1, 11.6

Applicability: Source Material

HPPOS-191 **PDR-9111210302**

Title: Licensing of Depleted Uranium Shielding for Use in Possessing of Mo-99/Tc-99m Generator

See the letter from V. L. Miller to All Medical Licensees and Commercial Nuclear Pharmacies dated January 9, 1986. This letter states that depleted uranium associated with Mo-99/Tc-99m generators is exempt from licensing requirements under 10 CFR 40.13 only when it is used as a shipping container. A specific license from NRC is needed to possess and use the depleted uranium as a shield.

Many of the addressees of this letter were authorized to possess and use Mo-99/Tc-99m generators ranging in activity from 200 millicuries to 16 curies of Mo-99. Although most generators are surrounded by lead shielding, some with Mo-99 activity greater than 4 curies are surrounded by depleted uranium first used as a shipping container and then, upon receipt, as shielding.

The NRC regulations covering depleted uranium are found in 10 CFR Part 40 and include revised provisions that became effective December 24, 1981.

The view of NRC is that depleted uranium associated with Mo-99/Tc-99m generators is exempted from licensing requirements [10 CFR 40.13(c)(6)] only when it is used as a shipping container (e.g., when the generator is in transit from the manufacturer). A specific license or authorization from NRC is needed to possess and use the depleted uranium as a shield (e.g., during the time the Mo-99/Tc-99m generators are stored or used by medical licensees or commercial nuclear pharmacies). Many licensee facilities using high activity Mo-99/Tc-99m generators do not have specific authorization from NRC to possess and use the depleted uranium as a shield.

The following license condition must be contained in or added to the license:

"Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, 'Domestic Licensing of Source Material,' the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license."

The absence of this condition on the licensees current license is not a health and safety problem and will not be considered an item of noncompliance. The next time the license is amended, NRC will formally add this condition to licenses authorizing possession and use of 4 curies or more of Mo-99/Tc-99m generators. Amendments to increase generator possession limits to 4 curies or more will also include this license condition.

Regulatory references: 10 CFR 40.13

Subject codes: 11.1, 11.6

Applicability: Source Material

HPPOS-202 **PDR-9111210343**

Title: Licensing Status of Titanium Bearing Ores and Waste Products From Titanium Dioxide Manufacturing

See the letter from R. L. Fonner to G. V. Johnson (E.I. du Pont de Nemours & Co.) dated November 2, 1984. 10 CFR Part 40.13(c) does not authorize manufacturing of any of the products listed in Paragraph (c), reinforcing the historical view of the limited application of the exemption to products only, and not to raw materials and waste, such as waste products from titanium dioxide. HPPOS-029 contains a related topic.

NRC examined the question of exemption and licensing status for titanium bearing ores and waste products resulting from titanium dioxide manufacturing at a plant in Tennessee. Some ores (monazite and xenotime-rare earth ores) and some waste products (barium salts in scale in piping, and some process wastewater) contain thorium and uranium in excess of 0.05% by weight, but less than 0.25% by weight. It was suggested that these materials were covered by 10 CFR 40.13(c)(1)(vi) and should, therefore, be exempt from licensing.

10 CFR 40.13(c)(1)(vi) provides an exemption for licensing for thorium contained in rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight of thorium, uranium, or any combination of thorium and uranium. This exemption was promulgated in 1961 upon the petition of American Potash and Chemical Company to restore a *status quo ante*. American Potash was then processing rare earth ores for thorium and rare earths at its facility in West Chicago, Illinois. The exemption of 10 CFR 40.13(c)(1)(vi) can be traced to Schedule I of 10 CFR 40.60.

Schedule I was first promulgated in 1947 (12 FR 1855, March 20, 1947) in conjunction with a provision requiring unlicensed persons in possession of 10 pounds of source material ore, or 1 pound of refined source material, to register with the Atomic Energy Commission. However, products listed in Schedule I were exempted. This history indicates that the exemption applies only to products, not to raw materials or process wastes. Further, the petitioner, American Potash and Chemical Company, always proceeded under license with respect to ores exceeding 0.05% by weight thorium.

NRC emphasizes the fact that only products are involved in the several exemptions in paragraph 40.13(c). Under the regulatory system of 10 CFR Part 40, unrefined and unprocessed ores are exempt without limit on quantity and quality pursuant to paragraph 40.13(b). If source material ore has been refined or processed (see 10 CFR 40.4(k)) it is subject to licensing. 10 CFR 40.13(c)(9) states that paragraph 40.13(c) does not authorize manufacturing of any products listed in paragraph (c), reinforcing the historical

view of the limited application of the exemption to products only, and not to raw materials and waste.

Regulatory references: 10 CFR 40.13

Subject codes: 11.1, 11.6

Applicability: Source Material

HPPOS-293 PDR-9306220028

Title: Technical Assistance Request for Guidance on Exemption/Modification Per 10 CFR 34.20 to Industrial Radiography Equipment (Source Guide Tube)

See the memorandum from J.E. Glenn to D.M. Collins dated August 19, 1992. This memo responds to a technical assistance request by Region II concerning an application by Fluor Daniel, Inc., for one-time-only modification of the source guide tubes for Amersham (TechOps) cobalt-60 devices.

Guidance was requested by Region II on whether the licensee requested exemption was acceptable. If it was acceptable, guidance was needed on how the request should be granted since Fluor Daniel is a South Carolina licensee operating in NRC jurisdiction under reciprocity (10 CFR 150.20). It was always the intention of NRC to grant exemptions to 10 CFR 34.20 for persons who have special requirements (see enclosed Part 34 statement of consideration). After reviewing the information submitted by the licensee in their application, it was concluded that the proposed administrative and radiation safety controls were sufficient to meet the intent of the regulations and were acceptable.

Regarding the request by Region II for guidance on how to grant the exemption to Fluor Daniel, a general licensee, it is normally recommended that exemptions of this type be granted directly by license amendment. However, since Fluor Daniel is a South Carolina licensee working under reciprocity authorized by 10 CFR 150.20 and the requested exemption is a one-time-only request for a limited period, it was determined that the administrative procedure of granting a temporary waiver of compliance to 10 CFR 34.20(b) is appropriate.

Regulatory references: 10 CFR 34.20, 10 CFR 150.20

Subject codes: 11.1, 12.2, 12.9

Applicability: All

HPPOS-311 PDR-9306250080

Title: Technical Assistance Request, Capintec Instruments, Inc., Request for Definition of Sealed Source as Used in 10 CFR 30.35

See the memorandum from J. E. Glenn to R. R. Bellamy dated January 30, 1991, and the memorandum from J. H. Austin to J. E. Glenn dated January 24, 1991. These memos concern a technical assistance request from Capintec Instruments, Inc., regarding the definition of sealed sources as used in 10 CFR 30.35 and specifically whether sealed vials manufactured by Capintec meet the requirements (see enclosures).

The definition of a sealed source in 10 CFR 30.4 requires the capsule to be designed to prevent contact with and dispersion of the radioactive material under the conditions of use for which it was designed. Certain low energy and low activity calibration and reference sources have been confined by using glass vials for numerous years. These vials are typically used in conjunction with expensive counting equipment and have demonstrated a good operational history.

The ampoule in question is flame sealed to prevent leakage or escape of its contents and therefore can be considered to be a sealed source. This conclusion is consistent with past NRC practice. The radionuclide content of the sources are small, and the impact on decommissioning of the facility if one or a few were to fail is minor.

Regulatory references: 10 CFR 30.4, 10 CFR 30.35

Subject codes: 11.2

Applicability: Byproduct Material

HPPOS-200 PDR-9111210337

Title: Authorizations Under 10 CFR 40.22, General License

See the memorandum from J. Hickey to files dated September 3, 1986. 10 CFR 40.22 allows each facility of the same company to possess and/or manufacture up to 15 pounds of source material under a general license. A general licensee does not need an exempt distribution ("E") license to distribute exempt products. Receivers of products from a general licensee may or may not be licensed.

On August 26, 1986, discussions were held with the Office of General Counsel concerning the provisions of 10 CFR Section 40.22, "Small quantities of source material", and how it would apply to a manufacturer operating multiple facilities. Section 40.22 allows organizations (but not individuals) to possess up to 15 pounds of source material (thorium or natural uranium) under general license, subject to restrictions. A summary of the issues discussed is provided below:

1. If a company operates several facilities in several locations, can each facility possess up to 15 pounds of source material under general license?

Yes. NRC has normally considered separate facilities to be separate general licensees, even if both facilities are in different parts of the same city. By the same token, a separate facility can be a general licensee and be covered by the exemption in 40.22(b), even if the same company holds a specific Part 40 license at another facility.

2. Does Section 40.22 allow manufacturing of products containing source material?

Section 40.22 does not appear to have originally intended to authorize manufacturing. However, the regulation is so broad, allowing "commercial or operational" use, that NRC has interpreted it to allow manufacturing.

3. Do persons who receive products from a general licensee have to be licensed?

It depends on the product. A customer can receive an exempt product (such as a gas mantel or a lamp) without a license, or may qualify for the general license to possess a non-exempt product.

4. Do general licensees distributing exempt products have to have an exempt distribution ("E") license?

No. Section 40.13 allows transfer of exempt products and does not prohibit commercial distribution (as opposed to 30.18(c), which prohibits unlicensed commercial distribution of exempt quantities of byproduct material). Although 40.13 does not appear to have been intended to allow exempt commercial distribution, its wording allows it. Section 40.13 does prohibit manufacturing, which must be covered by a general (40.22) license or specific license.

Regulatory references: 10 CFR 40.22

Subject codes: 11.2, 11.6

Applicability: Source Material

HPPOS-261 PDR-306070203

Title: Policy and Guidance Directive FC 92-04, "Issuance of New Licenses for Material Use Programs"

See the memorandum from R. E. Cunningham to R. W. Cooper (and others) dated September 14, 1992. The purpose of this Directive is to summarize current NMSS policy for issuance of new licenses for material use programs (Enclosure 1) and to provide guidance to the reviewer (Enclosure 2). The enclosed guidance is based on concerns raised by NRC staff pertaining to specific items in applications for material use, e.g., industrial or medical. The Directive identifies two specific areas that may require additional information from the applicant, i.e., the status of the facility and the present use of the proposed location of the facility.

The general rule governing domestic licensing of byproduct material are contained in 10 CFR Part 30. Section 30.33, "General requirements for issuance of specific licenses", provides, among other things, that the proposed equipment and facilities are adequate to protect health and minimize danger to life and property. NRC staff anticipates, and as a matter of practice encourages, license applicants to delay completion of facilities and acquisition of equipment until after the application review is completed. This allows for cost-effective safety improvements in the applicant's facilities and equipment when indicated as a result of NRC's technical review. It also ensures the adequacy of the facilities and equipment prior to significant financial investment by the applicant.

However, the applicant may not possess and use licensed material until the approved facilities are completed and equipment procured.

The technical review of the application should include an evaluation of the completeness and accuracy of the information submitted and should identify any necessary safety improvements in the facilities and equipment. If the following information is not evident in the license application, or is ambiguous, or appears to be misleading, the review should contact the applicant by telephone to request the additional information:

A. Status of the facility.

1. If completed, document the discussion.

2. If not in existence or completed, inquire as to the plans for completing the facility. If construction is not to be completed within 12 months after receiving the license determine: (a) when the applicant intends to possess and use licensed material in the proposed facility at the locations of use described in the license application; or (b) if the applicant indicates only future use at a facility or location other than that described in the license application (which would require a license application revision), why the license is requested at this time.

B. Present use of the proposed location.

If the location of use is a private residence, the applicant must submit the following additional information:

1. Confirmation that the use of licensed material does not conflict with local codes and zoning laws; and

2. Diagrams of the facility to include the building and adjacent areas, including above and below restricted areas. The facility should be of adequate design to permit security of licensed material and prevent unauthorized access from the residence. Commitments that restricted areas do not include residential quarters are required. The applicant should discuss how radiation levels in unrestricted areas will be controlled and monitored to comply with 10 CFR 20.105 or 20.1301.

The two enclosures to this Directive should be consulted for additional guidance concerning the issuance of new licenses for material use programs.

Regulatory references: 10 CFR 30

Subject codes: 5.0, 11.2, 11.3

Applicability: Byproduct material

HPPOS-120 **PDR-9111210277**

Title: Licensing of Reactor Facilities Prior to Issuance of Operating License

See the memorandum from G. H. Cunningham III to D. A. Nussbaumer dated April 18, 1980. For reactors in Agreement States, it is an OELD opinion that NRC retains jurisdiction to license use of radioactive materials that are directly connected with reactor operations and are needed during the construction and preoperational phases of a reactor. HPPOS-265 contains a related topic.

Guidance was sought concerning the licensing of utilities located in Agreement States to possess and use radioactive materials at reactor facilities prior to the issuance of operating licenses. The particular question raised was whether NRC or the Agreement State was authorized to issue licenses for radioactive materials possessed and used at such facilities when the materials were directly connected with reactor operations and were needed during the construction and preoperational phases of a reactor.

It is OELD opinion that NRC retains exclusive jurisdiction to license such materials when the materials are possessed and used by the utility for the purposes described. This conclusion flows from Section 274c of the Atomic Energy Act of 1954, as amended, which provides in pertinent part that "No agreement entered into [with a state] ... shall provide for discontinuance of any authority and the Commission shall retain authority and operation of any production or utilization facility ...." The attached informal legal memo, prepared in 1969, sets forth the rationale for this conclusion.

Regulatory references: Atomic Energy Act, 10 CFR 150.15

Subject codes: 11.3, 12.2, 12.9

Applicability: Byproduct and Special Nuclear Materials

HPPOS-320 PDR-9307060045

Title: Technical Assistance Request, Mediq Imaging Associates, Inc., Providing Service to a Private Practice (Non-licensee) Located within a Hospital

See the memorandum from J. E. Glenn to R. E. Bellamy dated January 25, 1993. This NMSS memo responds to a technical assistance request (TAR) from Region I, dated July 16, 1992, regarding Mediq Imaging Associates, Inc., (MEDIQ) providing service to a private practice (non-licensee) located within a hospital.

MEDIQ rents space in the cardiology section of Atlanticare Medical Center in Lynn, Massachusetts. It is in this rented space that MEDIQ proposed the operation of a mobile nuclear cardiology laboratory, with the full knowledge of the Atlanticare administration. There will be no formal relationship between the established nuclear medicine program in the hospital and the MEDIQ mobile operation, and only ambulatory outpatients will be seen in the MEDIQ nuclear cardiology clinic; none of these patients would be expected to be returning to a hospital bed following a nuclear procedure. This program is basically a continuation of the long-standing mobile clinic that MEDIQ operated at Union Hospital in Lynn, an institution which is now closed due to a merger with the Atlanticare facility. The continuing need for cardiac nuclear medicine in this community is the basis for this request. That need is even more profound with the closure of Union Hospital, since the cardiologists involved have relocated to the Atlanticare Medical Center, the only remaining hospital in Lynn.

The NMSS responses to the two issues raised in the TAR are as follows:

1. Clarify whether a mobile licensee can provide service to a private practice (non-licensee) located within a hospital (institution).

The mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed hospital (institution).

2. Is the hospital required to assume responsibility as the client as specified in 10 CFR 35.29(c)?

According to the Statements of Consideration regarding 10 CFR 35.29: "When an NRC licensed hospital exercises its authority to invite a mobile nuclear medicine service to provide medical service, the NRC will deal with this as though the licensee has delegated tasks to another licensee. The NRC licensed hospital, not the mobile nuclear medicine service, will normally be held responsible for items of non-compliance that occur at the hospital." Therefore, since the hospital would need to invite MEDIQ to perform medical services, the hospital will be required to assume responsibility as the client.

The intent of 10 CFR 35.12(a) and 10 CFR 35.29(c) are to prevent confusion or conflicting requirements regarding control of access to byproduct materials. MEDIQ has not presented any explanation as to why the hospital cannot assume this responsibility nor how MEDIQ could assure adequate control of byproduct material given that there "will be no formal relationship between the established nuclear medicine program in the hospital and the MEDIQ operation."

Regulatory references: 10 CFR 35.12, 10 CFR 35.29

Subject codes: 11.3

Applicability: Byproduct Material

HPPOS-262 PDR-9306070215

Title: Policy and Guidance Directive FC 86-1, Revision 1, "Radioactive Drug Research Committees"

See the memorandum from R. E. Cunningham to Distribution dated August 28, 1989. This directive provides guidance about review of requests from specific licensees (both limited scope and broad scope) that want to administer radioactive materials to humans for research purposes.

Background Information: Some research studies involve the administration of radioactive materials to humans that are within the purview of the Food and Drug Administration's (FDA's) Radioactive Drug

Research Committees (RDRCs). The regulations establishing RDRCs and defining their role are found in Section 361.1 of 21 CFR 361 revised April 1985, and are contained in Enclosure 1. The most current listing of FDA-approved RDRCs was revised July 27, 1988, and is contained in Enclosure 2. Enclosure 3 is a letter from FDA to the chair-person of each FDA-approved RDRC, clarifying the role of RDRCs and the types of studies that come within an RDRCs purview. Enclosure 4 contains a sample limited scope license condition, and Enclosure 5 contains a broad scope license condition.

Keep in mind that an RDRC, acting in its official role as a committee approved by FDA, may deal only with research projects involving drugs. Accordingly, research studies that involve a bone mineral analyzer, brachytherapy sources, or other sealed sources are not within the scope of Section 361.1 of 21 CFR 361. Further, Section 361.1 excludes clinical studies with a diagnostic or therapeutic benefit. However, FDA has indicated that "this regulation does not in any way prohibit an institution from involving its Radioactive Drug Research Committee in other policy matters, ... if it so chooses" (40 FR 31304, July 25, 1975).

Every broad scope licensee authorized to perform "medical research" is also authorized to perform human research studies. Therefore, most broad scope licensees are required to confirm access to an approved RDRC as part of the NRC license application or renewal process. Some are only authorized for medical uses and *in vitro* uses under 10 CFR Parts 35 and 31, respectively, and do not need to confirm access to an RDRC. Note that the FDA allows an RDRC at one institution to review and approve research studies proposed to be done at another institution that does not have its own RDRC. However, an RDRC at one institution is not required, by FDA regulations, to assist a second organization by reviewing its research proposals. The NRC has received reports that several institutions have decided that they did not want to accept responsibility for having their RDRC review proposals from other organizations.

On occasion, non-medical institutions have proposed to perform Section 361.1 human research studies. Typically, these institutions do not have the required nuclear medicine personnel to perform the studies. In the past, such situations have been resolved after encouraging the institution to associate with, or contract to, a nearby medical institution in order to secure the appropriate personnel and facilities. If the information specified below has been supplied and we are satisfied that all regulations are met, the proposed human research study may be authorized.

Licensing: NRC has authorized its licensees to conduct these types of studies provided certain criteria are met or certain commitments are made.

1. Specific Licenses of Limited Scope - Be sure that:

   a. The proposed authorized user is a physician as defined in paragraph 35.2 of 10 CFR Part 35.

   b. The proposed physician-user has adequate training and experience. Any physician whose training and experience meet or exceed those specified in Section 35.910 or 35.920 of 10 CFR Part 35 has adequate training and experience. Physicians with less training and experience must be considered on a case-by-case basis; contact the Medical, Academic, and Commercial Use Safety Branch staff for assistance.

   c. The proposed research project meets all the requirements of 21 CFR 361.1 and has been approved by an FDA-approved RDRC. If the reviewer is unsure of whether the RDRC has the authority to permit a proposed human research study, as required in 21 CFR 361.1, contact the Medical, Academic, and Commercial Use Safety Branch staff for assistance.

   d. The licensee has adequate facilities, equipment, and radiation safety procedures for handling the radioactive material proposed for use in the research study. In most cases, the licensee will not need to supply additional information because the typical RDRC research study involves use of no more than several millicuries of tritium or carbon-14 or other materials that require radiation safety procedures similar to those required by Section 35.100 of 10 CFR Part 35.

   Enclosure 4 contains a sample license condition for a limited scope medical license showing how a human research study may be authorized.

2. Specific Licenses of Broad Scope - Be sure that:

   a. The licensee's description of its Radiation Safety Committee's (RSC's) criteria for selecting users should describe criteria for those wanting to administer radioactive materials to humans for

research purposes. These proposed users must be physicians as defined in Section 35.2 of 10 CFR Part 35 and must have adequate training and experience. If the licensee proposes to accept training and experience that are less than those described in Sections 35.910 and 35.920 of 10 CFR Part 35, the reviewer must be sure that the criteria are adequate and reasonable in light of the licensee's entire program and should consult with the Regional section leader before accepting the proposed criteria. The section leader may in turn wish to consult with members of the ACMUI before making a licensing decision.

b. The licensee's description of its RSC's criteria for approving proposed uses of radioactive material shall require, among other things, that research studies involving the administration of radioactive materials to humans are approved by a FDA-approved RDRC. In its review of proposed RDRC studies, it is expected that the RSC will also consider the need for special equipment and facilities or for special radiation safety procedures.

Enclosure 5 contains a sample license condition for a broad scope license showing how a human research study may be authorized.

Regulatory references: 10 CFR 31, 10 CFR 35, 21 CFR 361

Subject codes: 1.3, 11.3, 11.5, 12.13

Applicability: Byproduct material

HPPOS-194 **PDR-9111210320**

Title: Licensee's Responsibility for Shipment of Waste and Radioactive Materials

See the letter from V. L. Miller to J. Mangusi (Transnuclear, Inc.) dated August 1, 1986. NRC's general policy is that the generator of radioactive contamination and waste should be responsible for all onsite processing and any shipments offsite. Therefore, NMSS has not normally licensed service companies to possess waste at power reactors.

In a letter dated June 26, 1986, it was asked whether Transnuclear could obtain a license to possess contaminated equipment at reactor sites for the purpose of turning the radioactive material over to a carrier for shipment. NRC general policy is that the generators of radioactive contamination and waste should be responsible for all onsite processing and any shipments offsite. NRC believes that it is not in the interest of public health and safety to divide this responsibility between generators and service companies because the consequences of any accidents or problems associated with contamination and waste could be aggravated by questions of responsibility. Therefore, NRC has not normally licensed service companies to possess radioactive contamination or waste at power reactor sites. Rather, any onsite service companies operate under the reactor license, and the reactor licensee is responsible for all onsite service activities and offsite shipments.

Regulatory references: 10 CFR 30

Subject codes: 9.0, 11.3

Applicability: All

HPPOS-196 **PDR-9111210326**

Title: Explosive Detectors for Use at Airports

See the memorandum from S. A. Treby to R. E. Cunningham dated April 17, 1987, and the memorandum from R. E. Cunningham to S. A. Treby dated March 19, 1987. NRC has no direct authority to regulate neutron activated materials from byproduct sources such as californium-252. However, under 10 CFR 20.105(a), NRC can require the licensee to consider radiation safety from all sources in unrestricted areas. Also see 10 CFR 51.20(a). This health physics position applies to "new" 10 CFR 20.1301(c).

Considerations by NMSS raised questions concerning the proposed use of neutron sources to detect explosives in baggage prior to loading onto aircraft. The device contains a Cf-252 source which meets the definition of byproduct material in 10 CFR 30.3(d). The Cf-252 is used as a source of neutrons to excite nitrogen which is commonly found in explosives. The excited nitrogen-15 undergoes radioactive decay by emission of 10.8-MeV gamma rays. The gamma rays are detected and configured by an array of scintillation detectors on three sides of the baggage. A microcomputer warns a user of the device that the baggage is likely to contain explosives. During this process,

some activation of materials both in the baggage and the baggage itself occurs.

The response of OGC to various questions are provided seriatim below:

1. We find no direct statutory authority for NRC to exercise regulatory jurisdiction over material made radioactive though neutron activation where byproduct material is the neutron source. Such radionuclides would not be byproduct material as defined in AEA Section 11e. Apparently, activation using byproduct material was not contemplated by Congress when it defined byproduct material. NRC does have clear authority under AEA Section 81 to license and regulate the use of Cf-252 to protect the public health and safety from any radiological hazard present and associated with that use; and it remains the fact that the induced radiation created through the use of Cf-252 in the described manner creates a potential exposure of the public to radiation. NRC regulations require the licensee to consider radiation from all sources in radiation safety in unrestricted areas [10 CFR 20.105(a) or 10 CFR 20.1301(c)]. Because of this, it is our opinion that NRC has the authority to take into account all the potential radiation effects associated with the described use of licensed material.

2. It is our understanding from talking with a staff member in NMSS, that the anticipated exposure levels will be far less than the thresholds of exposure addressed in 10 CFR Part 20. Since the anticipated material is not "byproduct" material, no regulatory action would be needed for its "possession" by travelers. This would not preclude placing appropriate licensing conditions on the use of Cf-252 so as to insure no harm to the public health and safety.

3. Whether the public should be informed that materials within their baggage may be subject to activation because of exposure to the Cf-252 source appears to be more a public relations policy decision rather than a legal question. The desirability of fully informing the public may be offset by the possible unreasonable fear of "radiation exposure." Having said this, in our opinion open candor would be the preferred policy.

4. Agreement States, having been given authority over licensing the use of byproduct material, would have the authority to license the proposed use.

5. The proposed licensing action does not appear to fall within the categorical exclusion contained in 10 CFR 51.22; nor on its face does it appear to meet the criteria requiring an environmental impact statement as set out in 51.20(b). Therefore, an environmental assessment must be made pursuant to 51.21 unless the Commission, in the exercise of its discretion, determines that the licensing action should be covered by an environmental impact statement [51.20(a)(2)]. The environmental assessment would be made and further processed in accordance with 51.25, 51.30, etc.

Regulatory references: 10 CFR 20.105, 10 CFR 20.1301, 10 CFR 51.20, 10 CFR 51.22

Subject codes: 11.3, 11.5, 12.9

Applicability: Byproduct Material

HPPOS-256 **PDR-306070047**

Title: Supplement to Policy and Guidance Directive FC 84-20, "Impact of Revision of 10 CFR Part 51 on Materials Licensing Actions"

See memorandum from R. E. Cunningham dated February 19, 1992, providing guidance for determining when field studies are eligible for a categorical exclusion in accordance with 10 CFR 51.22 and do not require coordination with NMSS. The memo contains two enclosures which should be consulted for additional information. HPPOS-209 contains a related topic.

A major revision of 10 CFR Part 51 was published in the Federal Register in March 1984 (49 FR 9352) and established which categories of licensing actions are categorical exclusions and no not require an environmental assessment. A categorical exclusion for the use of radioactive material for research and development, and for educational purposes is granted in 10 CFR 51.22(c)(14)(v). However, the Statements of Consideration state that, "This categorical exclusion dose not encompass performance of field studies in which licensed material is deliberately released directly into the environment for purposes of study." The need for an environmental assessment for field studies should continue to be determined on a case-by-case basis. A request for an environmental assessment can always be required in accordance with the provisions specified in 10 CFR 51.22(b).

Field studies that deliberately release radioactive material into the environment, such as tagging of animals which remain in the wild, may require an environmental assessment in accordance with 10 CFR 51.21. Further, if the proposed activity is not similar to normal routine research, development and educational activities, then an environmental assessment may be needed. All studies that may require an environmental assessment must be coordinated with NMSS as a Technical Assistance Request (TAR).

Field studies that do not deliberately release radioactive material to the environment, such as tagging of animals and penning then to prevent escape, may be eligible for a categorical exclusion (see Enclosure 1 for additional examples). If the field study does not involve the "intentional or deliberate" release of radioactive material into the environment (e.g., the release is recoverable, retrievable, revocable) and it is a research, development, or educational activity, then the field study qualifies for a categorical exclusion in accordance with 10 CFR 51.22(c)(14)(v). If the field study is not research, development or education, but the field study could qualify as a "similar" activity compared with other 10 CFR 51.22(c)(14)(xvi) activities, then the field study qualifies for a categorical exclusion in accordance with 10 CFR 51.22(c)(14)(xvi). In these cases, a written explanatory memorandum must be prepared describing that the amount, type, and activity is similar to routine research, development, or educational activities and criteria for a categorical exclusion listed in 10 CFR 51.22(c)(14)(xvi). The information which should be contained in the memorandum includes:

1. A description of the study which includes the radionuclide (chemical characteristics and solubility), total activity, procedures to control and control the radioactive material, location of study, size of study, and length of time study will be conducted (material must be controlled and cleaned up to qualify),

2. The potential dose to individuals and estimated effluent releases (dose and releases must be less than 10 percent of the 10 CFR Part 20 limits to qualify),

3. A statement that there is no impact to endangered species, and

4. A statement on the ability to restrict access to the study area.

This memorandum must be made part of the permanent docket file and be approved by the appropriate Division Director or his delegate. The flow diagram in Figure 1 (Enclosure 2) assists in determining when field studies are eligible for categorical exclusion.

Regulatory references: 10 CFR 51.21, 10 CFR 51.22

Subject codes: 11.1, 11.8

Applicability: All

HPPOS-209 **PDR-9111210367**

Title: Part 51 Review of Amendment Request From Boston University

See the memorandum from V. L. Miller to J. E. Glenn dated January 27, 1986. This memo states that the proposed amendment request from Boston University to conduct a limited field study involving 15 microcuries of Zn-65, Sr-85, or Se-75 for each of 30 prairie dogs would not need an environmental assessment since the study fell within the categorical exclusion of 10 CFR 51.22(c)(14)(v).

The proposed action was a limited field study involving about 15 microcuries of zinc-65, strontium-85, and selenium-75 for each of 30 prairie dogs. An environmental assessment for the proposal was not needed because the half-lives of the radioactive material were short and 10 microcuries is an exempt quantity. The proposed study would have negligible radiological impact and falls within the categorical exclusion of 10 CFR 51.22(c)(14)(v).

Regulatory references: 10 CFR 51.22

Subject codes: 11.5, 11.8, 12.8

Applicability: All

HPPOS-218 **PDR-9111220023**

Title: Regulatory Responsibilities for Byproduct Materials in Non-Power Reactors

See the memorandum from D. M. Crutchfield to F. J. Congel (and others) dated March 8, 1988. Byproduct materials within non-power reactors is covered under the reactor license. NMSS does not normally issue

separate licenses which authorize possession of licensed material within an operating reactor facility. All byproduct material inserted into or removed from the reactor, is covered by the reactor license while the material is within the facility. The facility boundaries for non-power reactors are normally defined in the FSAR or TS, and exceptions should be referred immediately to HQ.

In a memorandum dated June 8, 1987, Region IV requested guidance for determining cases where licensed material in a non-power reactor facility may be covered by an NRC license or an Agreement State license, rather than the reactor license. This issue becomes important in determining compliance and issuing notices of violation involving licensed material in a reactor facility. All Regions were asked to comment on this issue, and after consideration of these comments, NRR provided the following guidance. The guidance was coordinated with NMSS, GPA, and OGC.

1. Generic guidance related to this issue is contained in Inspection Manual Chapter 2882, Appendices 1 and 2. Normally, material within a non-power reactor facility will generally be assumed to be possessed by the reactor licensee, unless there is prior documentation approved by NRC or some other clear demonstration that the licensed material is covered under another license.

2. Consistent with (1) above, NMSS does not normally issue separate licenses which authorize possession of licensed material within an operating reactor facility. If a reactor facility license is silent with regard to possession of byproduct material, it should be amended. NRC normally exercises exclusive federal jurisdiction within operating reactor facilities.

3. All byproduct material which is to be inserted into a reactor, or which is removed from the reactor, must be covered by the reactor license while the material is within the facility.

4. The facility boundaries for a non-power reactor are normally defined by the Safety Analysis Report or Technical Specifications. In the absence of identifiable facility boundaries, the Regions should establish a facility boundary with the license for compliance purposes, and the boundary should be specified in the TS or FSAR.

5. As indicated in Manual Chapter 2882, Appendix 2, there are exceptions to the above guidelines, and specific cases can be complex. Questionable cases should be referred to HQ for resolution along with a proposed course of action.

Regulatory references: 10 CFR 50, Technical Specifications

Subject codes: 3.3, 11.5, 12.9

Applicability: Non-Power Reactors

HPPOS-195 **PDR-9111210322**

Title: Transport License Condition - Radiography License

See the memorandum from J. Liberman to G. H. Bidinger dated August 24, 1978. This memo states that license conditions give the licensee notice of required compliance with DOT regulations under 10 CFR Part 71.5, but in no sense is the licensee excused from compliance with other provisions of 10 CFR Part 71 and other applicable regulations.

Guidance was sought as to the intent of the following standard license condition: "The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, 'Packaging of Radioactive Material for Transport'."

The intent of this license condition is to emphasize to the licensee that transport of licensed materials is subject to applicable DOT regulations pertaining to packaging, labelling, marking, and like matters. The condition should not be read to exempt licensees from compliance with other regulations under Part 71 or other NRC regulations.

10 CFR Part 71, including paragraph 71.5, was amended in 1972, with the intent of bringing within the scope of DOT regulations, shipments by AEC licensees that were not then subject to DOT jurisdiction. DOT's packaging and labelling requirements were to be imposed on all future cases, either under DOT or AEC authority. Under the 1972 revisions, DOT regulations apply to all transport of licensed materials by carrier outside the confines of the licensee's plant or place of licensed material use (10

CFR 71.2). The requirements of Part 71 are in addition to, not in substitution for other requirements related to packaging and transport [10 CFR 71.1(b)], and the regulations of Part 71 apply to each person authorized by specific license to receive, possess, use or transfer licensed materials. The required compliance with DOT regulations imposed on licensees in 10 CFR 71.5 is not exclusive; compliance with other portions of Part 71 and other applicable regulations is required.

10 CFR 71.3 requires licensees who transport or deliver licensed materials to a carrier for transport to hold a general or specific license issued by NRC, unless exempted from such requirements under 10 CFR 71.6-71.9. For shipments within the limits set by 10 CFR 71.11, a general license can deliver licensed material to a carrier for transport without compliance with the package standards of Subpart C of Part 71. Under 10 CFR 71.12, a general license is issued for shipments delivered to a carrier in DOT-specification containers, NMSS approved packages, or in packages approved by a foreign government meeting IAEA requirements.

If a licensee can not qualify for an exemption or general license, a specific license is required. The necessary contents of a specific license for transport of licensed materials include: (1) a package description as required in 10 CFR 71.22; (2) a package evaluation as required in 10 CFR 71.23; (3) a description of proposed procedural controls as required in 10 CFR 71.24; and (4) in case of fissile material, an identification of the proposed fissile class. Private carriage is permissible; however, such carriage is subject to DOT and NRC regulations as described above.

10 CFR 71.5 requires compliance with regulations of DOT 49 CFR Parts 170-189, 14 CFR Part 103, 46 CFR Part 146, and of the U.S. Postal Service in 39 CFR Parts 14-15. However, regulations in 14 CFR Part 103 and 39 CFR Parts 14-15 have been withdrawn or removed and consolidated under DOT regulation in 49 CFR Parts 170-189.

License conditions give the licensee notice of required compliance with DOT regulations under 10 CFR 71.5, particularly for the benefit of licensees who themselves intend to transport their own licensed material. The licensee is not excused, however, from compliance with other provisions of Part 71 and other applicable regulations.

Regulatory references: 10 CFR 71, License Conditions

Subject codes: 11.5, 12.17

Applicability: Byproduct Material

HPPOS-029 **PDR-9111210151**

Title: Application of 10 CFR 40.13(c)(1)(vi)

See the memorandum from R. L. Fonner to J. Joyner dated December 14, 1982. This memorandum states the OELD opinion that 10 CFR 40.13(c)(1)(vi) applies only to rare earth products containing <0.25% source material by weight. The exemption does not apply to incoming ore or to waste streams. The health physics position was written in the context of 10 CFR 20.301, but it also applies to "new" 10 CFR 20.2001.

In its licensing application, Molybdenum Corporation of America was urging a view of 10 CFR 40.13(c)(1)(vi) that would permit it to include both incoming raw material for rare earth processing and end of processing waste streams under the exemption for rare earth products that do not exceed 0.25% source material by weight.

OELD ruled that 10 CFR 40.13(c)(1)(vi) applies only to rare earth products containing less than 0.25% source materials by weight. The exemption does not apply to incoming ore or to waste streams. In justifying their decision, OELD stated that 10 CFR 40.13(c)(1)(vi) has identical wording to that contained in 10 CFR 40.60 Schedule I, first promulgated by the Atomic Energy Commission on March 20, 1947. Schedule I stated:

> "(f) Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight thorium, uranium, or any combination of these."

Therefore, items referred to in 10 CFR 40.13(c)(1)(vi) are finished commercial products of the rare earth refining process. An exemption for raw material (e.g., for ores or concentrates used as raw material) has to be justified in terms of either 10 CFR 40.13(a) or (b). The disposal of radioactive waste should be regulated under 10 CFR 20.301 [or, at present, under the requirements of the 10 CFR 20.2001(a) and (b)] and 10 CFR 61.

Regulatory references: 20.301, 10 CFR 20.2001, 10 CFR 40.13, 10 CFR 61

Subject codes: 3.8, 9.0, 11.6

Applicability: Source Material

HPPOS-184 PDR-9111210289

Title: Licensing for Crushing of Uranium Ore per 10 CFR 40.4(k)

See the memorandum from G. D. Brown to G. W. Roy dated July 13, 1977, and the informal note from R. L. Fonner to G. W. Kerr dated March 1, 1977. Crushing of uranium ore is a form of processing subject to licensing by definition in 10 CFR 40.4(k).

A licensee possessed an NRC license for the milling of uranium ore. During an inspection, the licensee was cited as follows:

> 10 CFR 20.207(a) states that licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage. [Note: Similar requirements can be found in the "new" 10 CFR Part 20, Section 20.1801.]
>
> Contrary to the above, crushed ore was observed by the inspector to be outside the fenced restricted area and unsecured in two areas: the facility parking lot, and the area adjacent to the ore stockpile along Highway 160.

The licensee contended that the crushed ore (run through a crusher at the mill) was not licensed material pursuant to 10 CFR 40.13(b), "Unimportant Quantities of Source Material," since it was unrefined and unprocessed ore as defined in 10 CFR 40.4. The licensee contended that grinding, in the milling industry, is part of the milling process, whereas, crushing is not. Therefore, their position was that the citation was not legally valid, and a legal ruling was needed as to whether or not the crushed ore was unrefined ore or ore that was licensable.

10 CFR 40.13(b) exempts for licensing unrefined and unprocessed ore (excepting export). 10 CFR 40.4(k) defines "unrefined and unprocessed ore" as ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. "Processing" in this definition includes both physical and chemical procedures that alter the ore from the condition it was in just after removal from its place of deposit in nature.

It is accepted interpretation of the AEA of 1954, as amended, that section 52 does not authorize the regulation of uranium mining by licensing. However, AEA does permit regulation by licensing at any stage after mining. 10 CFR 40.13(b), by exempting the transportation and handling of unprocessed ore, implicitly recognizes this authority to regulate. Further, by drawing the exemption lines at unprocessed and unrefined ore (i.e., ore whose gross appearance and chemical state has not been altered from the point of mining), there is recognition of underlying health and safety considerations. The assumption is that any processing or refining may alter the radiological environment associated with the source material enough so that the health and safety of workers and others becomes a matter of legitimate regulatory concern.

If the handling of the ore (e.g., sorting) exposes workers to an increase in exposure to radioactive material (i.e., radium, radon, etc.), it may be viewed as a licensable situation. Crushing of ore is obviously a form of processing subject to licensing by definition in 10 CFR 40.4(k).

Regulatory references: 10 CFR 40.3, 10 CFR 40.4

Subject codes: 3.8, 11.6, 12.9

Applicability: Fuel Cycle

2.15 ENFORCEMENT

HPPOS-113 **PDR-9111210260**

Title: Enforcement of Regulatory Guides

See the memorandum from D. Thompson to J. P. O'Reilly (and others) dated February 17, 1977. OELD advises that if licensee Regulatory Guides state that the intent of the Regulatory Guide will be accomplished or that the licensee will generally follow the guide, IE can not enforce against such statements except in rare cases where conditions of noncompliance are obvious.

Problems with enforcement have been encountered by Regions with respect to licensees committing to Regulatory Guides in Safety Analysis Reports or security plans in such a manner as to be not legally binding. Licensees may state in their plan that they will accomplish certain functions according to the "intent" of a Regulatory Guide. The "intent" of the Guide, and whether the licensee met the "intent", may be subject to interpretation by inspectors and licensees. The Executive Legal Director advises that if a licensee states in their plan that the "intent" of the guide will be accomplished, or that they will "generally" follow the guide, enforcement against such loosely worded statements can not be made except when conditions of noncompliance are clearly obvious. Enforcement can be made against those sections of the Regulatory Guides referenced in the Regulations as "shall", but enforcement can not be made against those sections which are recommended "should" or allowed as optional "may".

The position of IE and the Legal Staff is that Licensing should assure that those functions which the licensee must perform be stated clearly in the requirement to assure that they are enforceable. Therefore, the Regulatory Guides should adopt standard terms such as "shall" be accomplished (meaning required), "should" be accomplished (meaning recommended), and "may" be accomplished (permissive). Such licensing functions, however, will likely require legal review. It is requested that specific matters involving enforcement problems encountered during inspections be forwarded to IE Headquarters so that they can be brought to the attention of Licensing.

Regulatory references: Regulatory Guides

Subject codes: 12.7

Applicability: Reactors

HPPOS-058 **PDR-9111210237**

Title: Processing of Transportation Enforcement Cases Based on Third Party Data Collected by Agreement State Agencies

See the memorandum from H. D. Thornburg to B. H. Grier (and others) dated December 5, 1980, and the two enclosed memoranda from S. Sohinki to J. H. Sniezek dated November 13, 1980, and J. H. Sniezek to J. Lieberman dated November 3, 1980. It is appropriate to process enforcement actions against NRC licensees on the basis of data obtained by a State.

On October 17, 1980, NRC representatives met with officials of the South Carolina Bureau of Radiological Health to discuss matters of mutual interest regarding inspection of incoming waste shipments to a waste disposal site. Among the items discussed was the question of whether or not NRC was planning to use data and evidence collected by the State inspectors to process enforcement actions on violations by NRC licensee/shippers in those cases when an NRC inspector was not physically present at the site when the shipment was inspected. This question had arisen on a number of occasions and its answer became all the more important since NRC coverage at the site was about 3 to 5 days per month.

It is an OELD opinion that should any transportation enforcement action result in a hearing, the results of inspections performed by state inspectors which form the bases for NRC action would be admissible provided the state inspectors are available to testify. OELD has spoken to the Assistant Attorney General for the Division of Health and Environmental Control, and informed that the state inspectors were anxious to cooperate in any way they can in the event of a hearing. In order to effectively foster that cooperation, however, two items were discussed that are believed to be helpful.

First, both NRC headquarters and the Region II staff must recognize that, to the extent of reliance upon state inspectors in South Carolina, the state should be kept informed with regard to every step of NRC

proposed enforcement actions. This includes providing the Division of Health and Environmental Control with drafts of all proposed enforcement documents so that they are aware of the action and can assure our enforcement document does not mischaracterize any actions taken by state inspectors.

Second, from time to time NRC issues Bulletins that interpret IE enforcement criteria or standards. To the extent that any of these Bulletins or other interpretive documents relate to activities conducted by state inspectors, the Division of Health and Environmental Control should receive copies.

The discussions with South Carolina were somewhat further advanced than with other states. Accordingly, Region II was asked to finalize any necessary details with South Carolina and proceed to process a "test case" when the appropriate opportunity presents itself. Region V was asked to explore the idea with state licensing authorities in Nevada and Washington, with the view of obtaining their agreement to cooperate on such cases. If they appeared agreeable, all that would remain would be to coordinate the protocols and proceed on some test cases.

Regulatory references: 10 CFR 2, 10 CFR 71

Subject codes: 12.7, 12.17

Applicability: All

HPPOS-123 **PDR-9111210285**

Title: Ellis Fischel State Cancer Hospital - Violation of 10 CFR 19.16(c)

See the memorandum from D. Thompson to J. G. Keppler dated February 27, 1981. The authority of the Department of Labor (DOL) in employee protection does not abridge NRC authority to investigate alleged discrimination and take enforcement action. The preservation of the flow of safety information to NRC must entail enforcement actions of both DOL and NRC. Although 10 CFR 19.16(c) is no longer in the regulations, the material is still applicable.

It is a matter of NRC policy that the authority of the DOL in employee protection matters does not in any way abridge the NRC's preexisting authority under Section 161 of the Atomic Energy Act to investigate an alleged act of discrimination and to take appropriate enforcement action. The NRC's goal in such matters is to protect the flow of health and safety information needed to further regulatory responsibilities. The actions of DOL focus primarily on the protection of the individual employee. It is the NRC belief that the preservation of this flow of safety information to the NRC must entail the enforcement actions of both DOL and NRC, the former to insulate employees from adverse actions resulting from their cooperation with the NRC, and the latter to communicate clearly to the industry that the NRC will not tolerate acts of discrimination against employees as a result of such cooperation.

Regulatory references: 10 CFR 19.16, Atomic Energy Act

Subject codes: 12.7, 12.13, 12.19

Applicability: All

HPPOS-109 **PDR-9111210257**

Title: Requirements in ANSI Standards vs. Facility Technical Specifications

See the memorandum from T. M. Novak to S. E. Bryan dated April 21, 1981. When there are conflicts between requirements in Technical Specifications and "requirements" in ANSI Standards, the requirements contained in the Technical Specifications override those in the ANSI Standards. But, requirements in ANSI Standards should be complied with when they supplement and are not in conflict with similar requirements in Technical Specifications.

Regulatory references: ANSI Standards, Technical Specifications

Subject codes: 12.7

Applicability: Reactors

HPPOS-151 **PDR-9111220098**

Title: Transportation Enforcement Guidance

See the memorandum from D. Thompson to R. Carlson (and others) dated May 4, 1981. This memo provides enforcement guidance for transportation violations (with and without State actions) involving

transport of low specific activity (LSA) radwaste to a commercial disposal site. References to Interim Enforcement Policy are outdated.

The Region should first determine whether the appropriate State has taken any enforcement action (e.g., imposition of a civil penalty or suspension or revocation of the licensee's burial permit) against the licensee as a result of the violation. If the State has taken action, the only further NRC enforcement action is the issuance of a Notice of Violation (NOV). If the Severity Level of the violation, as determined by the Region, is IV, V, or VI, the NOV is issued by the Region. If the Severity Level of the violation determined by the Region is I, II, or III, the enforcement package should be forwarded to IE Headquarters for issuance of a Headquarters NOV. In either case, the NOV and accompanying documents will require the licensee to submit a description of the corrective action the licensee proposes to take or has taken in order to insure against future violations of a similar nature. The corrective action will be reviewed by the Region and if deemed unsatisfactory, further enforcement action to ensure compliance with NRC regulations will be considered.

Violations categorized at Severity Levels I, II, or III and discovered by the NRC at the licensee's facility or where the State has not taken action will be forwarded by the Region to Headquarters in the standard enforcement package with recommendations for appropriate enforcement (civil penalties, etc.). In situations where the violation is "similar" to a previous violation committed by the licensee, enforcement action beyond the issuance of a Regional or Headquarters NOV will normally be taken, even when the State itself has taken enforcement action. In order to determine "similar" violations, previous corrective actions undertaken by the licensee will be examined. If previous corrective actions could have prevented the violation from occurring, the violation will be considered "similar" and further enforcement action is appropriate.

For those cases where appropriate enforcement action to be taken beyond the level of a NOV involves a civil penalty (e.g., where the State has not taken any enforcement action or where "similar" violations have occurred), the amount of base civil penalty is calculated as follows. For first time violations, penalties are assessed at 25% of the values described in Table 1 of the Interim Enforcement Policy (45 Fed. Reg. 66756). If the violation is "similar" to one that previously occurred, penalties should be assessed at 50% of the values described in Table 1 of the Interim Enforcement Policy. For violations that have occurred more than twice, the appropriate level of civil penalty or other enforcement action will be determined on a case-by-case basis.

Regulatory references: 10 CFR 2

Subject codes: 12.7, 12.9, 12.17

Applicability: All

HPPOS-112 **PDR-9111210258**

Title: Degree of Proof Necessary in a Regulatory Enforcement Action

See the memorandum from M. G. Malsch to Chairman Palladino (and others) dated November 9, 1981. Presiding Board or judge must reach the result dictated by a preponderance of evidence in the record. This is less stringent than the criminal standard of proof beyond a reasonable doubt.

At a Commission briefing concerning enforcement matters on October 27, 1981, a statement was requested on the degree of proof necessary in a regulatory enforcement action as opposed to a criminal case. Assuming that the question refers to the legal standard for proof in an adjudicatory hearing on an enforcement action, the answer is that the presiding board or administrative law judge must reach the result dictated by a preponderance of evidence in the record. This is true because the agency has made its rules for adjudications applicable to enforcement matters [see 10 CFR 2.700 and 2.204 (e)] and the preponderance standard has been held to be the correct one under those rules [Tennessee Valley Authority (Hartsville Nuclear Plant, Units 1A, 2A, 1B and 2B), ALAB-463, 7 NRC 341, 360 (1878), citing *inter alia* Charlton v. FTC, 543 F.2d 903, 907 (D. C. Cir. 1976); Consolidated Edison Co. of New York (Indian Point Station, Unit No. 2), ALAB-188, 7 AEC 323, 356-357 (1974)]. Moreover, in license suspension and revocation proceedings the APA applies as provided by sections 181 and 189a of the Atomic Energy Act, and under the APA the preponderance of the evidence is the proper standard. This is a less stringent standard than the criminal standard which, as the Commission is aware, requires proof beyond a reasonable doubt.

The Supreme Court upheld the preponderance standard in a challenge to an SEC disciplinary proceeding that resulted in debarring a petitioner from practicing his profession. The Court found that where Congress has not specifically required a different standard and the proceeding is an adjudication subject to the APA, the preponderance standard and the proceeding is an adjudication subject to the APA, the preponderance standard is the correct one [Steadman v. SEC, ___ U.S. ____, 67 L.Ed.2d 69, rehearing den. 68 L.Ed.2d 318 (1981)]. For a more complete discussion of this case see the March 2, 1981 memorandum from Bickwith [SECY-81-129]. Congress has not provided specifically for a standard of proof in civil penalty hearings and, while such hearings may not technically be subject to the APA, by agency rule they apply the same standard the agency applies to adjudications governed by the APA. Thus it is safe to say that the preponderance standard would be upheld even in an NRC enforcement action that had serious personal consequences for a named offender. This assumes a challenge in the Court of Appeals. An aggrieved party has the alternative of a trial *de novo* in the district court. See also Vance v. Terrazas [444 U.S. 252 (1980) (finding no constitutional infirmity in deprivation of citizenship based on preponderance of evidence)]. In Steadman, the petitioner did not argue for the criminal standard, but urged that a "clear and convincing" evidence standard should be applied. "Clear, convincing and unequivocal" was the standard at issue in Vance.

Although it need not do so, the Commission could probably require a greater burden of persuasion depending on the gravity of the matters in question or the gravity of the anticipated effect in terms of imposition on individuals of severe penalties or permanent stigma. See Virginia Electric and Power Company [(North Anna Power Station, Units 1,2,3 and 4), 1 NRC 10, 17 n.18), and Steadman v. SEC at 80 (Justices Powell and Stewart dissenting)]. As the Supreme Court has frequently stated, agencies are free to grant the public greater protection than the APA requires. See, for example, Vermont Yankee Nuclear Power Co. v. NRDC [435 U.S. 519, 545 (1978)]. The Commission could consider such action in its review of enforcement policy.

A different but related question refers to the standard that should underlie the agency's decision to proceed with an enforcement action. Such a decision is in the nature of a prosecutorial decision and must in large measure be guided by the Commission's policy on how aggressive an enforcement stance it wishes to maintain. The decision must, of course, recognize that in the event the party against whom the enforcement action is brought requests a hearing, the agency must meet its burden of proof. At that time, however, the full panoply of trial procedures are available to assist in meeting that burden.

Regulatory references: 10 CFR 2

Subject codes: 12.7, 12.19

Applicability: All

HPPOS-059 **PDR-9111210240**

Title: Enforcement of License Conditions in Material Licenses

See the memorandum from J. A. Axelrad to H. E. Book dated June 30, 1983. Regions should follow the policy that licensees be cited for not meeting their license conditions even if the conditions are more restrictive than the minimally acceptable practices specified in regulatory guides.

In a memorandum dated December 23, 1982, Region V staff were informed that licensees should not be cited for commitments in their license applications that are more restrictive than the minimally acceptable guidance in regulatory guides, provided the licensee is complying with that guidance. This policy was questioned by NMSS in a March 14, 1983 memorandum that stated licensees should be cited for not meeting the commitments made in applications even if they are more restrictive than the minimally acceptable practices specified in regulatory guides. Further, licensees who desire relief from commitments made in their applications should apply for license amendments.

In their memorandum dated June 30,1983, IE stated that they agreed with NMSS and commitments made by licensees in applications and incorporated as license conditions should be enforced, provided that meeting the commitments would not lead to unsafe conditions. Regulatory guides can not and should not alter commitments made in license applications that are subsequently incorporated into the license. If a licensee wants relief from a license commitment, an amendment to the license should be requested.

Regulatory references: License Conditions

Subject codes: 12.7

Applicability: All

HPPOS-141 **PDR-9111210379**

Title: Employee Protection from Employers for Revealing Safety Violations

See the letter from J. M. Taylor to W. H. Owen (Duke Power Company) dated June 30, 1986. The letter was written concerning a Notice of Violation (NOV) for alleged discrimination against an employee for engaging in protected activities. The Evaluation and Conclusion Appendix enclosed with the letter states that protected activities include the reporting of QA discrepancies and nuclear safety problems by an employee to his employer. Employees are protected from retaliation and discrimination for internal safety activities that involve no contact with NRC.

A licensee had disputed the NRC's view that "protected activities" under 10 CFR 50.7, as well as under paragraph 210 of the Energy Reorganization Act, include the reporting of quality assurance discrepancies and nuclear safety problems by an employee to his employer. The licensee argued that an employee must contact the NRC "or some other competent organization of government." The licensee based its view on the decision of the U.S. Court of Appeals for the Fifth Circuit in Brown & Root, Inc., v. Donovan, 747 F.2d 1029 (5th Cir. 1984), in which that court held that "employee conduct which does not involve the employee's contact or involvement with a competent organization of government is not protected" under paragraph 210 of the Energy Reorganization Act.

The NRC believes that the better view of "protected activities" under paragraph 210 is that employees are protected from retaliation and discrimination under the statute for purely internal safety activities that involve no contact with representatives of the NRC. The Ninth and Tenth Circuit Courts of Appeals support this construction of paragraph 210 and have rejected the analysis of the Fifth Circuit Court (see Mackowiak v. University Nuclear Systems, Inc., 735 F.2d 1159, 1162-63, Ninth Circuit 1984; Kansas Gas and Electric Co. v. Brock, 780 F2.d 1505, 1510-12, Tenth Circuit 1985). The Commission follows this view in the application of its own employee protection regulations such as 10 CFR 50.7.

Regulatory references: 10 CFR 19.20, 10 CFR 30.7, 10 CFR 50.7

Subject codes: 12.1, 12.7, 12.13

Applicability: All

HPPOS-244 **PDR-9111220090**

Title: Enforcement Discretion by NRC Concerning Violations that are Self-Identifying

See the letter from M. R. Knapp to C. D. Frizzle (President, Maine Atomic Power Company) dated October 24, 1990. The exercise of enforcement discretion by NRC requires that the problems be both licensee-identified and corrected in a timely manner. If timely action is not taken, the exercise of enforcement discretion is not appropriate.

On July 13, 1990, I sent you a letter and Notice of Violation for violations of NRC requirements associated with an event at the Maine Yankee facility involving a lack of adequate radiological control of work activities at your facility. The violations and the associated event, which included elevated dose rates and unplanned radiation exposure, had been discussed during an enforcement conference on June 27, 1990.

At the enforcement conference, you contended that the NRC should exercise enforcement discretion and not issue a Notice of Violation because, in part, the violations were licensee-identified. In my July 13, 1990 letter transmitting the notice, I stated that the exercise of enforcement discretion in this case was not appropriate since "the violations were clearly self-identifying in that the workers, who had received the unplanned, unmonitored radiation exposures, personally informed radiological controls personnel that they were receiving radiation exposure that was not being properly monitored by their dosimetry."

While the NRC continues to maintain that the exercise of enforcement discretion was not appropriate in this case, the explanation provided in my July 13, 1990 letter was incorrect. Contrary to this letter, the NRC does consider the problems to be licensee-identified. The NRC wishes to encourage licensee identification and correction of problems to the

maximum extent possible, whether through formal audit and oversight programs or other forms of identification, including identification of problems which may be considered "self-identifying".

In this case, the problems were identified by Maine Yankee through your representatives who were contractor personnel. Since they notified radiological controls personnel of their concerns about higher that expected radiation doses in their work area, the violations were licensee-identified.

With regard to the use of enforcement discretion by the NRC, the exercise of such discretion requires that the problems be both licensee-identified and corrected in a timely way. In this case, timely action was not taken by the radiological controls personnel, and it was not until later that the elevated dose rates and unplanned radiation exposures were discovered. Therefore, on this basis, the exercise of enforcement discretion is not appropriate. We do note that you later took prompt and vigorous corrective actions (as recognized in my July 13, 1990 letter) following your confirmation of the unplanned, unmonitored radiation exposures of the workers.

I trust that the above discussion clearly describes the NRC position on licensee-identified violations and our reasons for not exercising enforcement discretion in this case. I regret any difficulties which my July 13, 1990 letter may have caused Maine Yankee Atomic Power Company.

Regulatory references: None

Subject codes: 12.7

Applicability: All

HPPOS-232 **PDR-9111210339**

Title: Enforcement Guidance Concerning "Substantial Potential" for Overexposure or Release ....

See the memorandum from L. J. Cunningham to J. Lieberman dated May 15, 1991. An event presents a substantial potential when it was fortuitous that the resulting exposure or release did not exceed the limits of 10 CFR Part 20. If it is possible to construct a reasonable scenario in which a minor alteration of circumstances would have resulted in a violation of Part 20 limits, enforcement action should be considered due to the substantial potential for overexposure.

Enclosure 1 provides the final draft of enforcement guidance on what constitutes a "substantial potential" for overexposure, as used in C.4 of Supplement IV to 10 CFR 2, Appendix C. This input to the Enforcement Manual was provided following several enforcement actions where Regions applied a narrow interpretation of "substantial potential." The Severity Level III examples of Section C.4 of Supplement IV involve situations that present a "substantial potential for an exposure or release in excess of 10 CFR 20 whether or not such an exposure or release occurs.

An event presents a substantial potential when it was fortuitous that the resulting exposure or release did not exceed the limits of 10 CFR 20. The concern is not the significance of the resulting, or potential, exposure (Example C.1 of Supplement IV addresses exposures in excess of Part 20 limits), but whether the licensee provided adequate controls over the situation, as required, to prevent exceeding the Part 20 limits. No credit is given for luck. When taking escalated enforcement action for this example consider if it is possible to construct a reasonable scenario in which a minor alteration of circumstances would have resulted in a violation of the Part 20 limits. The following circumstances should be considered:

1. Timing - Could the exposure period have reasonably been longer?

An individual in the proximity of an unknown source of radiation receives an unplanned excessive exposure. Because of the duration of the exposure, no limits were exceeded; however, the individual could have reasonably stayed in the proximity of the source long enough to be overexposed.

2. Source Strength - Could the radiation source have reasonably been stronger?

An inadvertent release results from a worker venting the wrong waste gas decay tank. Although the release did not exceed Part 20 limits, the same mistake could have resulted in venting a decay tank with enough activity to exceed the limits.

3. Distance - Could the person have reasonably been closer to the source?

In example (1) above, the individual could have been overexposed by standing closer to the source of the radiation.

4. Shielding - Could some unintended shielding have been reasonably removed?

A radioactive source was accidently left in an office area. Shielding afforded by a desk prevented the overexposure of an individual worker in the office. However, nothing prevented the source from being left in an area of the office, that would not have been shielded by the desk, where the individual would likely have been overexposed.

Regions were solicited for comments and they were incorporated in this final draft, with the exception of two comments in Enclosure 2 to this memorandum. The responses to these two comments were as follows.

1. Supplement IV clearly refers to the exposure and release limits in 10 CFR 20, not the 24-hour reporting requirements of 10 CFR 20.403(b) [or "new" 10 CFR 20.2202(b)].

2. A Severity Level III violation does not have to present the risk of a serious violation of Part 20; there is no reference to serious violations in example C.1 of Supplement IV. An event meets the "substantial potential" test if the licensee's controls were not effective in preventing a violation of Part 20 and the consequences of the event were a matter of chance.

Regulatory references: 10 CFR 2

Subject codes: 12.7

Applicability: All

HPPOS-236 **PDR-9111210355**

Title: The Meaning of "... May Have Caused or Threatens to Cause ..." in 10 CFR 20.403

See the memorandum from L. J. Cunningham to J. H. Joyner (and others) dated June 20, 1991. The words "may have caused" in 10 CFR 20.403 apply to a retrospective view of the event at the time prompt reporting is being considered, and the words "threatens to cause" apply to a prospective view at that time. In consideration of the ordinary meanings of "threaten", NRC understands "threaten to cause" in 10 CFR 20.403 to mean "probably is about to cause" or, in other words, "likely will cause soon." The health physics position was written in the context 10 CFR 20.403, but it also applies to "new" 10 CFR 20.2202.

A comment on the proposed revision of "old" 10 CFR 20.403 (55FR 19890, 5/14/90) and the applicability of 10 CFR 20.403 to one circumstance of an enforcement case (Hatch, Inspection Report No. 50-321/91-05) has resulted in a clarification of the meaning, with respect to exposure and releases, of the condition, "... any event involving licensed material that may have caused or threatens to cause ..." in 10 CFR 20.403(a) and (b). [Note: Similar wording is found in the requirements of 10 CFR 20.2202(a) and (b).] The words "may have caused" in 10 CFR 20.403 [or 10 CFR 20.2202] apply to a retrospective view of the event at the time prompt reporting is being considered. The words "threatens to cause" apply to a prospective view at that time.

The words "... may have caused ... [an] exposure ... or ... release" in 10 CFR 20.403 [and 10 CFR 20.2202] are used in the context of the rapid assessment of the significance of an event with respect to determining whether or not the event must be reported "immediately" or "within 24 hours." Somewhat similar words, "substantial potential for an exposure or release ..." are used in supplement IV.C.4 of the NRC Enforcement Policy (10 CFR Part 2, Appendix C) in the context of determining the significance of an event with respect to determining the Severity Level of a violation after it has been determined that the violation has occurred. However, the words "may have caused ..." in 10 CFR 20.403 [10 CFR 20.2202] do not have exactly the same meaning as the words "substantial potential ..." in the Enforcement Policy. The words "may have caused" do not refer to an exposure or release that (at the time the need for prompt reporting is being considered) is known not to have occurred even though there was a "substantial potential" for the exposure or release.

For an example of the difference between "may have caused" and "substantial potential," consider a hypothetical event (based on the event at Hatch) in which there was a "substantial potential" for someone entering a particular room and receiving a whole-body exposure of 5 rems or more while in the room. When considering the need for prompt reporting of an event, if it is known that someone entered the room and that the person received, or may have received, an exposure of 5 rems or more, then that event is reportable under 10 CFR 20.403 [or 10 CFR 20.2202]. However, if it is known that no one entered the room, the event is not

reportable under 10 CFR 20.403 [or 10 CFR 20.2202] even though a substantial potential may have existed for someone to enter the room and receive the exposure.

With respect to the requirements of 10 CFR 20.403 [or 10 CFR 20.2202], the preceding discussion has considered situations in which an exposure or release that exceeded the specified values is known not to have occurred. If the conditions for a reportable release or overexposure are known to have been present (i.e., because of the known circumstances, there is at least a possibility that such an event did occur), and the licensee is unable to establish definitively that the suspected event actually did not occur, then the licensee must make a report. The report is not an admission on the part of the licensee that the event did occur; it merely allows NRC the opportunity to participate in evaluating whether or not the event did occur while the facts and circumstances are still fresh in the minds of the cognizant individuals.

Although not reported to the NRC, information on significant radiological exposures and releases at nuclear power reactors that fall below the reporting thresholds of 10 CFR 20.403 [or 10 CFR 20.2202] (including events that have a "substantial potential for an exposure or release ...") usually is available to inspectors in the files of licensee radiological event tracking systems or as feedback from resident inspectors. These events could result in violations. In consideration of the ordinary meanings (dictionary definitions) of "threaten," NRC understands "threatens to cause" in 10 CFR 20.403 [or 10 CFR 20.2202] to mean "probably is about to cause" or, in other words, "likely will cause soon." The clarifications given in this NRR memorandum have been coordinated with OE, NMSS, AEOD and RES. OGC has no legal objections.

Regulatory references: 10 CFR 20.403, 10 CFR 20.2202

Subject codes: 2.2, 12.7

Applicability: All

2.16 JURISDICTION

HPPOS-054 **PDR-9111210229**

Title: Applicability of State Regulations on NRC Inspectors

See the memorandum from J. Lieberman to E. L. Jordan dated October 3, 1978. States have no authority to impose additional qualifications or restrictions on the performance of government business by federal officers or agents. NRC inspectors are not subject to state regulations that are more restrictive than NRC regulations.

A request was made for OELD guidance on the binding effect on NRC inspectors of regulations found in Industrial Bulletin No. 5 of the Commonwealth of Massachusetts, Department of Labor and Industries, Division of Industrial Safety. Specifically, OELD was requested to evaluate: (1) whether NRC inspectors are subject to state regulations that are more restrictive than NRC regulations, and (2) how to convey the NRC position on this matter to licensees and to states. These questions arose as a result of a licensee's refusal to allow an NRC inspector to enter a containment area because the inspector did not have an annual physical examination as required under Section 12.1 of the state regulations. A confrontation with the licensee did not occur as the inspector chose not to insist on entry.

It is a fundamental principle of our federal system that the states have no power to impede, burden, or control the manner in which the federal government implements the lawful enactments of Congress [MuCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 436 (1819)]. Under this concept of federal supremacy, states have no authority to impose additional qualifications or restrictions on the performance of government business by federal officers or agents [Johnson v. Maryland, 254 U.S. 51 (1920)]. The federal government and its agents are not liable for criminal or civil penalties imposed by state statutes or regulations for lawful actions pursuant to federal law [Massachusetts v. Hills, 437 F. Supp. 351 (D. Mass. 1977)]. As the inspector here was clearly authorized to conduct a lawful inspection under the Atomic Energy Act of 1954, as amended, the licensee had no basis for refusing the inspector's entry to the containment, either on the theory that the inspector did not comply with state regula-

tions or that the licensee itself would suffer liability if it permitted the inspector to enter. Neither the NRC, its inspector, nor the licensee could be liable to the state in this situation because of the supremacy of federal law [Leslie Miller, Inc. v. Arkansas, 352 U.S. 187 (1956)].

Moreover, Section 1.2 states that the regulations are "intended to be in harmony with federal regulations as they apply." Given this stated purpose, it does not appear that Massachusetts intended its regulations to interfere with NRC's inspection activities under the Atomic Energy Act of 1954, as amended, and other federal statutes. The Massachusetts regulations apply to "places of employment" where operations involve the use or emission of ionizing radiation. The requirement for medical examinations applies to employers who may assign employees, agents or contractors to operations at the site. As the NRC is not an employer subject to the jurisdiction of a state and since the licensee does not "assign" inspectors to this plant, the regulations are not applicable to the NRC.

Unless similar situations present increasing problems, OELD sees no need to raise this supremacy issue with the licensees. OELD would prefer to handle similar problems, if any, on a case-by-case basis. The inspectors should be informed that supposedly conflicting state regulations do not provide the licensee an acceptable basis for refusing an NRC inspection. In the individual case, inspectors should follow normal procedures and notify headquarters if a licensee refuses inspection of its facilities. If discussions between IE:HQ and licensee management, including discussion between their respective counsels, cannot remedy the situation, consideration might be given to issuing an order to permit the inspection.

Regulatory references: None

Subject codes: 12.9, 12.18

Applicability: All

HPPOS-265 **PDR-9306070303**

Title: Policy and Guidance Directive FC 83-19, "Jurisdiction at Reactor Facilities"

See the memorandum from R. E. Cunningham to Regional Administrators (and Branch Chiefs, Division of Fuel Cycle and Material Safety) dated September 16, 1983. The possession and use of radioactive materials at a reactor facility prior to issuance of an operating license and subsequent to issuance of a construction permit are under exclusive NRC jurisdiction when the materials are directly connected with reactor operation and are needed during the construction and preoperational phases of a reactor. HPPOS-120 contains a related topic.

The possession and use of radioactive materials at a reactor facility that has an operating license is under exclusive NRC jurisdiction when the materials are used in connection with reactor operations. Contractors to the reactor licensee may not be separately licensed. All activities must be carried out under the operating license.

The exception to the rule of exclusive NRC jurisdiction is the possession and use of byproduct material for performance of industrial radiography. A firm which holds an NRC or Agreement State license that authorizes performance of radiography may do radiography at reactor sites pursuant to that license.

Occasionally a reactor licensee may wish to do industrial radiography at the reactor site. If the site is located in an Agreement State, the license for the performance should be obtained from the Agreement State. If the site is in a non-Agreement State, a separate license issued pursuant to 10 CFR Part 34 should be obtained from the NRC by the reactor licensee.

Regulatory references: Atomic Energy Act, 10 CFR 150.15

Subject codes: 12.2, 12.9

Applicability: Byproduct and Special Nuclear Materials

HPPOS-197 **PDR-9111210327**

Title: Authority of Agreement States Concerning Their Licensees Working at DOE Facilities

See the memorandum from R. L. Fonner to G. L. Sjoblom dated March 20, 1987. Agreement States have continuing authority over their licensees working at DOE facilities, such as the case of the radiography overexposure incident at Idaho National Engineering

Laboratory. This is not true for the rare situation of exclusive federal jurisdiction.

Numerous documents are enclosed that describe an incident at the DOE's Idaho National Engineering Laboratory (INEL) where a source disconnect occurred while radiography operations were being conducted on December 8, 1976. Film badges worn by the two radiographers involved showed total body doses of 3.2 rems and 4.8 rems.

Guidance was sought because DOE's Chief Counsel at the Idaho Operations Office stated that, although INEL was not an area of exclusive federal jurisdiction but rather one of proprietary jurisdiction, DOE considered the site as exclusive for licensing purposes and that DOE does not recognize any State responsibility at INEL. The State of Idaho, however, questioned this opinion in regards to the State's role in licensing and investigative responsibility.

The Office of General Council, NRC, stated that the enforcement jurisdiction in this case was vested in the State of Idaho. This would also be the situation under the reciprocity provisions of State law if the radiography company had been licensed by NRC but engaged in activities in an Agreement State. (See the parallel reciprocity provisions contained in 10 CFR 150.20.)

As to jurisdiction, the NRC does not exercise regulatory or enforcement authority over radiographers at INEL. In Agreement States, the NRC would license and regulate private parties, such as the radiographers, who are normally subject to State jurisdiction only in areas of exclusive federal jurisdiction. Exclusive federal jurisdiction is based upon Article I, Section 8, Clause 17 of the Constitution and applies only to land acquired according to its terms; primarily that the State Legislature has ceded exclusive jurisdiction over the land to the federal government and Congress has accepted the land on that basis. Relatively few areas such as described exist.

Regulatory references: 10 CFR 30.12, 10 CFR 150.20

Subject codes: 12.2, 12.9

Applicability: Byproduct Material

HPPOS-207 PDR-9111210359

Title: Licensing of Industrial Radiographers at NRC Licensed Operating Reactors and Reactor Construction Sites

See the letter from D. A. Nussbaumer to All Agreement States dated August 29, 1983. This letter states that Agreement States radiography licensees working at NRC licensed operating reactors and at reactor construction sites are subject to the Agreement State's jurisdiction, unless other factors apply. Factors that may apply include exclusive federal jurisdiction over the land where the reactor is located or the reactor is being built or operated by a federal agency. HPPOS-197 contains a related topic.

The NRC received inquiries concerning the licensing of industrial radiography operations not only at reactor construction sites, but also at NRC licensed operating reactors. In some cases, the radiography was performed by contracted radiographers and in other cases by the utility. The specific question asked was whether such radiography operations were considered to be "directly connected with operations" and subject to exclusive NRC jurisdiction.

The OELD reviewed the question and advised that such radiography is subject to Agreement State jurisdiction when occurring in Agreement States (unless other factors apply such as exclusive federal jurisdiction over the land where the reactor is situated or the reactor is being built or operated by a federal agency).

Regulatory references: 10 CFR 34, 10 CFR 150.20

Subject codes: 11.5, 12.2, 12.9

Applicability: All

HPPOS-092 PDR-9111210185

Title: Commercial Storage at Power Plant Sites of Radwaste Not Generated by the Utility

See the letter from W. J. Dircks to All Licensees dated August 1, 1985. NRC is opposed to any activity at a reactor site that is not supportive of authorized activities. Interim storage of low-level radioactive waste (LLW) within the exclusion area of a reactor site is subject to NRC jurisdiction. In an Agreement

State, for storage outside the exclusion area, the State has authority.

The Low-Level Radioactive Waste Act of 1980 assigned states the responsibility for disposal of commercial LLW generated within each state, and a few states have expressed some interest in the use of existing nuclear power sites. As a matter of policy, NRC is opposed to any activity at a nuclear reactor site which may divert 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). Within Agreement States, for locations outside the exclusion areas, the licensing authority is in the Agreement State.

In order for NRC to consider any proposal for commercial LLW storage at a reactor site, the NRC must be convinced that no significant environmental impact will result and that the commercial storage activities will be consistent with and not compromise the safe operation of the licensee's activities, including diverting reactor management attention from the continued safety of reactor operations. The Office of Nuclear Reactor Regulation (NRR) will conduct an environmental review and review the application to determine if the LLW commercial storage activities on a reactor site will impact the safe operation of the reactor. Following NRR review, the licensing authority for commercial storage under NRC jurisdiction is the Office of Nuclear Material Safety and Safeguards (NMSS). A Part 30 license is required for the LLW storage and a Part 50 license amendment may also be required. The application must address the following issues.

BY THE UTILITY: A determination by the utility licensee that the LLW commercial storage activities do not involve a safety or environmental question, and that safe operation of the reactor will not be affected. In making this determination, the licensee shall consider:

1. Direct impacts of commercial storage activities on reactor operations during normal and accident conditions.

2. Diversion of utility management and personnel attention from safe reactor operation.

3. Combined effects of onsite and offsite dose during normal and accident conditions.

4. Influence on effectiveness of both reactor emergency plans and reactor security plans.

5. Financial liability provisions, including impact on indemnity coverage.

6. Environmental impact of the storage facility, including potential interaction with the generating station.

BY THE APPLICANT: The utility or another person shall consider:

1. Safety of the commercial storage operation.

2. Environmental impact of the storage operation in sufficient detail for NRC to establish the need for an Environmental Impact Statement.

3. Financial assurance to provide for commercial storage operation and decommissioning including any necessary repackaging, transportation and disposal of the waste.

4. Written agreement from the jurisdiction responsible for ultimate disposal, the State, that provisions are sufficient to assure ultimate disposal of the stored waste.

As part of the procedures, the 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 NRC staff's intent regarding preparation of an environmental assessment and its circulation for public review and comment. The environmental assessment will most likely require the preparation of an Environmental Impact Statement in accordance with the provisions of 10 CFR 51.20, 51.21 and 51.25.

Regulatory references: 10 CFR 100.3, 10 CFR 150.15

Subject codes: 9.6, 12.2, 12.9

Applicability: Reactors

HPPOS-097 **PDR-9111210206**

Title: Jurisdiction Over Low Level Waste Management at Reactor Sites in Agreement States

See the memorandum from G. H. Cunningham to H. R. Denton dated September 13, 1985. This memo provides the following OELD opinion. The NRC has jurisdiction over the handling and storage of low-level wastes within the reactor exclusion area. In Agreement States, the states have control over land burial of low level wastes, even in the exclusion area. The opinion also extends to reactor decommissioning.

In Agreement States, the NRC licenses and regulates the handling and storage of low level waste in the exclusion area. When wastes are derived from offsite waste generators, NRC jurisdiction is based on 10 CFR 100.3(a), which requires the reactor licensee to have an exclusion area in which the licensee maintains and has full control over all activities in order to protect public health and safety from the release of possible fission products from hypothetical major accidents. Under Generic Letter 85-14, any program sponsored by a state to fulfill its low level waste obligations in accordance with the Low Level Radioactive Waste Policy Act (Public Law 96-573, 42 U.S.C. 2021b-2021d) by storage of waste within the exclusion area of a nuclear power reactor is subject to the licensing and regulatory jurisdiction of the NRC pursuant to 10 CFR 150.15(e)(1).

The disposal of low level radioactive waste generated by the operation of a nuclear reactor was omitted in 10 CFR 150.15 as a function reserved to the federal government. This implies that it was relinquished to the Agreement States. Therefore, because of the hazards or potential hazards of high level atomic energy wastes from the chemical processing of irradiated fuel elements, its disposal is governed by license pursuant to CFR 150.15(a)(4). However, the states have control over land burial of low level wastes (27 FR 1351, February 14, 1962).

In regards to the decommissioning of nuclear reactors, after removal of all special nuclear material from the site and fixing the reactor so that it can never again be used in the production or utilization of special nuclear material, Agreement States may regulate the remaining byproduct radioactivity provided the NRC takes the position that leaving the radioactive structures on site in a safe configuration is the method of choice for disposal. But, assuming a continued legal viability for 10 CFR 150.15(a)(1), a storage option preserves NRC jurisdiction.

Regulatory references: 10 CFR 20.302, 10 CFR 100.3, 10 CFR 150.15, 10 CFR 20.2002

Subject codes: 9.6, 12.2, 12.9

Applicability: Reactors

HPPOS-078 **PDR-9111210199**

Title: Jurisdiction of Mobile Radwaste Units Operating at Nuclear Power Plants

See the letter from V. Stello, Jr., to J. S. Grant (Toledo Edison Company) dated February 28, 1979, and the enclosed letter from R. E. Cunningham to J. S. Stewart (Chem-Nuclear Systems, Inc.) dated September 14, 1978. The functions performed by mobile radwaste units at power plants fall within the operation of the facility under 10 CFR Part 50. During transportation, the carrier possesses the licensed material in transit.

In a letter dated November 21, 1978, the Toledo Edison Company raised several questions concerning possession of radioactive waste material at nuclear power reactor sites and during shipment of these materials to Chem-Nuclear's waste burial grounds.

The functions performed by mobile radwaste units at nuclear power reactor sites fall within the scope of activities that may be carried out as part of reactor operations under a facility operating license issued pursuant to 10 CFR Part 50. Control of radioactive waste generated at a reactor site is the responsibility of the reactor facility licensee under its license. A letter dated September 14, 1978, to Chem-Nuclear Systems, Inc., provides some information about the regulatory requirements on the use of contractor mobile radwaste systems. In any case, regardless of the method of processing radwaste, the reactor facility licensee is responsible for assuring that all activities on its site are carried out in a manner consistent with the facility operating license and the Commission's regulations. The reactor facility licensee is also responsible for assuring that all activities are conducted in a manner that provide adequate protection from the standpoint of radiological health and safety.

In answer to specific questions raised in the letter dated November 21, 1978:

1. The responsibility for control of reactor radwaste on the reactor site is governed by the reactor operating license. It is the reactor licensee's responsibility to assure that these activities are carried out in accordance with the requirements of the reactor operating license and the regulations of the NRC. The reactor licensee may have the activities carried out by employees or contractors. However, the responsibilities for radiological safety and the common defense and security imposed on the licensee by the reactor license and by the Commission's regulations remain with the reactor licensee.

2. By 10 CFR 50.11(c), common or contract carriers are exempt from licensing requirements. Private carriers require an NRC or Agreement State license to possess the material in carriage. In any case, the carrier possesses the licensed radioactive material in transit.

3. The reactor licensee is responsible for assuring compliance with all NRC regulations applicable to radioactive material generated in the operation of the reactor. These include all applicable requirements relating to the transfer of radioactive materials contained in 10 CFR Parts 20, 30, 70, 71, and 73. The reactor licensee, depending on circumstances, may also have obligations under transportation regulations, such as 49 CFR Parts 170 through 189.

Regulatory references: 10 CFR 50

Subject codes: 9.0, 12.9

Applicability: Reactors

HPPOS-111 **PDR-9111210255**

Title: Response to Inquiry Regarding Deletion of NRC Water Quality Requirements from Maine Yankee

See the memorandum from H. K. Shapar and H. R. Denton to Commissioner Bradford dated March 21, 1980. This memo concerns the NRC role in assessing water quality. Based on Appeal Board rulings, NRC does not have the authority to impose conditions of operation, including monitoring requirements, in the water quality area. Regulation of water quality lies in the NPDES system under EPA or the States. HPPOS-115 contains a related topic.

The Appeal Board, after analysis of the legislative history of the Federal Water Pollution Control Act Amendments of 1972, concluded that by virtue of Section 511(c)(2) of the Act, EPA, or those states to whom permitting authority has been delegated, had exclusive responsibility for water quality protection and that the regulation of water quality lies in the NPDES permit system. The NRC's role in water quality is limited to assessing aquatic impacts as part of its NEPA cost-benefit balance in its licensing decision. The NRC role does not include any right for "undertaking its own analysis and reaching its own conclusions on water quality issues already decided by EPA" (8 NRC at 715), or including any limiting conditions of operation or monitoring requirements of its own in the license for the protection of the aquatic environment (8 NRC at 713-714). The NRC will continue to require aquatic monitoring programs and NRC notification if the NPDES permit limits are exceeded, or if the limits are revised. Under review is the issue of whether NRC has jurisdiction under NEPA to impose conditions protecting the aquatic environment where EPA or a permitting state has not issued an NPDES or the NPDES permit is not effective because of appeal proceedings.

The deletion of conditions relating to water quality from technical specifications are considered license amendments. They are noticed in the Federal Register after they have been effected. These changes are considered ministerial actions required as a matter of law and therefore no environmental impact assessment need be prepared as a condition precedent to taking the action.

Regulatory references: Technical Specifications

Subject codes: 12.9, 12.13

Applicability: Reactors

HPPOS-115 **PDR-9111210267**

Title: EPA Inspections for Compliance with NPDES Permits Issued to NRC Licensees

See the memorandum from L. B. Higginbotham to G. D. Brown dated April 14, 1976. The EPA has authority to make inspections related to a National

Pollutant Discharge Elimination System (NPDES) permit. The EPA can grant States the authority to issue NPDES permits; giving the States similar authority to make inspections.

The EPA, under the Federal Water Pollution Control Act (Public Law 92-500), is acting within its jurisdiction to conduct periodic inspections to determine the degree of compliance by licensees with NPDES permits. Representatives of the EPA can observe process operations, inspect monitoring and laboratory equipment and methods, collect samples, examine appropriate records, and be concerned with other related matters. The NPDES permit system was implemented by the EPA under Title 10 "Protection of the Environment," Code of Federal Regulations, Chapter I. Section 309 (Federal Enforcement) gives the EPA the authority to levy civil monetary penalties for noncompliance.

The EPA can also grant the States the authority to issue NPDES permits. This gives those States the authority, having issued an NPDES permit to an NRC licensee, to inspect and assure compliance with the permit.

Regulatory references: None

Subject codes: 12.9, 12.13

Applicability: Reactors

HPPOS-301 PDR-9306220344

Title: Technical Assistance Request, Heritage Minerals, Inc., Possession and Transfer of Monazite-Rich Product

See the memorandum from R. L. Fonner to J. D. Kinneman dated November 30, 1990, and the memorandum from J. E. Glenn to R. R. Bellamy dated April 29, 1992. The memos response to a TAR from Region I regarding the Heritage Minerals, Inc. ("Heritage"), request which proposed onsite disposal of monazite-rich sands by returning this monazite material to the host material from which it was derived. The disposal of the monazite sands involves complicated issues because the radiation hazard is caused mostly by naturally occurring radioactive materials (NORM) not covered by the Atomic Energy Act (AEA).

Heritage discontinued operations in July 1990, and they have decontaminated their building and equipment in accordance with their license (enclosures). They estimate, however, that 695 cubic yards of monazite sand remain on the site. The monazite-rich sand contains about 2,000 picocuries of thorium-232 per gram based on analysis for actinium-228 and a dry density for the monazite-rich sand of approximately 2.7 grams per cubic centimeter. This sand resulted from separation of the monazite-rich sands from previously processed subsurface deposits. The licensee has been unable to sell the monazite-rich sand and proposes onsite disposal by mixing it with an estimated 102,500 cubic yards of processed sand located in the salvage storage, recycled tailings, and original new feed areas (also known as the blue and gray areas, after the coloring of maps submitted by the licensee). The licensee intends to also submit a proposal to the State of New Jersey Department of Environmental Protection (NJDEP) to place a deed restriction on the property, cover the sand with a layer of soil, and use the area as a golf course. This approach will dispose of both the NRC licensed sand and the other sand of much lower concentration about which NJDEP is concerned.

Senior personnel of OGC have met to considered the question of NRC regulation of source material under NRC rules and AEA as applied to the areas referred to in License Condition 15 as the "original new feed area", "recycled tailings area", and "salvage storage area". The areas referred to as the gray and blue areas. The problem arises from the fact that the source material content in these areas is less than 0.05% by weight, and therefore represents a pre-existing unimportant quantity under 10 CFR 40.13(a) which is exempt from regulation. It should be noted that the AEA required the Commission to establish unimportant quantities (AEA Section 62). The first consensus reached was that regulation could not be based upon a characterization of the areas as having directly licensable material. That is, the contamination is an unimportant quantity (the contamination is clearly not byproduct material).

The second issue was whether the activities in the plant (in the red area) that resulted in separating out a monazite-rich product with source material in excess of .05% by weight provided a basis for jurisdiction over the blue and gray areas. The Commission has asserted jurisdiction over activities of licensees that were ancillary to the primary licensed activity. In the 1970s, the NRC staff relied upon the NEPA theory to

condition uranium milling licenses for remediation of mill tailings disposal areas prior to the enactment of the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978. All of these cases and practices, however, are marked by a feature that distinguishes them from Heritage Minerals. That is, the fact that the ancillary matters regulated under the National Environmental Policy Act (NEPA) theory would not occur or be present but for the primary licensed activity, i.e., the nuclear power plant or the uranium mill.

Initially, the separation of the monazite-rich product was ephemeral. It was considered a waste and put back into the waste stream. Indeed, during this period the process was not considered a licensable operation. The dry mill tailings were not stored (in the gray area) for reprocessing because of their source material value, but for other minerals such as ilmenite and rutile. Any source material in this feedstock was an unimportant quantity. The gray and blue areas would exist even if no monazite-rich materials were ever separated in the process; thus, the contamination is not the necessary consequence of a licensed (in the Heritage situation-licensable) activity, and which would not occur but for the licensed activity. The consensus is that the NEPA theory provides no basis to regulate the gray and blue areas. This result is consistent with the analogous licensing of side stream extraction of uranium at mineral processing facilities in the western states. The NRC has licensed the side stream extraction of uranium from the effluent of processing of nonsource material ores. In so doing, it has not attempted to regulated the process before the uranium extraction step, nor after, particularly with respect to waste streams.

Although OGC is mindful of the staff's concern about the radiation levels in the blue and gray areas, the OGC conclusion is that it is doubtful that NRC should undertake to regulate in the blue and gray areas. Accordingly, we suggest that License Condition 15 be revised. We see two options, although more may exist. First, remove reference to the areas of questionable regulation altogether, which would leave the question of regulation totally in the State of New Jersey. This option would recognize that the radiation hazard is caused mostly by naturally occurring radioactive material not covered by the AEA (actinium-228 and lead-212 predominate), presenting a legal situation identical to the radium in uranium mill tailings prior to the enactment of UMTRCA, but lacking the NEPA link as discussed above. Second, cover these areas in the license on a basis of acceptance by Heritage, as a voluntary commitment, to adhere to an NRC position (for example, to Option 3 in the Branch Technical Position, 46 FR 52061-52063). In any case the State of New Jersey authorities should be informed and included in any further discussions of this matter. Based upon the conclusions noted above, i.e., that the radiation hazard results predominantly from NORM, we would not consider regulation of the radiation hazards in the blue and gray areas to be preempted.

Regulatory references: Atomic Energy Act

Subject codes: 9.0, 12.9, 12.19

Applicability: Source Material

HPPOS-283 PDR-9306160232

Title: Technical Assistance Request Regarding Issues in Several U.S. Air Force Submittals Dated February 15, 1990, March 26, 1990, and October 23, 1990

See the memorandum from J. E. Glenn to L. J. Callan dated January 4, 1993. This memo responds to a technical assistance request from Region IV, dated October 2, 1992 (Enclosure 1), regarding issues in several U.S. Air Force submittals dated February 15, 1990, March 26, 1990, and October 23, 1990 (Attachments to Enclosure 1).

The following are the issues summarized in the TAR by Region IV and the NMSS comments on these issues:

1. USAF letter dated February 15, 1990, requests an exemption from 10 CFR Part 71 requirements when using the following Department of Transportation (DOT) exemptions: (1) Department of Defense (DOD) Exemption DOT-E 2136, March 31, 1988; and (2) DOD Exemption DOT-E7573, July 7, 1988 (Attachments to Enclosure 1).

One example cited by the USAF is the transportation of munitions containing explosives and licensed depleted uranium components by rail or in troop-carrying aircraft under sensitive circumstances involving national security or national defense. 10 CFR 71.7 states that on application of any interested person or on its own initiative, the Commission may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will

not endanger life or property or the common defense or security.

An exemption to 10 CFR 71 is appropriate based on the exemptions granted by DOT. However, it appears from a review of these exemptions that they have both expired and are no longer valid. Therefore, the region may only grant the exemptions from 10 CFR Part 71 contingent upon the DOT exemptions being current.

2. USAF letter dated March 26, 1990, requests exemption from leak testing carbon-14 (C-14) reference light sources used in hermetically sealed Astroinertial Navigational (AIN) units installed on aircraft.

This exemption appeared to be justified because (1) of the small size of the sources and the radionuclide involved and (2) the sources are hermetically sealed units that USAF does not repair or maintain. The sources range to a maximum activity of 500 microcurie (500 μCi), which is only five times the value specified for exempt C-14 in 10 CFR 30.71, Schedule B.

The request was referred by NMSS to the Source Containment and Devices Branch in a memorandum, dated November 13, 1992 (Enclosure 2), and based on their response (Enclosure 3), the revision to the leak test condition may be granted to the USAF.

3. USAF letter dated October 23, 1990, requests approval for alternate disposal under 10 CFR 20.302 [or, at present, 10 CFR 20.2002] to release 2.6 millicuries (mCi) of krypton-85 (Kr-85) to unrestricted areas by slowly venting the gas into a fume hood which exhausts directly to the effluent.

Alternative disposal was requested because burial sites will not accept Kr-85 at pressures above 22.044 pounds per square inch. The proposed alternate disposal is by venting the gas to unrestricted areas as discussed above. USAF's calculations show that annual limits of 10 CFR 20.106 [or, at present, 10 CFR 20.1302] for Kr-85 will not be exceeded by the venting request. Additionally, Wright-Patterson AFB (Ohio) has received concurrence from the Ohio Radiological Health Program and the Regional Air Pollution Agency for the action contingent upon NRC approval and compliance with National Emission Standards.

The requested method of disposal and consideration appears to be similar to the method discussed in the memorandum to W. Fisher, Region IV, dated January 30, 1992 (Enclosure 4), regarding an earlier Air Force request to dispose of the Kr-85 sources. This method should be approved provided that the limits of 10 CFR 20.106(a) [or 10 CFR 20.1302(b)] are not exceeded and actual exposures are maintained ALARA.

Regulatory references: 10 CFR 20.302, 10 CFR 20.2002, 10 CFR 30, 10 CFR 71

Subject codes: 7.8, 9.0, 9.1, 11.1, 12.17

Applicability: Byproduct and Special Nuclear Material

HPPOS-199 PDR-9111210334

Title: NRC's Jurisdiction at U.S. Armed Forces Bases Abroad

See the memorandum from T. F. Dorian to V. Miller dated July 16, 1985. The NRC has both territorial and personal jurisdiction at U.S. armed forces bases in foreign countries. At these bases, NRC personal jurisdiction applies but may conflict with the regulations of the host country and is not normally exercised.

The NRC has both territorial and personal jurisdiction at U.S. armed forces bases abroad. Normally, the NRC's territorial jurisdiction is limited to the licensing and regulation of special, source, and byproduct nuclear material within the geographical limits of the U.S. and its trust territories and possessions. This type of jurisdiction ceases when a person exports nuclear material outside U.S. territorial limits (i.e., the person sends or takes the material past U.S. customs). The NRC's personal jurisdiction is not limited in this manner. Personal jurisdiction travels with a U.S. person, whether as an individual licensee or the entire U.S. Army as a licensee, wherever that person may be using nuclear materials - in the U.S., neutral territories, on the high seas, abroad, or in space. As a legal matter, NRC has no problem regulating U.S. persons when they use nuclear materials in the U.S. or in such areas as Antarctica, Puerto Rico, on the high seas, or in space. It does run into a problem, though, when it attempts to regulate U.S. persons using nuclear materials within the geographical jurisdiction of another country.

The problem arises because NRC's jurisdiction over a U.S. person using nuclear materials in another country

may conflict with that country's jurisdiction. The NRC has solved this possible conflict of laws in the same manner for private persons and for public persons such as the armed forces. For individuals, the NRC policy has been to exert its jurisdiction only until they reach the geographical jurisdiction or the customs area of another country. For the armed forces using nuclear materials at U.S. bases around the world without having exported these materials, it has had to temper this policy. U.S. armed forces bases abroad are considered part of the U.S. for the purpose of carrying out U.S. laws; however, they also are part of the territory of the country in which they are located. Consequently, the rights and responsibilities of both the U.S. and the host country are spelled out in treaties and other documents. To avoid any conflict with other countries or with the armed forces, NRC's policy has been that it will not exercise its jurisdiction, personal or territorial, as long as the armed forces use their own internal permit systems.

Regulatory references: Atomic Energy Act, License Conditions

Subject codes: 11.3, 12.7, 12.9

Applicability: Byproduct Material

HPPOS-198 **PDR-9111210330**

Title: Licensing of Nuclear Materials for Use on the High Seas and in Antarctica

See the memorandum from J. R. Wolf to N. Bassin dated September 18, 1979. NRC's authority under the Atomic Energy Act is not restricted to the territory of the United States. The Commission has the authority to regulate licensed materials of U.S. ships on the high seas and U.S. bases in Antarctica.

Your proposed letter to Commander Vogt makes an assumption, which we regard as erroneous, that NRC authority under the Atomic Energy Act is restricted to the territory of the United States. While our authority arguably may not attach unless there is some territorial connection at the outset, our interest and jurisdiction once acquired can reasonably be invoked to regulate the use and possession of byproduct and special nuclear material until it has been terminated by virtue of licensed transfer, disposal, or export. This approach to jurisdiction is manifest in those provisions which distinguish between domestic distribution ("... to any person within the United States ...") and foreign distribution ("... for a use which is not under the jurisdiction of the United States.") (AEA Section 57c; see, also, AEA Sections 103d and 104d). Note that the latter clause refers to the United States in a juridical rather than a geographic sense. AEA Section 82 does differentiate between distributions of byproduct material between persons "outside the United States" on the one hand and "within the United States" on the other. However, even here, there is no bar to exercising regulatory jurisdiction outside territorial limits where the initial distribution is under AEA Section 81.

In construing the provisions of the Atomic Energy Act, it has long been our view that the Commission is authorized to license activities beyond continental limits so long as the activities are subject to United States jurisdiction. This jurisdiction may extend to United States citizens upon the high seas or even in foreign countries when the rights of other nations or their nationals are not infringed. On this basis, according to our legal memoranda files, the AEC found no limitation upon the Commission's power to exercise authority over the N. S. Savannah upon the high seas. Our prior licensing of the Navy to possess radioisotope thermal generators reflects a similar construction of the Atomic Energy Act. Moreover, the exercise of regulatory authority to protect the health and safety of the public (AEA Section 2e) is no less necessary outside territorial limits, particularly if the materials subject to regulation continue to present potential hazards to United States citizens.

For these reasons, we advise that you process the applications in the same manner as you would process applications for activities that are restricted to the territory of the United States. We note, however, that under the Antarctic Treaty, 12 U.S.T. 794, TIAS 4780, procedures have been established for the formulation of measures regarding questions relating to the exercise of jurisdiction in Antarctica, Article IX 1.(e). We should perhaps inquire of the Department of State regarding any measures as may have been adopted under Article IX, in order to assure that the exercise of NRC jurisdiction there is appropriate.

Regulatory references: Atomic Energy Act

Subject codes: 11.3, 12.9

Applicability: Byproduct Material

HPPOS-271 **PDR-9306100048**

Title: Technical Assistance Request Regarding Disposal of Liquid Waste into Arctic Ocean

See the memorandum from J. E. Glenn to R. R. Bellamy dated June 25, 1991. This memo was written in response to the May 28, 1991 letter (Enclosure 1) from R. F. Rivkin, University of Maryland, Center for Environmental and Estuarine Studies, which was sent to NMSS by Region 1 as a TAR. As indicated in Mr. Rivkin's letter, the National Science Foundation is sponsoring a research project involving the use of carbon-14 (C-14) and tritium (H-3). This project will take place in the Arctic Ocean during a research cruise from Murmansk, USSR, to Nome, Alaska, aboard a Soviet icebreaker, Sovetskiy Soyuz, from July 27 to August 16, 1991. Mr. Rivkin is seeking permission to dispose of about 10 millicuries of H-3 and 40 millicuries of C-14 in the Arctic Ocean.

Enclosure 1 states: "... the use of the radioisotopes will be to determine the rates of carbon incorporation of phytoplankton assemblages, the rates of bacterial production and the ingestion of bacteria and phytoplankton by microzooplankton in the Arctic Ocean. Briefly, either $NaH^{14}CO_3$ or *methyl*, ^{3}H-thymidine (^{3}H-TdR) will be added to seawater samples in glass or polycarbonate bottles and after an appropriate incubation interval, the particulate material will be collected onto a filter pad. The filter is retained and returned to the investigators home institution for further analysis. The seawater which passes through the filters contains the dissolved $NaH^{14}CO_3$ or ^{3}H-TdR which was not incorporated by the microbial organisms." And, "If this were a "normal" research cruise aboard the UNOLS fleet (i.e. the research vessels operated by U.S. universities), the liquid waste (*in the filtered seawater*) would be contained and returned to our university (*in Maryland*) for disposal. Unfortunately this will not be possible during this cruise. The port of debarkation is Nome, Alaska, which totally lacks rail and road service to the continental United States. The only way to retrograde the liquid waste would be by air which represents a significant safety hazard."

By memorandum dated June 5, 1991 (Enclosure 2), NMSS asked the Office of the General Counsel (OGC) for guidance in responding to Mr. Rivkin. OGC's June 20, 1991 memorandum is Enclosure 3. In summary, OGC indicates:

1. The Soviet icebreaker, a nuclear powered ship, cannot debark at Nome, Alaska, and cannot enter the territorial waters of the United States.

2. The NRC does not have jurisdiction over the proposed discharges of radioactive material into international waters. OGC suggests that Mr. Rivkin contact the State Department to learn if there are applicable international agreements or conventions governing such discharges. OGC also suggests that Mr. Rivkin discuss the proposed discharges with his Soviet colleagues.

Regulatory references: 10 CFR 20.2002

Subject codes: 9.0, 12.9, 12.13

Applicability: Byproduct Material

HPPOS-119 **PDR-9111210276**

Title: Interpretative Letter No. 76-02, "Radiography, Agreement State Licensed Materials Aboard U.S. Ships"

See the letter from G. W. Kerr to All Agreement States dated October 20, 1976. NRC was questioned concerning Agreement State-licensed radiographers who perform work on board U.S. Navy ships while in port for maintenance. It has been determined that persons working with Agreement State licensed materials on board U.S. Navy ships are subject to NRC jurisdiction. The subject radiographers will need a specific NRC license if they do not qualify for reciprocity pursuant to 10 CFR 150.20.

Regulatory references: 10 CFR 150.20

Subject codes: 12.2, 12.9

Applicability: Byproduct Material

2.17 TRANSPORTATION AND SHIPPING

HPPOS-153 PDR-9111220120

Title: Lost or Stolen Radioactive Sources Involved in Transportation

See the Interpretive Guide from the IE Manual entitled as above and dated April 1, 1980. The guide states that a licensee should not be cited against 10 CFR 20.402 for failure to report that licensed material has been delivered to a common carrier for transport and then has been lost, stolen, misplaced, misrouted or otherwise unaccounted for. The health physics position was written in the context of 10 CFR 20.402, but it also applies to "new" 10 CFR 20.2201.

Section 10 CFR 20.402 [or 10 CFR 20.2201] of the Commission's regulations requires that a licensee make a report to the Commission immediately after the occurrence of certain losses and thefts of licensed material becomes known to the licensee. This regulation could be interpreted as requiring the licensee-shipper to make the report upon notice of the loss or theft. The report would not be required of the licensee-shipper if the transfer to the licensee-receiver had occurred at place of shipment (FOB-shipment) but would be required if the transfer to the licensee-receiver had occurred at place of receipt (FOB-receipt). On the other hand, this requirement could be interpreted to mean that the licensee must only make the required report if the material was in the actual possession of the licensee when lost or stolen.

The matter is further clouded by the Memorandum of Understanding between the DOT and NRC dated June 22, 1979. Under the agreement, NRC will require its licensees to make reports if the reportable event "occurs prior to delivery to a carrier for transport or after delivery to a receiver" (Section V.B.). The DOT will require carriers subject to its jurisdiction to make reports to DOT if the reportable event "occurs in transit" (Section V.A.). The term "reportable event" is clarified in DOT regulations, Section 49 CFR 171.15 and 171.16. These events include "fire, breakage, spillage, or suspected radioactive contamination" but do not include lost, stolen, mislaid or waylaid shipments. Accordingly, in view of the ambiguity in 10 CFR 20.402 [or 10 CFR 20.2201] and the meaning of reportable event within DOT regulations, a licensee should not be cited for violating 10 CFR 20.402 [or 10 CFR 20.2201] in circumstances where licensed material has been delivered to a carrier and then is lost, stolen, misplaced, misrouted, or otherwise unaccounted for.

Since carriers are exempt from NRC regulations, there is no obligation for regional manpower to be used to assist in locating waylaid shipments, whether lost or stolen, or to put pressure on carriers to locate such shipments. However, if it is known that a serious health and safety problem does exist, one or all of representatives from either IE, DOT, States, or licensee-shippers should become involved in the interest of public health and safety. The events of interest would be those set forth in 49 CFR 171.15 and 171.16 as well as high radiation levels. In addition, while extremely rare, stolen sources should be followed up in the interest of public health and safety.

If a report is received of "lost" radioactive material in transit by common carrier, licensees should be encouraged to place a tracer on the shipment; IE need not become further involved.

Regulatory references: 10 CFR 20.402, 10 CFR 20.2201

Subject codes: 2.2, 3.7, 12.17

Applicability: All

HPPOS-013 PDR-9111210108

Title: Averaging of Radiation Levels Over the Detector Probe Area

See the letter from L. V. Gossick to J. J. Munro (Tech/Ops, Radiation Products Division) concerning PRM-20-9 and dated March 23, 1979. The letter states that averaging of radiation levels over the cross-sectional area of a probe of reasonable size is acceptable for demonstrating compliance with the requirements of 10 CFR 20.205(c)(2). This health physics position also applies to "new" 10 CFR 20.1906(d)(2).

PRM-20-9 was a petition submitted to NRR requesting amendment of 10 CFR Part 20.205(c)(2) regarding surface radiation level limits of packages for transport. It was requested that 10 CFR Part 20.205(c)(2) be amended so that radiation levels found five centimeters from the external surface of the

package in excess of 100 millirem/hour or three feet from the package in excess of 10 millirem/hour would require the immediate notification of the Director of the appropriate NRC Regional Office and the final delivering carrier. In determining the radiation levels, the measurements were to be averaged over a cross-sectional area of ten square centimeters with no linear dimension being greater than five centimeters.

As written, 10 CFR 20.205(c)(2) required a licensee who received a package of radioactive material in excess of Type A quantity to monitor the external radiation levels both at the surface and at three feet from the surface of the package. If the radiation levels exceeded 200 millirems per hour at the surface or 10 millirems per hour three feet from the surface, the licensee was to immediately report to the Director of the appropriate NRC Regional Office and to the final delivering carrier.

In denying the petition, the NRC stated that the proposed changes to 10 CFR Part 20.205(c)(2) would result in increased costs to the licensee without a corresponding benefit in improved public health or safety. In fact, the proposed changes would result in higher collective hand doses being delivered to package handlers.

In its ruling, the NRC stated that radiation levels averaged over a cross-sectional area of a probe of reasonable size is acceptable for demonstrating compliance with the requirements specified in 10 CFR 20.205(c)(2) [or 10 CFR 20.1906(d)(2)]. "A probe of reasonable size" was defined as: (1) the sensitive volume of the probe being small compared to the volume of the package being measured, and (2) the largest linear dimension of the sensitive volume of the probe being no greater than the smallest dimension of the package. Geiger-Mueller tubes may be used for both small and large packages but ionization chambers should be used only for large packages. Averaging is not acceptable for demonstrating cracks, pinholes, uncontrolled voids, or other defects prior to the first use of any packaging for the shipment of licensed materials as required by 10 CFR 71.53.

Regulatory references: 10 CFR 20.201, 10 CFR 20.205, 10 CFR 20.1501, 10 CFR 20.1906, 10 CFR 71.53

Subject codes: 7.1, 12.17

Applicability: All

HPPOS-038 **PDR-9111210177**

Title: Request for Interpretation of Applicability of DOT Regulations to NRC-Licensed State or Federal Entities

See the memorandum from W. J. Olmstead to L. I. Cobb dated April 11, 1985, and the memo from L. I. Cobb to J. H. Joyner (and others) dated April 16, 1985. It is an OELD opinion that federal, state, and other governmental entities transporting NRC-licensed material are not regulated by DOT but they are subject to the requirements of 10 CFR 71.5(b). For Agreement State-licensed material, regulatory authority appears to be vested in the various states.

The University of Missouri raised the question with Region III as to whether it was exempt from NRC requirements for transportation of radioactive material. NRC requirements in 10 CFR 71 incorporates DOT regulations for transportation of radioactive material by reference to certain specific sections of 49 CFR Parts 171, 172, 173, 174, and 176.

On a number of occasions DOT has stated that its regulations did not apply to purely governmental, non-business activities. However, OELD has stated, among other things, that federal, state, and other governmental entities transporting NRC-licensed material are subject to 10 CFR 71.5(b). This section refers to specific DOT rules that apply to NRC licensees.

One area which has not been addressed is transportation of Agreement State-licensed material by a government entity. Subsection 274b of the Atomic Energy Act of 1954, as amended, authorizes the NRC to enter into agreements with the individual States providing for the discontinuance of the regulatory authority of the NRC under chapters 6, 7, and 8, and section 161 the Act with respect to byproduct, source, and special nuclear material in quantities not sufficient to from a critical mass.

In conclusion, since federal, state, and other governmental entities transporting NRC-licensed material are not regulated by DOT, they are subject to 10 CFR 71.5(b). The provisions of 71.5(b) require these governmental entities to "conform to the standards and requirements of the DOT" referenced in 71.5(a). Where NRC-licensed material is involved, IE has the authority pursuant to 10 CFR 71.5 to require that governmental entities comply with the provisions of 71.5(a). Where the licensed material involved is Agreement State-licensed material, the regulatory authority appears to be vested in the various states.

Regulatory references: 10 CFR 71

Subject codes: 12.2, 12.9, 12.17

Applicability: All

HPPOS-208 **PDR-9111210363**

Title: Applicability of Federal Regulations to NRC Licensees Transfer of Radiative Materials to DOE for Shipment

See the memorandum from L. B. Higginbotham to G. H. Smith dated October 1, 1979. An NRC licensee may transfer licensed material to DOE and DOE then becomes the shipper. In this situation, the licensee does not have to meet the requirements of Part 71. However, the licensee-to-DOE material transfer must occur before shipment is made.

Questions were raised about the applicability of 10 CFR 71 to licensees who process licensed material for DOE. As explained below, it is an OELD opinion that 10 CFR 30.41, 40.51 and 70.42 provide adequate authority, if the requirements of these Sections are met, to permit the transfer to DOE of byproduct, source, or special nuclear material or of a radioactive-contaminated facility component without the need to amend any specific license.

NRC regulations prohibit the transfer of byproduct, source, and special nuclear material except as authorized in a specific or general license issued by the Commission pursuant to those regulations. NRC regulations also provide that licenses issued under 10 CFR Parts 30, 40 and 70 are subject to all valid rules, regulations and orders of the Commission.

10 CFR 30.41, 40.51 and 70.42 specify, respectively, the kinds of transfers that licensees holding byproduct material licenses, source material licenses and special nuclear material licenses are authorized to make. Licensees who are able to satisfy the requirements of these sections may rely on this authority to make transfers even though the work "transfer" does not appear in their licenses because the Commission regulations expressly provide that the terms and conditions of a license include the condition that the license is issued subject of Commission regulations. A licensee, under 10 CFR Parts 30, 40 and 70 of the Commission's regulations, is subject to all the provisions of the regulations, including 10 CFR 30.41, 40.51, and 70.42. Accordingly, it may rely on these provisions for the authority necessary to make transfers as long as the requirements of these provisions are met. Thus, no NRC specific license need be amended to accomplish the desired transfer to DOE.

Paragraphs (a) and (b)(1) of 10 CFR 70.42 provide as follows:

(a) No licensee shall transfer special nuclear material except as authorized pursuant to this section.

(b) Except as otherwise provided in this license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer special nuclear material:

> (1) To the [Energy Research and Development] Administration; ....

Pursuant to the provisions of 10 CFR 30.41, 40.51 and 70.42, DOE (formerly, the Energy Research and Development Administration) may take possession of the radioactive material or the contaminated facility component from an NRC licensee. As a practical matter, this could be accomplished by having an authorized employee or representative of DOE present at the licensee's site to assume responsibility and control of the shipment from the site.

If onsite transfer to DOE is completed, the NRC licensee will no longer be in the position of delivering "licensed material to the carrier for transport" under the general license provisions of 10 CFR 71.11 and 71.12 and the conditions precedent (e.g., an NRC-approved QA program for shipping packages) to the licensee's use of such a general license would no longer be applicable. For the same reason as above,

10 CFR 73.37 would not apply to NRC licensees who transfer spent fuel to DOE prior to shipment by DOE.

An NRC licensee may transfer byproduct, source, or special nuclear material or radioactive-contaminated facility components to DOE (or one of its duly authorized representatives) pursuant to the provisions of 10 CFR 30.41, 40.51 and/or 70.42 provided that such a transfer is consistent with the constraints described here. NRC regulations contained in 10 CFR 71.11, 71.12 and 73.37 would then be inapplicable to subsequent of the transferred material by DOE.

Regulatory references: 10 CFR 71

Subject codes: 12.9, 12.17

Applicability: All

HPPOS-100 **PDR-9111210221**

Title: Gasket Defects

See the memorandum from C. E. MacDonald to A. N. Fasano dated February 11, 1982. This memo discusses requirements of 10 CFR 71.54(c) which is now recodified as 71.87(c). A gasket containing obvious imperfections is not "free from defects." Packages sealed with such a gasket do not meet the requirements of 10 CFR 71.87(c).

A licensee contended that a gasket with a circumferential crack and a missing piece on the outer circumference was not defective. The licensee did not consider the gasket defective because the 3 to 4 inch-long crack in the gasket and the missing 1/4 by 1/4 by 1 inch-piece from the outer edge of the same gasket did not go through the full gasket radially. In addition, the licensee stated that criteria for defining a "defect" is not specified in 10 CFR Part 71 or the Certificate of Compliance. Also, the licensee referenced a definition of a defect found in 10 CFR Part 21.

Part 71 and the Certificate of Compliance do not provide an explicit definition of "defect." The definition of "defect" in 10 CFR 21.3 applies only to Part 21. The requirement in 10 CFR 71.54(c) on routine determinations (prior to each use of the package) states: "The closure of the package and any sealing gaskets are present and are free from defects" (emphasis provided). The word "defect" is defined as "imperfection" in the dictionary. It is NRC opinion that when imperfections are obvious to the naked eye, a gasket is not free of defects (see, also, HPPOS-090).

Regulatory references: 10 CFR 71.87

Subject codes: 12.15, 12.17

Applicability: All

HPPOS-060 **PDR-9111210243**

Title: Clarification of Scope of Quality Assurance (QA) Programs for Transport Packages Pursuant to 10 CFR 50, Appendix B

See IE Information Notice No. 84-50 entitled as above and dated June 21, 1984. Certain aspects of QA programs required by 10 CFR 71, Subpart H are distinctly packaging related. Utility QA programs must address all applicable elements for transport packages. The purpose of IE-84-50 is to eliminate any confusion as to the applicability of the QA provisions of 10 CFR 50, Appendix B, to certain transport packages for which a QA program is required by the provisions of 10 CFR 71, Subpart H.

Pursuant to 10 CFR 71.12(b), 71.14(b), and 71.16(c)(2), licensees who transport certain transport packages or deliver them to a carrier for transport are required to have an NRC-approved QA program. Such a program must have been approved as satisfying the applicable provisions of 10 CFR 71, Subpart H [formerly Appendix E]. An applicant's request for such a program approval must be in accordance with 10 CFR 71.101(c). Also, pursuant to 10 CFR 71.101(b) [formerly 10 CFR 71.51], each licensee must establish, maintain, and execute a QA program that satisfies each of the applicable criteria of Subpart H. Under the provisions of 10 CFR 71.101(f), however, a licensee may utilize a QA program which has been approved pursuant to 10 CFR 50, Appendix B, "provided that the QA program is established, maintained, and executed with regard to transport packages." Therefore, an Appendix B program is acceptable in lieu of one approved specifically under Subpart H.

Past inspections of transport activities and associated QA programs of nuclear utilities have sometimes revealed a generic inadequacy regarding implementation by licensees of NRC-approved, 10 CFR 50, Appendix B, QA programs for "transport packages."

Specifically, this inadequacy usually is evidenced by nonexistent or deficiently written QA audits for "transport packages." Apparently, some licensees have erroneously concluded that the previous NRC approval of the 10 CFR 50, Appendix B, program implies fulfillment of the implementing QA requirements for transport packages, without reservation.

Several of the criteria of 10 CFR 50, Appendix B, or 10 CFR 71, Subpart H, are programmatic (e.g., control of measuring and test equipment; document control). For these criteria, the associated implementing procedures may sometimes be common for both transport packing and non-transport activities. Certain other aspects, however, are distinctly packaging related (e.g., procedures controlling procurement of packaging; preparation of packaging for use, loading, and unloading the packaging; maintenance of the packaging, QA records, audits, checklists). Consequently, the utility QA program must include and address all of the applicable elements for transport packages to meet the intent of 10 CFR 71.101(f). Licensees should "not" automatically assume that such implementing procedures developed for Appendix B are adequate for transport packages unless such procedures do, in fact, address transport packages.

Regulatory references: 10 CFR 50, 10 CFR 71.101

Subject codes: 12.15, 12.17

Applicability: Reactors

HPPOS-064 **PDR-9111210250**

Title: Clarification of Several Aspects of Removable Radioactive Surface Contamination Limits for Transport Packages

See IE Information Notice No. 85-46 entitled as above and dated June 10, 1985. Clarification and guidance are provided on (1) averaging of wipe samples, (2) use of higher efficiency (>10%) wipe sampling methods, (3) wrapping of packages (casks), and (4) exclusive-use vehicle surveys for surface contamination.

AVERAGING OF WIPE SAMPLES: The DOT regulations currently state in 49 CFR 173.443(a) that "... the amount of radioactivity measured on any single wiping material when averaged over the surface wiped ..." shall not exceed the limits of 49 CFR 173.443, Table 10. Prior to the regulatory amendments by DOT in 1983 (Docket HM-169, 48 FR 10238, March 10, 1983), formerly applicable 173.397(a) provided that wipe samples could be "... averaged over any area of 300 cm^2 of any part of the package surface." We understand that it was "not" DOT's intention to disallow such averaging and further that DOT will consider processing a future rule change to restore such a provision to 173.443. In the interim, until the text has been formally modified, we will continue to consider that averaging of multiple wipe samples over any 300 cm^2 area of a package surface is an acceptable practice. [Note: Never changed in DOT 49 CFR 173.443(a)(1). See 10 CFR 71.87(h)(i)(1). NRC adopted DOT language.]

USE OF HIGHER EFFICIENCY WIPE SAMPLES: 49 CFR 173.433(a) states: "Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used shall be taken into account and in no case shall the nonfixed contamination on the external surfaces of the package exceed ten times the limits listed in Table 10." DOT considers that the statement "other methods of assessment of equal or greater efficiency may be used," also includes other wipe sampling methods wherein the efficiency has actually been demonstrated to be greater than 10%. Therefore, in effect, the wipe sample limits stated in 173.443(a) and (b) and Table 10 therein, are limits "by default," which do not take advantage of utilizing an efficiency greater than 10%. In evaluations of licensees' package surveys, NRC plans to accept assessments based on efficiencies which have been appropriately demonstrated to have an efficiency higher than 10%. The higher efficiency of the wipe sampling method must be documented and in no case may the removable levels exceed 10 times the values in Table 10 of 49 CFR 173.443.

WRAPPING OF PACKAGES (CASKS): "Weeping" of contamination may occur on casks that have been immersed in spent fuel storage pools. The issue of whether exterior "wrapping" of casks can be used to achieve compliance with removable contamination limits has been raised on a number of occasions. The reply from DOT on this matter read as follows: "For both NRC-certified and non-NRC-certified packages, any wrapping must be addressed in the package design evaluation" (e.g., heat retention since the contents are a heat source). "For NRC-certified packages this would include specific mention in the certificate of compliance. For DOT Specification 7A, Type A, packages, the shipper's package safety evaluation

would have to document the ability of the wrapping to successfully pass the Type A tests" (e.g., the wrapping would maintain its closure integrity during normal conditions of transport).

EXCLUSIVE-USE VEHICLE SURVEYS FOR SURFACE CONTAMINATION: For packages shipped as exclusive-use by rail or highway, the provision of 173.443(b) provides that the removable (nonfixed) radioactive surface contamination at any time "during transport" may not exceed "10 times" the limits of 49 CFR 173.443 Table 10. At the "beginning" of transport, however, the levels may not exceed those stated above. Further, pursuant to 173.443(c), any transport vehicle in which packages are transported within the "factor of 10" higher values (e.g., above the Table 10 limits), must be surveyed with appropriate radiation detection instruments after each use and shall not be returned to service until the radiation dose rate is below 0.5 mrem/hr and the removable contamination is below the limits stated above (49 CFR 173.443, Table 10). An exception to this vehicle survey requirement is provided by 173.443(d) for closed transport vehicles (highway) which are dedicated solely to the transport of radioactive material packages and are appropriately marked on the exterior of the vehicle. Also, in such cases the removable surface contamination on packages within such vehicles may be at the "factor of 10" limits at the "start" of transport.

Regulatory references: 10 CFR 71, 49 CFR 173

Subject codes: 7.6, 12.4, 12.17

Applicability: Reactors

HPPOS-063 **PDR-9111210249**

Title: DOT Reply to NRC Request for Clarification on *Ex Post Facto* Declarations by Shippers of Radioactive Materials

See the memorandum from J. G. Partlow to T. T. Martin (and others) dated January 11, 1984. This memo provides DOT clarification on *ex post facto* declarations by shippers of radioactive materials. It is inappropriate for a shipper to declare, after the act of shipment, that alternative packaging or shipping requirements could have been applied in lieu of those actually applied.

A licensee had shipped "exclusive-use packaged" low specific activity (LSA) wastes in steel drums under the provisions of 49 CFR 173.392(b) and (c). During an inspection of the incoming drums at a commercial burial site, twenty-one were found to be punctured. This was considered to be a violation of 173.392(c)(1), and the licensee was subsequently cited. In response to the citation, the licensee stated that the shipment could have been transported unpackaged because the content of the shipment was a LSA radioactive material, was transported in a closed sole-use transport vehicle, and otherwise met the criteria stipulated in 173.392(d)(1)(iii). (This paragraph provides that materials of low radioactive concentration may be transported unpackaged.) The licensee asked DOT for an interpretation of the provisions of 49 CFR 173.392(d) as they applied to their shipment. DOT replied that any packaging of choice may be used provided there is compliance with all requirements of 173.392(d). On the basis of DOT's interpretation, NRC withdrew the violation against the licensee.

NRC sent a letter to DOT concerning the above situation on February 23, 1983. Specifically, NRC asked whether a licensee was allowed to recategorize LSA material, even though there existed a pervasive weight of evidence that it had originally been considered to be and was described in the shipping papers as "packaged", rather than "unpackaged" bulk. DOT responded on September 29, 1983, and stated that it is inappropriate for a shipper to declare after the act of shipment that alternative packaging or shipping requirements could have applied in lieu of those actually applied. While the shipper may "package" a bulk shipment for convenience, this option does not allow the shipper to improperly prepare a packaged shipment and declare it as bulk after shipment improprieties have been discovered. Specific actions must be taken prior to making a bulk shipment to ensure "no leakage of radioactive material from the vehicle" [49 CFR 173.425(c)(6)]. A shipment of packages that leak or release its contents onto a typical wooden trailer floor could not be construed as meeting requirements unless actions had been taken to ensure the leak-tightness of the floor. If such action had not been taken, then the "packages" themselves must remain leak-tight in order to meet 49 CFR 173.425(c).

Regulatory references: 10 CFR 71, 49 CFR 173

Subject codes: 12.13, 12.17

Applicability: All

HPPOS-080 **PDR-9111210216**

Title: Packing Greater Than Type A Quantities of LSA Radioactive Material for Transport

See IE Circular No. 78.03 entitled as above and dated May 12, 1978. This circular describes a situation at nuclear power facilities that could occur wherever greater than Type A quantities of low specific activity (LSA) radioactive materials are packaged for transport. Shipment of greater than Type A quantities of LSA material may be done only in packages certified by NRC under 10 CFR Part 71. Department of Transportation (DOT) regulations require "strong, tight packages" for LSA material and make no mention of total activity that may be shipped.

Some licensees subject to the requirements of 10 CFR Part 71 have shipped packages containing greater than Type A quantities of LSA material in packages which are not authorized by NRC. These unauthorized shipments have resulted from an inadequate understanding of Part 71 regarding LSA material. Differences between Part 71 and DOT requirements in 49 CFR Parts 170 to 189 have apparently contributed to these misunderstandings.

Specifically, 49 CFR 173.392 authorizes the shipment of LSA material in "strong, tight packages" when transported in vehicles assigned for the sole use of the consignor. DOT regulations make no mention of the total activity that may be shipped in this manner. On the other hand, NRC regulations (10 CFR 71.3) require that no licensee shall (a) deliver any licensed materials to a carrier for transport or (b) transport licensed material except as authorized in a general or specific license issued by the NRC, or as exempted in Part 71. The general license of 10 CFR 71.12 has requirements for the type of container when more than a Type A quantity of radioactive material is to be transported. LSA material in excess of a Type A quantity is not exempt from the general license requirements. Several Licensees have failed to recognize the difference between the DOT and NRC requirements and have packaged greater than Type A quantities of LSA material for transport in containers other than those authorized by the general license of 10 CFR 71.12.

Compliance with Part 71 is the responsibility of the NRC licensee who delivers licensed material to a carrier for transport or who transports such materials outside the confines of its plant or other place of use.

Regulatory references: 10 CFR 71.2, 49 CFR 173

Subject codes: 12.17

Applicability: All

HPPOS-165 **PDR-9111220178**

Title: Two Recent DOT Interpretations on 49 CFR Sections 173.398(a)(1) and 173.391(c)(4)

See the memorandum from A. W. Grella to G. H. Smith (and others) dated January 29, 1981.
This memo provides two updated interpretations issued by DOT. IAEA Certificates of Competent Authority issued by DOT are adequate to meet 49 CFR 173.398(a)(1). Securely sealed metal cans meet the metallic sheath requirements of 49 CFR 173.391(c)(4).

The first interpretation was concerned with the necessary certification of special form radioactive materials. DOT stated that International Atomic Energy Agency (IAEA) Certificates of Competent Authority issued by DOT for special form materials are adequate certification to meet the requirements of 49 CFR 173.398(a)(1). Therefore, a shipper may use a currently valid certificate issued by DOT in lieu of a "complete certification and supporting safety analysis." DOT issued certificates used in this manner must be current and valid. Since the certificates expire and are revised periodically, the shipper must have a current certificate.

The second DOT interpretation dealt with metallic sheath requirements of 49 CFR 173.391(c)(4). The intent of this regulation is to prevent the spreading or loss of the oxide surface layer that forms on uranium metal. The use of securely sealed metal cans satisfy this requirement.

Regulatory references: 49 CFR 173

Subject codes: 12.17

Applicability: All

HPPOS-152 **PDR-9111220116**

Title: Request for Guidance Concerning Use of NRC Certified Casks

See the memorandum from L. B. Higginbotham to L. R. Greger dated October 19, 1982, and the incoming request from L. R. Greger dated October 6, 1982. It is acceptable for a licensee to use an NRC-certified cask as an outer enclosure. In this case, it is appropriate to obliterate or cover the certificate identification on the cask exterior and refrain from referencing the certificate on shipping papers. HPPOS-064 contains a related topic.

Frequently, licensees ship 55-gallon drums containing LSA material inside shielded casks. When this is done, the licensee may consider the drums to be packages and the cask as a shield to meet the transport vehicle dose rate limits (10 mr/hr at 2 meters and 2 mr/hr in the cab). IE Information Notice No. 82-32, Revision 1, acknowledges this practice and finds it acceptable under the specified circumstances. However, a telephone conversation with NMSS prompted this request for clarification concerning the acceptability of such action when the cask is an NRC certified package.

Specifically, is it acceptable for a licensee to use an NRC certified cask in the same manner as an uncertified cask, as described above, without regard to the certificate of compliance requirements? If such use is acceptable, must anything be done to clarify the intended use of the cask, such as obliterating the cask identification? Obliteration of the cask identification was suggested by NMSS.

IE has no objection to the use of an NRC certified cask as an outer enclosure for inside packages, effectively simulating a "closed transport vehicle, as illustrated in Appendix B (Left side scenario), IE Information Notice 80-32, Revision 1 (see HPPOS-064). In such a case it would be appropriate to obliterate or cover over the NRC certification identification marking on the cask exterior, and refrain from any reference to the certificate on shipping orders.

Regulatory references: 10 CFR 71, 49 CFR 173

Subject codes: 7.1, 12.17

Applicability: All

HPPOS-084 **PDR-9111210232**

Title: Clarification of Certain Requirements for Exclusive-Use Shipments of Radioactive Materials

See IE Information Notice No. 80-32 dated August 29, 1980. This notice clarifies requirements regarding open and closed transport vehicles, personnel barriers, packages enclosed within an outer cask shield, exclusive-use shipments, and radiation limits. See Revision 1 to this IE information notice (HPPOS-085).

In mid-1979, NRC initiated an enhanced program for inspection of shipments of radiation materials. This augmented inspection/enforcement program prompted a number of questions on the proper application of certain regulatory requirements. These questions involved the problems and deficiencies associated with exclusive-use highway shipments of low-level radioactive wastes. The purpose of this Notice is to discuss the following fourteen questions to clarify the application of certain requirements, particularly the application of the limits of radiation levels of exclusive-use shipments as prescribed in 49 CFR 173.393(j).

1. What limits would apply to packages being transported on an open, exclusive-use transport vehicle?

2. What constitutes a closed transport vehicle?

3. In the situation described above, is such a "personnel barrier" considered to be the "package" or a component of the package?

4. In the above situation, what are the limits for radiation levels on the packages within such a personnel barrier?

5. If "packages" such as drums are enclosed within an outer cask "shield" (as opposed to a personnel barrier or closed vehicle) wherein the other shield is necessary to achieve compliance with the limit of either 173.393(i) or 173.393(j), may the inner drum(s) be considered to be the "package"?

6. In the situation described above, would the levels of radiation on the inner drums be limited to the levels of 173.393(j)(1) (e.g., 1000 mrem/hr at 3 ft)?

7. In monitoring the radiation levels at the external surface of the transport vehicle, as prescribed in 173.393(j)(2), do the limits apply at the bottom and top of the vehicle, as well as at the sides?

8. In the above situation, does this mean that in applying the limit of 173.393(j)(3) (e.g., 10 mrem/hr at 6 ft from the sides of the vehicle) the limit also applies at the top and "bottom" of the vehicle?

9. In 173.393(j)(3) the radiation level limit is prescribed at 10 mrem/hr at 2 m (6 ft) from the outer lateral surfaces of an exclusive-use vehicle. Since 2 m is 6.6 ft, which limit would apply (6 ft or 6.6 ft)?

10. What is an "exclusive-use" shipment?

11. Frequently shipments of radioactive waste are made as "exclusive-use" shipments under arrangements whereby the original generator of the waste utilizes the services of a waste collector (i.e., "broker) who in turn usually engages a common or contract carrier to transport the shipment or transport the material in his own vehicle as a private carrier. On occasion this "broker" may also be the consignee (e.g., a waste burial site operator). Because of this complex arrangement, confusion often arises as to which party is responsible for performing the regulatory requirements of the "shipper" or "consignor." Can you clarify this?

12. In the above situation, assume that a "broker" picks up or arranges for pickup radioactive waste from more than one generator's facility for transport as a single shipment by a common carrier or by himself as a private carrier. Is it not required that an exclusive-use shipment be from a "single consignor"?

13. In an exclusive-use shipment of LSA materials, the shipper is required by 173.392(c)(9) to provide specific instructions to the carrier for maintenance of exclusive-use shipment controls. What should such specific instructions include?

14. 49 CFR 173.393(j)(4) requires that the radiation level in any "... normally occupied position in the car or vehicle ..." be limited to 2 mrem/hr. Where should this limit be applied in a tractor with a sleeper cab?

Regulatory references: 10 CFR 71, 49 CFR 173

Subject codes: 7.1, 12.17

Applicability: All

HPPOS-085 **PDR-9111210234**

Title: Clarification of Certain Requirements for Exclusive-Use Shipments

See IE Information Notice No. 80-32, Rev. 1, entitled as above and dated February 12, 1982. This document clarifies guidance on radiation limits for open exclusive use vehicles and use of packages within an outer shield. In some cases, the inner container plus shield is the "package" while in others, the outer shield may constitute a closed transport vehicle.

The radiation limits that apply to shipments being transported by an open exclusive-use transport vehicle must follow the constraints of 49 CFR 173.393(j)(3) and (4); e.g., 10 mrem/hr at 2 meters from the open planes projected by the outer lateral edges of the vehicle and 2 mrem/hr in any normally occupied area of the vehicle (or cab). NRC has been informed by DOT that the existing language of 49 CFR 173.393(j) does not clearly reflect the original intent of the regulation; i.e., to limit the radiation level at the accessible exterior surface of a package on an open exclusive-use vehicle to 200 mrem/hr (such as the same limit applied to the surface of a closed transport vehicle) and is taking steps to revise 49 CFR 173.393(j). In the interim, NRC licensees are cautioned to adhere to a surface radiation level limit of 200 mrem/hr on a package transported by an open exclusive-use transport vehicle. [Note: This problem was addressed in the current revision of 40 CFR 173. See 49 CFR 173.441(b) and also 10 CFR 71.47(a).]

A definition of what constitutes a "package" is illustrated in the enclosures to IE Information Notice No. 80-32, Rev. 1. Generally speaking, the criteria considered include the following: whether any single inner container has a radiation level of less than 1 rem/hr at 3 feet [49 CFR 173.393(j)(1)]; and whether any single inner container, if bearing LSA material, has a quantity of radioactivity exceeding Type A [10 CFR 71.7(b), 71.11(b)(1), 71.12(b), and 71.35].

With the above considerations and the DOT definitions of "closed transport vehicle" [49 CFR

173.389(q)] and "packaging" [49 CFR 171.8], each inner drum within an outer shield integrally attached to the vehicle may be considered a "package" provided that each inner drum complies with 10 CFR 173.393(j)(1) [1 rem/hr at 3 feet], and also provided that the content within any single inner drum does not exceed a Type A quantity of LSA material. In this configuration, the outer enclosure may be considered as the closed transport vehicle and may incorporate integral shielding to meet the vehicle limit of 173.393(j)(2) [200 mrem/hr]. The inner drums are marked as packages and the outer enclosure placarded as a vehicle.

The combination of inner container plus the outer shield are considered the "package" if any single inner container has a quantity of radioactivity as LSA exceeding Type A or if any single inner container must be certified as Type A by the NRC Office of Nuclear Materials Safety and Standards.

Regulatory references: 10 CFR 71, 49 CFR 173

Subject codes: 7.1, 12.17

Applicability: All

HPPOS-275 PDR-9306140057

Title: Technical Assistance Request for an Interpretation of the 10 CFR 30.13 Exemption

See the memorandum from J. E. Glenn to J. A. Gobe dated February 27, 1992. This memo responds to a technical assistance request concerning an inquiry on interpretation of the 10 CFR 30.13 exemption by Stan A. Huber Consultants, Inc. (see enclosed letter dated January 29, 1992). The description of proposed operations which includes load consolidation, packaging, surveying, and/or manifesting requires a specific license in accordance with 10 CFR 30.32 and may require an environmental assessment if operations are not categorically exempt in accordance with 10 CFR 51.22(c)(14)(xii). The exemption in 10 CFR 30.13 applies only to common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

Regulatory references: 10 CFR 30.13, 10 CFR 30.32, 10 CFR 51.22

Subject codes: 11.1, 12.17

Applicability: Byproduct Material

HPPOS-161 PDR-9111220147

Title: Consideration of NRC Independent Measurement Samples as "Research" Pursuant to 49 CFR 175.700(c) and 172.204(c)(4)

See the memorandum from A. W. Gella to J. Buchanan dated September 4, 1986. The memo, presented in its entirety, expresses a DOT informal opinion that independent measurement samples collected by NRC inspectors may be considered as materials used in research per 49 CFR 172.204(c)(4) and 10 CFR 175.700(c). Therefore, these samples may be shipped on passenger-carrying aircraft.

As agreed to in our conversation on August 27, 1986, on that date I contacted Mr. Walt Greiner, the Hazardous Materials Specialist of FAA Headquarters. My question to him was whether or not the independent measurement samples collected by NRC inspectors could legitimately be considered as "research" pursuant to the subject regulation, and therefore, allowable as freight to be offered for transport aboard passenger-carrying aircraft. After describing the sampling program and type of samples, materials involved, etc., as well as the purpose of the samples, he gave his opinion that the samples could be considered as "research." I therefore recommend that this be the case and that such a position continue to be taken with regard to Section 05.04(d) of MC 1232, currently under revision and the subject DOT regulation.

Regulatory references: 49 CFR 172.204, 49 CFR 175.700

Subject codes: 12.13, 12.17, 12.18

Applicability: All

HPPOS-241 **PDR-9111220085**

Title: Transportation of Limited Quantities of Radioactive Materials on Passenger Carrying Aircraft

See the letter from V. L. Miller to All Agreement States dated August 8, 1991, and the enclosed letter from P. T. McDonnell (Federal Aviation Commission) to C. Kammerer dated March 19, 1991. These two letters state that DOT regulations allow the practice of carrying small check or calibration sources or other small quantities of radioactive materials onto passenger carrying aircraft.

With the exception of incident reporting requirements, radioactive materials prepared for shipment under the provisions of 49 CFR 173.421 or 49 CFR 173.422 are not subject to the requirements of the Hazardous Materials Regulations (HMR: 49 CFR Parts 100-199) when transported by air. Limited quantities of radioactive materials (49 CFR 173.421) or exempted instruments or articles (49 CFR 173.422) may be transported in carry-on or checked baggage on a passenger aircraft. A passenger carrying the radioactive material may hand-carry the documentation required by 10 CFR 49.421-1(a).

Radioactive materials prepared in accordance with 49 CFR 173.421 or 49 CFR 173.422, may be carried on a passenger aircraft regardless of the end use of the material. The provision in 49 CFR 175.700(c) that limits the carriage of radioactive material in carry-on luggage to materials intended for use in, or incident to, research, medical diagnosis or treatment, would not apply.

It must be noted that under the provisions of 49 CFR 171.11(a), shippers are given the option of preparing shipments of hazardous materials in accordance with the International Civil Aviation Organization (ICAO) Technical Instructions for The Safe Transport of Dangerous Goods by Air. 49 CFR 175.30(a) permits air carriers to accept shipments offered in compliance with the ICAO Technical Instructions.

The requirements for excepted packages of radioactive materials are found in Part 2;7.9 of the ICAO Technical Instructions. The provisions of Part 2;7.9 except limited quantities, instruments, and manufactured articles from regulatory requirements in a manner similar to 49 CFR 173.421-1(b).

Regulatory references: 49 CFR 171, 49 CFR 173, 49 CFR 175

Subject codes: 12.8, 12.17

Applicability: All

HPPOS-263 **PDR-9306070226**

Title: Policy and Guidance Directive FC 84-18, "Transportation of Irradiator Units Not Meeting Current Requirements of 10 CFR Part 71"

See the memorandum from R. E. Cunningham to Regional Administrators (and Branch Chiefs of the Division of Fuel Cycle and Material Safety) dated November 6, 1984. Prior to the adoption of the requirements of 10 CFR 71 in 1966, irradiators could be transported without being evaluated under the accident damage test requirements that are now incorporated in 10 CFR 71. Many of these irradiators are in use and from time to time need to be transported to a new location.

In those cases where the irradiator cannot be practically transported in packaging which meet requirements of 10 CFR 71, the licensee may request a one-time shipment in accordance with 10 CFR 71.7 and 71.41(c). The shipment can only be authorized by Headquarters. In applying for a one-time shipment, the licensee must provide adequate controls such that the shipment will not endanger life or property.

Information that is typical of what the licensee has been requested to submit to Division of Fuel Cycle and Material Safety, NMSS, to support one-time shipments includes:

1. The circumstances as to why an existing package cannot be used,

2. Engineering drawings of the irradiator, and

3. Information to confirm:

   a. Transport during time of low road usage,

   b. The use of good roads which avoid residential areas to the maximum extent possible,

c. Accompaniment of the shipment by escort knowledgeable in the use of radiation survey instrument,

d. Provision an escort with appropriate survey instrument and supplies to permit the establishment of a radiation exclusion area,

e. Written procedures to be followed by the escort in an emergency situation,

f. Use of exclusive use vehicle and shoring to limit movement of package during transport, and

g. Notification of state health officials and local fire department of time and route of shipment.

Prior to applying to the NRC for its approval, the licensee should contact the State Health Officer of each state through which the shipment will be made to confirm points of contact and to discuss the proposed controls for the shipment. In several recent cases, short distance shipment of irradiators have been successfully made with the cooperation of state officials.

All requests for shipments of irradiators containing the information should be referred to the Material Licensing Branch who will coordinate the approval authorizing the shipment with the Transportation Certification Branch. All new Irradiators are expected to meet the requirements of 10 CFR 71.

Regulatory references: 10 CFR 71.7, 10 CFR 71.45

Subject codes: 12.17

Applicability: Byproduct Material

2.18 OTHER TOPICS

HPPOS-074 **PDR-9111210181**

Title: Criteria in NUREG Are Not Substitutes for Regulations

See the letter from R. C. DeYoung to Ira Myers, M.D., dated August 10, 1983, and the incoming request from Dr. Ira Myers (State Health Officer, Alabama Department of Public Health) dated June 9, 1983. NUREG-0654 contains criteria that the NRC will use in evaluating if a licensee meets regulatory requirements. The criteria in a NUREG are not substitutes for the regulations and compliance is not a requirement.

The State of Alabama requested a formal binding interpretation of 10 CFR 50.47(b) by the General Counsel. Specifically, the State wanted to know whether the provisions of NUREG-0654 were binding regulation or advisory guidance. Given the lack of dispute about the "guidance" nature of the document, an official interpretation was not needed in order to confirm the NRC's view on this subject. In order for a nuclear power plant to continue operations or to receive an operating license, the regulations require that the NRC find emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Section 50.47 of 10 CFR establishes standards that must be met by the onsite and offsite emergency response plans in order for the NRC staff to make a positive reasonable assurance finding.

Guidance to licensees and applicants, as well as to offsite organizations, on methods acceptable to the NRC staff for complying with the Commission's emergency planning regulations for nuclear power reactors is provided in NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," Revision 1. This document was published in November 1980 to provide specific acceptance criteria for complying with the standards set forth in Section 50.47 of 10 CFR. The criteria in NUREG-0654/ FEMA-REP-1 have been endorsed in Regulatory Guide 1.101, "Emergency Planning and Preparedness for Nuclear Power Reactors," Revision 2, dated October 1981.

The criteria in NUREG-0654/FEMA-REP-1, as well as the criteria in any NUREG document, were issued to establish criteria that the NRC staff intends to use in evaluating if an applicant/licensee meets the applicable regulatory requirements. The criteria in a NUREG document are not a substitute for the regulations, and compliance is not a requirement. However, the use of methods or criteria different from those set forth in NUREG documents will be acceptable only if such methods or criteria clearly provide a proper basis for determining that the regulatory requirements have been met.

Regulatory references: Regulatory Guide 1.101, NUREG-0654

Subject codes: 12.6, 12.19

Applicability: Reactors

HPPOS-055 **PDR-9111210231**

Title: IE Position - Unduly Restricted Access of Female NRC Inspectors to Radiation Areas

See the memorandum from J. H. Sniezek to B. H. Grier (and others) dated October 2, 1980. It is an IE position that states each female NRC inspector has to read and be familiar with Regulatory Guide (RG) 8.13. Therefore, licensees shall not restrict access of an NRC inspector because of requirements considered to be imposed by 10 CFR 19.12 regarding instructions to workers on prenatal exposure.

During NRC onsite inspections, several licensees imposed additional restrictions on the access of female NRC inspectors to radiation areas. These restrictions appeared to be honest attempts on the part of the licensees to comply with the requirements of 10 CFR 19.12 and the guidance of RG 8.13, "Instructions Concerning Prenatal Radiation Exposure." It is not believed that the licensees were attempting to impede or hinder the inspection effort but rather were being overly cautious in their interpretation of the requirements.

RG 8.13 sets forth information to be presented by NRC licensees to female employees and to their supervisors and coworkers. This information is part of the instruction that should be provided pursuant to 10 CFR 19.12. The intent of RG 8.13 is not only to assure that employees are aware of the risk associated with radiation exposure of an embryo or fetus but also to permit women to make an informed decision when considering employment in situations involving their potential exposure to radiation. The dose limits in 10 CFR 20 do not differentiate between females and males. Licensees should not interpret the requirements of 10 CFR 19.12 and the guidance of RG 8.13 as imposing any additional radiation dose limits or restrictions on females.

Each female NRC inspector has to read and be familiar with RG 8.13. Therefore, licensees shall not restrict the access of an NRC inspector to any part of a facility because of requirements that are considered to be imposed by 10 CFR 19.12 as related to instructions of workers on the risks of prenatal radiation exposure.

Regulatory references: 10 CFR 19.12, Regulatory Guide 8.13, Regulatory Guide 8.36

Subject codes: 8.11, 12.9, 12.18

Applicability: All

HPPOS-249 **PDR-9206260114**

Title: Requests by Reactor Licensees That Women Inspectors Sign Statements That They are not Pregnant

See the memoranda from F. J. Congel to M. R. Knapp (and others) dated March 4, 1992, and from R. E. Cunningham to M. R. Knapp (and others) dated April 1, 1992. It is OGC opinion that a licensee request for a female inspector to sign a statement that she is not pregnant is not appropriate and is inconsistent with the law. A licensee denial of site access to a female inspector because she refuses to sign such a statement is a clear violation of federal regulations.

Licensee denial of site access to a female inspector who refuses to sign a statement that she is not pregnant is a violation of 10 CFR 30.52(a), 40.62(a), or 70.55(a). These regulations require each licensee to "... afford to the Commission at all reasonable times, opportunity to inspect..." byproduct, source, or special nuclear material and the premises and facilities where such material is used, produced or stored.

At Part 70 licensee facilities, licensee denial of site access to an inspector who refuses to sign such

statements would be a violation of 10 CFR 70.55(c)(3). This regulation requires the licensee to provide immediate unfettered access to the inspector following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

Regulatory references: 10 CFR 30.52, 10 CFR 40.62, 10 CFR 50.70, 10 CFR 70.55

Subject codes: 8.11, 12.9, 12.18

Applicability: All

HPPOS-252 **PDR-9208170137**

Title: Requests by Licensees that Women Inspectors Acknowledge Discriminatory Administrative Dose Limits Imposed on Them

See the joint memorandum with enclosures issued by F. J. Congel and R. E. Cunningham to W.F. Kane (and others) dated June 28, 1992. The memorandum reiterates the position that female NRC employees need not and should not sign statements provided by licensees concerning their pregnancy or their capability of becoming pregnant except for voluntary declarations of pregnancy. HPPOS-055 and HPPOS-249 contain related discussions.

NRC has learned that a female inspector was asked to sign a statement acknowledging an administrative radiation dose limit that was discriminatory before being granted site access at a nuclear power plant. The statement appeared near the bottom of the first page of a licensee document, "Female Radiation Exposure Policy," which is included as Enclosure 1 to the memorandum. Since then, the NRC has been informed that other reactor and materials licensees have similar policies.

The first paragraph of the licensee policy from Enclosure 1 reads as follows:

> "This policy provides administrative controls on radiation exposure to females with the objective limiting any potential radiation exposure to an unborn fetus to less than 0.5 rem during the entire nine month gestation period. This objective is accomplished by ensuring fertile women are given the opportunity to review the risks of fetal radiation exposure as discussed in NRC Regulatory Guide 8.13 and the opportunity to declare an actual or potential pregnancy before assignment to any task when more than 0.5 rem of radiation exposure may be received during a calendar quarter. This policy is not intended to restrict any access to work areas or limit any career opportunities for females. Extensions of administrative limits may be requested and granted any time to ensure females are provided equal opportunity to gain experience and progress in their careers in the same manner as males."

Notwithstanding the disclaimers in this paragraph, an administrative radiation dose limit for "fertile females" is discriminatory, inappropriate, and inconsistent with the law. The second page of the enclosed policy contains similar statements concerning pregnancy or the ability to become pregnant. NRC employees should be aware that they need not and should not sign agreements to, or acknowledgements of, licensee administrative dose limits for women not declared pregnant as defined in 10 CFR 20.1003 that are different from administrative limits for men. In addition, female NRC employees need not and should not sign statements provided by licensees concerning their pregnancy, or capability of becoming pregnant, except as a voluntary declaration of pregnancy. Licensee denial of site access to NRC inspectors who refuse to sign statements acknowledging or agreeing to a discriminatory dose limit or who refuse to sign statements concerning pregnancy or the capability of becoming pregnant is a violation of federal regulations. The specific regulations involved include 10 CFR 50.70 for reactor licensees and 10 CFR 30.52(a), 10 CFR 40.62, 10 CFR 70.55(a), and 10 CFR 70.55(c)(3) for materials licensees. The NRC Office of the General Counsel concurs with this memorandum.

Regulatory references: 10 CFR 20.1003, 10 CFR 30.52, 10 CFR 40.62, 10 CFR 50.70, 10 CFR 70.55

Subject codes: 8.11, 12.9, 12.18

Applicability: All

HPPOS-164 **PDR-9111220176**

Title: Inspector Access to Facilities

See the memorandum from Dudley Thompson to C. M. Upright and C. E. Norelius dated May 13, 1980. It is an OELD opinion that nonresident inspectors

could be required to have an escort for access to vital, radiation, and contamination areas. In other areas, inspectors must be given immediate unescorted access. 10 CFR 14 covers claims for damages by any NRC employee while acting with the scope of his office or employment.

In an enclosed letter from Wisconsin Electric Power Company dated October 22, 1979, it is stated:

"Recently a Region III inspector questioned the Point Beach Nuclear Plant procedures related to the requirements of 10 CFR 50.70(b)(3). This section specifies:

> (3) The licensee or construction permit holder shall afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Director as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety."

"Wisconsin Electric intends to meet the requirements of the regulation by providing access to authorized inspectors to all areas of the plant where plant or inspector safety are not compromised and to allow inspector access to any plant employees for discussions related to carrying out the inspector's duties. The new regulation differs from the proposed regulation in that it demands "unfettered" access and deletes the sentence which provided for establishing the purpose and scope of the inspection so that planning can be done to facilitate an efficient inspection. No public comment was requested with respect to this matter. We are, of course, determined to cooperate with your inspection program consistent with assuring plant safety and the safety of all visitor to the plant, including NRC inspectors. Accordingly, we plan to implement this regulation by furnishing an escort for your inspectors following an entrance meeting."

"We believe that the NRC does not indemnify the utility or the public against any damage which might involve the actions of the inspector; therefore, we believe it necessary to provide an escort unless the inspector is so familiar with the plant, and the plant personnel with the inspector, that we determine such escort requirements can be waived. If unannounced inspections take place outside normal working hours, it may be necessary to call in an escort if the inspector desires access to plant areas outside the normal work stations of on-duty personnel. We do not believe that the minor delay which might be involved under such circumstances is in conflict with the regulations in view of the safety and security considerations already discussed. If the inspection is announced in advance, we would plan to have an escort available without delay."

Because of concerns by NRC Region III and other regional offices, OELD has provided guidance on 10 CFR 50.70, specifically those sections dealing with "immediate unfettered access" and "liability for damages." 10 CFR 50.70(b)(3) requires a licensee or construction permit holder to afford an NRC inspector "immediate unfettered access, equivalent to access provided regular plant employees" (emphasis supplied). If the licensee requires a training program of reasonable duration, or the presence of an escort during a reasonable site familiarization phase for regular plant employees, the inspector would be required by the current regulation to have such training and escort. It seems clear that once an inspector is familiar with a site, upon properly identifying himself at the gate, he should be allowed immediate unescorted access to the facility. However, it is also clear that a nonresident inspector could be required to have an escort to gain access to vital areas, radiation areas, or contaminated areas. But assuming an inspector does not intend to enter the prohibited areas without an escort, any delay caused by the licensee at the gate, in excess of that borne by regular employees, is a violation of Commission regulations.

As far as inspector liability is concerned, Part 14 of the Commission's regulations provides detailed procedures for filing a claim for any damages "caused by the negligent or wrongful act or omission of any employee of the NRC while acting within the scope of his office or employment" (10 CFR 14.1).

Regulatory references: 10 CFR 14.1, 10 CFR 50.70

Subject codes: 1.2, 12.18

Applicability: All

HPPOS-125 PDR-9111210295

Title: Safety Significance and Discussion About Important Matters

See the memorandum from V. Stello, Jr. to all IE Technical Personnel dated October 1, 1980. This memo defines IE policy in two important matters. First, the consideration of safety significance always precedes noncompliance in evaluating any concern, and second, inspectors are expected to communicate promptly to their supervisors all concerns involving public safety and national security.

The first IE policy statement asserts that the consideration of safety significance always precedes noncompliance in evaluating any concern. During an inspection, an NRC inspector apparently became diverted from the safety significance of control room operators sleeping while on duty by his belief that noncompliance could not be substantiated using his word against that of the operators. The inspector should have concluded that a sleeping control room operator is a matter of safety significance and then promptly and firmly followed this through up to the plant superintendent. The inspector was mistaken about the requirement for verification by someone else of his observation. In precedent cases, it has been established that when it comes down to an inspector's word against the word of the licensee or its employee, the inspector's word will be accepted, all other things being equal.

The second IE policy statement asserts that inspectors are expected to communicate promptly to their supervision all concerns involving public safety and national security. This policy is complementary to the first and serves as a backup line of defense to minimize the chance of either under-reacting or overreacting to safety issues. Failure of inspectors to notify management is contrary to the above policies and severely hampers NRC's ability to respond to safety issues and public concerns.

Regulatory references: None

Subject codes: 12.18, 12.19

Applicability: All

HPPOS-108 PDR-9111210256

Title: Protocol for Accompaniment on NRC Inspections

See the memorandum from R. K. Hoefling to F. Brenneman dated November 2, 1982. It provides a list of approved terms and conditions under which individuals are allowed to accompany NRC inspectors as observers on inspections of nuclear power plants.

The State of Pennsylvania expressed an interest in having personnel of their Department of Environmental Resources accompany NRC regional-based or resident inspectors as observers on inspections of nuclear plants located within that state.

A protocol was developed for signature for the Commonwealth of Pennsylvania that allowed persons employed by the Department of Environmental Resources to accompany NRC staff on inspections, under the following conditions:

1. Specific approval for each accompaniment will be obtained from NRC Region I Office prior to accompanying an NRC inspection.

2. Accompaniment is limited to no more than two individuals on any single inspection.

3. Individuals accompanying NRC inspectors shall not, in any manner, interfere with the orderly conduct of the inspection. NRC inspectors are authorized to refuse to permit continued accompaniment by an individual whose conduct interferes with a fair and orderly inspection or whose conduct does not follow the terms and conditions included within this Protocol. The reports of information obtained by State participants under this Protocol should be subject to supervisory review as are all findings of NRC Inspectors.

4. NRC inspectors will not normally object to the presence of individuals accompanying them during inspections or discussions with the licensee regarding inspection matters covered by the accompaniment. The NRC reserves the right to exclude such individuals on a case-by-case basis from any portion of an inspection or a discussion if the presence of such individuals has the potential for impeding the inspector's ability to carry out his/her inspection.

5. Notwithstanding the other provisions of this Protocol, individuals accompanying NRC inspectors

will not normally be provided access to proprietary information or information concerning the physical security plan for a facility. Exceptions to this provision will be considered on a case-by-case basis and may require execution of appropriate non-disclosure agreements.

6. Individuals accompanying NRC inspectors pursuant to this Protocol do so at their own risk. The Nuclear Regulatory Commission will accept no responsibility for injuries and exposures to harmful substances which may occur to such individuals during the inspection and will assume no liability for any incidents associated with the accompaniment. Individuals accompanying NRC inspectors agree to waive all claims of liability against the Commission.

7. The NRC will not make arrangements for the persons accompanying the NRC inspector to gain access to the licensee's facility, but will inform the licensee that the NRC has no objection to the specific individuals accompanying the NRC inspectors. Arrangements to gain access to the licensee's facilities are the responsibility of the accompanying individual, subject to not disclosing the date of the inspection.

Regulatory references: None

Subject codes: 12.18, 12.19

Applicability: Reactors

HPPOS-110 **PDR-9111210247**

Title: SECY-81-19 on Emergency Response Facilities

See the memorandum from M. G. Malsch to Chairman Ahearne (and others) dated January 30, 1981. It is inappropriate to use NUREG documents to issue quasi-requirements. The memo provides a discussion of the various types of quasi-requirements that are used within NRC.

General Counsel is having difficulty with the subject paper which we would like to call to the Commission's attention. In law school, law students learn from studying the Administrative Procedure Act that all of an agency's binding rules are published in the Federal Register (FR) and codified in the Code of Federal Regulations (CFR). After an individual has dealt with an agency for a few years, they learn that sources other than the FR and CFR must be consulted. This was already a fairly complicated matter with regard to NRC requirements prior to TMI, what with the extensive "gloss" placed on NRC's regulations by various adjudicatory decisions, regulatory guides, branch technical positions, standard review plans, and policy statements. After TMI came a new breed of quasi-requirements in the form of the TMI "Action Plan" and related lists of near term operating license and (to be issued in the future) near term construction permit requirements.

Now comes the subject paper with the Staff's proposal that a NUREG be published on the subject of emergency response facilities. While the January 26, 1981 correction notice clearly improves things, the NUREG still has the tone of a formal document which imposes binding legal requirements. Indeed, it is indicated at the outset in the "Abstract" that the report describes facilities and systems "to be used by nuclear power plant licensees" and that licensees "should follow" the report. We are fearful that Commission approval of this latest Staff proposal will be taken as Commission approval to launch a new series of NUREG quasi-requirements that will need to be added to the current burgeoning list of NRC rules, adjudicatory decisions, regulatory guides, branch technical positions, standard review plans, and policy statements. Use of NUREG's to issue quasi-requirements will be especially confusing because even the most careful reader will be hard pressed to distinguish such a NUREG from other NUREG documents that are merely informational.

We can't say that this latest NUREG is the proverbial straw that breaks the camel's back, but there will be some point in the future when the expanding categories of NRC requirements and quasi-requirements reach the point when even the most experienced NRC practitioners (scientists, engineers, and lawyers) will be totally confused as to what is, in fact, legally required. This process should be stopped before that point is reached. We suggest that the NUREG be reviewed and that those features of the NUREG that implement current regulations be issued in regulatory guide form, and that those features that do not implement any Commission regulation be considered for rulemaking. If adoption of this suggestion is not feasible, then the Commission could at least indicate that in the future NUREG's should not be used to issue new requirements or quasi-requirements.

Regulatory references: NUREG Documents

Subject codes: 12.7, 12.19

Applicability: All

HPPOS-057 **PDR-9111210236**

Title: Avoidance of Mischaracterization of Effect of Certain Communications to Licensees

See the memorandum from H. K. Shapar to H. R. Denton (and others) dated February 5, 1981. Included with this document is a second and similar memorandum written by W. J. Dircks to Chairman Hendrie and Commissioners Gilinsky, Bradford, and Ahearne dated March 9, 1981. These two memos emphasize that staff positions are not binding requirements unless formally issued as regulations or set forth in orders. NUREG guidance and acceptance criteria documents should not be viewed as requirements.

In several letters to licensees and in NUREG guidance and acceptance criteria documents reviewed by OELD, the actions requested of licensees or the guidance and criteria contained in staff documents were set forth as "requirements." Staff positions communicated to licensees are not binding requirements unless formally issued as regulations, set forth in orders, or are decisions of an appropriate commission adjudicatory body. Less formal methods of communicating staff positions often produce voluntary licensee action leading to the desired result.

Licensees and the public must be accurately informed as to when something is a requirement and when the NRC is merely setting forth guidance, establishing criteria, or asking licensees voluntarily to do something. To avoid confusion, guidance, criteria and requests should not contain language that states or implies that these staff documents are requirements.

Regulatory references: Regulatory Guides, NUREG Documents

Subject codes: 12.7, 12.19

Applicability: All

HPPOS-139 **PDR-9111210375**

Title: Use of "Open Items List" by Inspectors

See the memorandum from J. H. Sniezek to E. L. Jordan dated July 12, 1985. The memo states that open items declared on an inspection report, when based on new staff interpretations of existing positions, are plant-specific backfits in accordance with policy established by NRC Manual Chapter 0514. The memo is presented in its entirety.

The referenced memorandum (R. L. Baer to Branch Chiefs in Regions and NRR, June 12, 1985, Subject: "Proposed Guidelines for Inspecting Radioiodine Sampling Capability per NUREG-0737, Item II.F.1.2") encloses a draft memorandum to Region Division Directors advising that deviations by licensees from the technical guidance contained (in the draft memorandum) shall be "... held as open items on the inspection report and referred to NRR for evaluation on a case specific basis." You should note that open items declared on an inspection report, when based on new staff interpretations of existing positions, are plant-specific backfits in accordance with the policy established by NRC Manual Chapter 0514.

Further, in this case, the new interim guidelines for sampling system acceptance are obviously to be applied generically prior to imposition on licensees.

Regulatory references: 10 CFR 2, 10 CFR 50.109

Subject codes: 12.7, 12.19

Applicability: All

HPPOS-288 **PDR-9306180293**

Title: Acceptance for Referencing, RADMAN Topical Report (WMG-102, as Revised from WMG-101P)

See the letter from L. B. Higginbotham to P.T. Tuite (Waste Management Group, Inc.) dated July 25, 1983. The NRC reviewed the Waste Management Group (WMG) Topical Report on the RADMAN computer code which is a series of routines that can be used by radioactive waste generators to characterize packaged waste; classify waste packages by Part 61 waste classification requirements; and prepare documentation required by 10 CFR Part 61, Department of Transportation (DOT) regulations and license condi-

tions at existing low-level waste disposal sites. This health physics position was written in the context of 10 CFR 20.311, but it also applies to "new" 10 CFR 20.2006.

The RADMAN code operates on a waste stream characteristics data base specific to the types and forms of waste generated by individual facilities, as well as to the facility- and waste stream-specific distributions of radionuclides and chemical agents. Based on WMG submittals and after NRC review, RADMAN code provides an acceptable vehicle which can be used by licensees as part of compliance with the requirements in 10 CFR 20.311 [or, at present, 10 CFR 20.2006] and with 10 CFR 61.55. This conclusion is predicated on completion of the final Topical Report according to the review assignments and upon the following four conditions:

1. That radionuclide correlations are undated on a waste stream, plant, or generic basis as additional sampling data becomes available. The NRC staff believe that many correlations currently assumed in RADMAN between Co-60 and activation products, and between Cs-137 and fission products may not be valid. The current lack of sampling data, however, precludes established verified correlations at this time in RADMAN for a number of radionuclides of interest.

2. That the manifest formatting provisions of RADMAN are updated to include all of the information required in 10 CFR 20.311 [or 10 CFR 20.2006] when revised manifest forms are made available by disposal site operators.

3. That RADMAN is appropriately updated as State (South Carolina, Washington, Nevada) provisions for compliance with 10 CFR Part 61 waste classification and manifesting requirements are made available.

4. That RADMAN is updated as required to remain consistent with future modifications to NRC, DOT, State or other regulatory requirements as such requirements becomes effective, as well as changes to disposal site license conditions.

Should NRC criteria or regulations change such that our conclusions as to the acceptability of the Topical Report are invalidated, WMG, and/or applicants referencing the Topical Report, will be expected to revise or resubmit their respective documentation or submit justification for the continued effective applicability of the Topical Report without revision of their respective documentation.

Regulatory references: 10 CFR 20.311, 10 CFR 20.2006, 10 CFR 61.55

Subject codes: 12.15, 12.17

Applicability: All

HPPOS-126 **PDR-9111210297**

Title: Ex Parte Communication

See the memorandum from J. P. Murray to J. G. Keppler dated February 3, 1981. Ex parte provisions prohibit discussion - written or oral - by one party to a proceeding with a "judge." Judges include licensing boards, appeal boards, administrative law judges, the Commissioners, and staffs of all the above.

An explanation of the term "ex parte" in assisting IE personnel in the recognition of potential ex parte contacts was sought. Here is an attempt to briefly summarize the situation in simplified terms.

The latin phrase "ex parte" means "from one side only." It has application only in the context of a legal "proceeding". What is a "proceeding?" It is the agency's process for issuing, amending, suspending or revoking a license or issuing a civil penalty. When is it "going on?" It begins when a hearing has been noticed or when a request for a hearing is made. It ends with the final decision by the agency.

The basic idea behind the ex parte prohibition, codified in 10 CFR 2.780, is the prevention of the unfairness which could occur if one of two (or more) parties to a proceeding were to have secret discussions with the decisional authority on a matter at issue in the proceeding. One party ought not be allowed to discuss secretly with the judge matters at issue before the judge. This could be unfair to the party or parties left in the dark as to what was said.

In NRC's practice, the "judges" are: the licensing boards, the administrative law judge, the appeal board and, of course, the Commissioners themselves when there is a case pending before them. (This includes all members of the staffs of these "judges".) Also, in NRC's practice the "parties" to proceedings are: the

NRC staff, the applicant or licensee, and any intervenors.

So, the prohibition is against discussion - written or oral - between one of the parties and a judge concerning a matter at issue in a pending proceeding. Put another way, all parties to a proceeding are entitled to be in on any discussions which occur between the judge and any of the other parties.

One final observation is as follows. Although the subsequent revelation on the record of a prior ex parte contact serves, at least in most cases, to largely eliminate the pernicious effect which might otherwise occur, such a "curative" action does not eliminate the original illegality of the contact.

In summary, IE personnel should be sensitive to any contact they may have with the "judges" or their staffers and, never discuss a matter currently pending before one of the "judges," except on the formal record.

Regulatory references: 10 CFR 2.780

Subject codes: 12.19

Applicability: All

HPPOS-324 **PDR-9308260248**

Title: Recommending Third Party Assistance to Licensees

See the memorandum from J. M. Taylor to T. T. Martin (and others) dated July 15, 1993. This memo, which included an enclosure entitled "Guidance for Recommending Third Party Assistance to Licensees," concerns the recommendation of consultants and contractors to licensees by NRC employees.

To be responsive to licensees requesting assistance in getting help in solving programmatic problems, inspectors have provided aid by recommending consultants who could provide quality work. The NRC staff and management had informally decided that by recommending multiple consultants they were avoiding any potential conflict of interest. The issue was reviewed by the General Counsel in consultation with the Office of Government Ethics and concluded that an NRC employee is prohibited from recommending the services of any particular person or organization for a project under NRC regulatory jurisdiction. Providing such a recommendation violated 5 CFR 2635.702. This regulation prohibits Federal employees from using public office for endorsement of any product, service, or enterprise.

As an agency, however, the NRC has an obligation to provide assistance in helping licensees solve problems where the health and safety of the public are involved. With this in mind, guidance was issued to assist the Regions in developing office specific procedures for providing third party assistance to licensees. The procedures to be developed by the Regions should address cases where programmatic problems are involved and identify regional and national sources of assistance to licensees (see Case 1 below). Examples of sources include the Nuclear News Buyers Guide or other industry reference documents, another licensee who has solved a similar problem, or an appropriate professional society such as the Health Physics Society, the American Association of Physicists in Medicine, and the Society for Nuclear Medicine. The procedures should also address those cases where an immediate referral may be necessary (see Case 2 below). Once procedures are developed, their implementation should be discussed at courses on Fundamentals of Inspection and inspector counterpart meetings.

Case 1: An NRC employee receives a request for third party assistance from a licensee.

1. The employee should notify NRC management as soon as practical.

2. Following consultation with management, the employee may refer the licensee to any of the following sources:

   a. The current version of the Nuclear News Buyers Guide. If not otherwise available to the licensee, a copy of the Buyers Guide can be obtained by contacting the Accounting Department of the American Nuclear Society, 555 N. Kensington Ave., La Grange Park, IL 60525.

   b. After consultation with office/regional management, a licensee may be referred to another licensee that has solved a similar problem. When providing the name of a referral licensee, special care must be taken to avoid the perception of conflict of interest and that the referred licensee is not under an OI investigation for misconduct.

c. An appropriate professional society such as the American Society for Mechanical Engineers or the Health Physics Society. [Note: Regions may want to keep a list of local society chapters for referral purposes.]

d. For materials or medical licensees, the NRC employee may recommend the following professional groups as a reference source (the following list is not inclusive and may be added to after confirmation the professional group is willing to assist third party sources):

American Academy of Health Physics
8000 West Park Drive
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Case 2: An immediate health or safety issue exists and it is not practical to take the kind of action detailed in Case 1.

1. The NRC employee may refer the licensee to an appropriate equipment manufacturer.

2. After consultation and approval from NRC management, the NRC employee may refer the licensee to one or more qualified consultants or contractors who can provide prompt safety assistance. [Note: If the issue is so immediate that it is not practical to consult with NRC management, the employee should make the referral first, and then inform NRC management.] Special care should always be taken providing recommendations concerning consultants with whom the recommending staff has a personal or long standing relationship.

3. Following the action, the NRC employee must document the event and the justification for the action and provide a copy to the EDO.

Regulatory references: 5 CFR 2635.702

Subject codes: 12.19

Applicability: All

APPENDIX A

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Regulatory Guide 1.33; Quality Assurance Program Requirements (Operation) (Rev. 2, February, 1978)

Regulatory Guide 1.52; Design, Testing, and Maintenance Criteria for Post Accident Engineered-Safety-Feature Atmosphere Cleanup System Air Filtration and Adsorption Units of Light-Water-Cooled Nuclear

Regulatory Guide 1.8; Qualification and Training of Personnel for Nuclear Power Plants (Rev. 2, April,1987)

Regulatory Guide 3.66; Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR 30, 40, 70, and 72 (June, 1990)

Regulatory Guide 4.15; Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment (Rev. 1., February, 1979)

Regulatory Guide 8.13; Instruction Concerning Prenatal Radiation Exposure (Rev. 2, December, 1987)

Regulatory Guide 8.15; Acceptable Programs for Respiratory Protection (October, 1976)

Regulatory Guide 8.23; Radiation Safety Surveys at Medical Institutions, Rev 1 (1981)

Regulatory Guide 8.32; Criteria for Establishing a Tritium Bioassay Program (July, 1988)

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Regulatory Guide 8.38; Control of Access to High and Very High Radiation Areas of Nuclear Power Plants (June, 1993)

Regulatory Guide 10.8; Preparation of Applications for Medical Use Programs (Rev. 2), (August, 1987)

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ANSI/ANS 3.1-1981; Selection, Qualification and Training of Personnel for Nuclear Power Plants

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ANSI/ANS 3.1-1987; Selection, Qualification and Training of Personnel for Nuclear Power Plants (Revision of ANSI/ANS 3.1-1981)

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Title: Health Physics Position on Task Qualification of HP Technicians

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Regulatory Guide 8.36; Radiation Dose to the Embryo/Fetus (July, 1992)

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Regulatory Guide 8.38; Control of Access to High and Very High Radiation Areas of Nuclear Power Plants (June, 1993)

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Title: Access Control to High Radiation Areas - Turkey Point

HPPOS-016 Page 64
Title: Applicability of Access Controls for Spent Fuel Pools

Regulatory Guide 10.8; Preparation of Applications for Medical Use Programs (Rev. 2), (August, 1987)

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Appendix E

APPENDIX F

LIST OF APPLICABLE LICENSEES

All

Byproduct Material

Fuel Cycle

Non-Power Reactors

Radiography

Reactors

Reactors (BWR)

Source Material

Special Nuclear Material

APPENDIX G

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Title: Clarification of Certain Requirements for Exclusive-Use Shipments

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11. ABSTRACT *(200 words or less)*

The Health Physics Positions (HPPOS) Data Base of the Nuclear Regulatory Commission (NRC) is a collection of NRC staff positions on a wide range of topics involving radiation protection (health physics). It consists of 328 documents in the form of letters, memoranda, and excerpts from technical reports. The HPPOS Data Base was developed by the NRC Headquarters and Regional Offices to help ensure uniformity in inspections, enforcement, and licensing actions.
Staff members of the Oak Ridge National Laboratory (ORNL) have assisted the NRC staff in summarizing the documents during the preparation of this NUREG report. These summaries are also being made available as a "stand alone" software package for IBM and IBM-compatible personal computers. The software package for this report is called HPPOS Version 2.0. A variety of indexing schemes were used to increase the usefulness of the NUREG report and its associated software. The software package and the summaries in the report are written in the context of "new" 10 CFR Part 20 (§§20.1001 - 20.2401).
The purpose of this NUREG report is to allow interested individuals to familiarize themselves with the contents of the HPPOS Data Base and with the basis of many NRC decisions and regulations. The HPPOS summaries and original documents are intended to serve as a source of information for radiation protection programs at nuclear research and power reactors, nuclear medicine, and other industries that either process or use nuclear materials.

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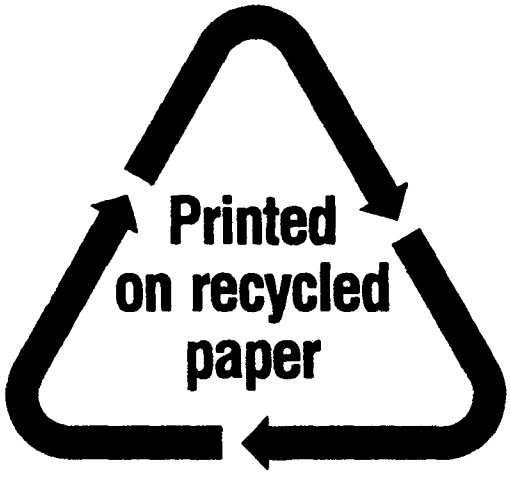

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