ADAMS Template: SECY-067

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TITLE: PRM-035-010 - 57FR08282 - AMERICAN COLLEGE OF NUCLEAR MEDICINE; RECEIPT OF PETITION FOR RULEMAKING (OUTPATIENT TREATMENT WITH RADIOPHARMACEUTICAL IN DOSES GREATER THAN 30 MCI)

CASE REFERENCE: PRM-035-010

57FR08282

KEY WORD: RULEMAKING COMMENTS

Document Sensitivity: Non-sensitive - SUNSI Review Complete

STATUS OF RULEMAKING

PROPOSED RULE: PRM-35-10 OPEN ITEM (Y/N) N

RULE NAME: AMERICAN COLLEGE OF NUCLEAR MEDICINE; RECEIPT OF PETITION FOR RULEMAKING (OUTPATIENT TREATMENT WITH RADIOPHARMACEUTICAL IN DOSES GREATER THAN 30 MCI)

PROPOSED RULE FED REG CITE: 57FR08282

PROPOSED RULE PUBLICATION DATE: 03/09/92 NUMBER OF COMMENTS: 34

ORIGINAL DATE FOR COMMENTS: 05/08/92 EXTENSION DATE: / /

FINAL RULE FED. REG. CITE: 62FR04120 FINAL RULE PUBLICATION DATE: 01/29/97

NOTES ON: PET. REQUESTED COMM. AMEND REGS. ON CONFINEMENT, SAFETY INSTRUCTIO
STATUS : S, & PRECAUTIONS FOR PATIENTS RECEIVING RADIOPHARMACEUTICAL THERAP
OF RULE : Y IN AMOUNTS GREATER THAN 30 MCI. SEE PR-20 & 35. FILE ON P1.

HISTORY OF THE RULE

PART AFFECTED: PRM-35-10

RULE TITLE: AMERICAN COLLEGE OF NUCLEAR MEDICINE; RECEIPT OF PETITION FOR RULEMAKING (OUTPATIENT TREATMENT WITH RADIOPHARMACEUTICAL IN DOSES GREATER THAN 30 MCI)

PROPOSED RULE SECY PAPER:	PROPOSED RULE SRM DATE: / /	DATE PROPOSED RULE SIGNED BY SECRETARY: 03/03/92
FINAL RULE SECY PAPER:	FINAL RULE SRM DATE: / /	DATE FINAL RULE SIGNED BY SECRETARY: / /

STAFF CONTACTS ON THE RULE

CONTACT1: MICHAEL T. LESAR	MAIL STOP: P-223	PHONE: 492-7758
CONTACT2:	MAIL STOP:	PHONE:

DOCKET NO. PRM-35-10
(57FR08282)

In the Matter of

AMERICAN COLLEGE OF NUCLEAR MEDICINE; RECEIPT OF PETITION FOR RULEMAKING (OUTPATIENT TREATMENT WITH RADIOPHARMACEUTICAL IN DOSES GREATER THAN 30 MCI)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
01/14/92	10/05/91	PETITION FOR RULEMAKING SUBMITTED BY RICHARD WETZEL ON THE BEHALF OF THE AMERICAN COLLEGE OF NUCLEAR MEDICINE
03/09/92	03/03/92	FEDERAL REGISTER NOTICE - RECEIPT OF PETITION FOR RULEMAKING
03/20/92	03/14/92	COMMENT OF CAROL S. MARCUS, PH.D, M.D. (1)
03/23/92	03/18/92	PETITION FOR RULEMAKING: NOTICE OF RECEIPT, CORRECTION, PUB ON 3/24/92 AT 57FR10143
04/07/92	03/30/92	COMMENT OF SAINT ANTHONY'S MEDICAL CENTER (BRUCE WALZ, M.D & FRED ABRATH, PH.D) (2)
04/09/92	04/06/92	COMMENT OF JUDITH A. GOULDIN, M.D. (3)
04/16/92	04/07/92	COMMENT OF MICHAEL T. GILLIN, PH.D (4)
04/16/92	04/11/92	COMMENT OF DAVID A. PARKER, M.D. (5)
04/17/92	04/10/92	LTR FRAZEE TO DSB REQUESTING AN EXTENSION OF THE COMMENT PERIOD.
04/21/92	04/16/92	COMMENT OF JAMES A. JOHNSON (6)
04/24/92	04/25/92	COMMENT OF TEXAS RADIATION ADVISORY BOARD (FREDERICK J. BONTE, M.D.) (7)
04/27/92	04/22/92	COMMENT OF J. K. GOODRICH, M.D. (8)
04/27/92	04/22/92	COMMENT OF ALLEN MABRY (9)
04/27/92	04/22/92	COMMENT OF (J. BHATNAGAR & J. GLUCKSON) (10)
04/29/92	04/16/92	CAROL S. MARCUS SUPPLEMENT TO COMMENT NUMBER 1
04/29/92	04/20/92	COMMENT OF CHERYL CULVER, M.S. (11)

DOCKET NO. PRM-35-10 (57FR08282)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
04/30/92	04/24/92	COMMENT OF AMERICAN COLLEGE OF NUCLEAR PHYSICIANS/SOC NUC MED (R. J. LULL, MD & L. S. MALMUD, MD) (12)
05/01/92	04/23/92	COMMENT OF DR. MARSHALL BRUCER (13)
05/04/92	04/30/92	COMMENT OF HARRY M. CULLINGS (14)
05/07/92	05/04/92	COMMENT OF DR. JAMES A. DEYE (15)
05/08/92	05/05/92	COMMENT OF DR. GEORGE H. ZENGER (16)
05/11/92	05/08/92	COMMENT OF HEALTH PHYSICS SOCIETY (N.Y. CHAPTER) (JADWIGA (JODI) STRZELCZYK) (17)
05/11/92	05/06/92	COMMENT OF KIRKSEY E. WHATLEY (18)
05/11/92	05/03/92	COMMENT OF VETERANS ADMINISTRATION (ZABLOCKI MED CENTER) (R. E. STRUBLE, DIRECTOR) (19)
05/11/92	05/04/92	COMMENT OF COLORADO DEPARTMENT OF HEALTH (ROBERT M. QUILLIN, DIRECTOR, RCD) (20)
05/11/92	05/07/92	COMMENT OF DR. W. A. WIATROWSKI (21)
05/12/92	05/08/92	COMMENT OF AMERICAN MEDICAL ASSOCIATION (DR. JAMES S. TODD) (22)
05/14/92	05/08/92	COMMENT OF TEXAS BUREAU OF RADIATION CONTROL (DAVID K. LACKER, CHIEF) (23)
05/19/92	05/07/92	COMMENT OF NEW YORK DEPARTMENT OF HEALTH (RITA ALDRICH, CHIEF, RMS) (24)
06/01/92	06/01/92	COMMENT OF UNIVERSITY RADIOLOGY ASSOCIATES, P.C. (THOMAS JUCHNEWICZ) (25)
06/01/92	06/01/92	COMMENT OF NEW YORK MEDICAL COLLEGE (DR. R. F. GIROLAMO) (26)
06/01/92	06/01/92	COMMENT OF UNIVERSITY RADIOLOGY ASSOCIATES, P.C. (DR. SUSAN FREEMAN) (27)
06/01/92	06/01/92	COMMENT OF WESTCHESTER COUNTY MEDICAL CENTER (DR. GRACE GEORGE) (28)
06/08/92	06/04/92	COMMENT OF DR. ARMAND F. LEONE (29)
06/08/92	06/03/92	COMMENT OF ILLINOIS DEPARTMENT OF NUCLEAR SAFETY (STEVEN C. COLLINS) (30)

DOCKET NO. PRM-35-10 (57FR08282)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
06/19/92	06/16/92	COMMENT OF CRCPD (AUBREY V. GODWIN, CRCPD CHAIRPERSON) (31)
06/22/92	06/15/92	COMMENT OF ALABAMA DEPT OF PUBLIC HEALTH (AUBREY V. GODWIN, DIRECTOR) (32)
06/29/92	06/25/92	COMMENT OF DAVID H. LEWIS, M.D. (33)
07/06/92	06/30/92	COMMENT OF H. JERRY MURRELL, M.D., F.A.C.R. (34)

MURRELL & WESTGATE, INC.
3600 W. Vaughter School Rd.
Columbia, Missouri 65203

34

H. Jerry Murrell, M.D.
Steven J. Westgate, M.D.
Mary Margaret Davis, M.D.

June 30, 1992

Samuel J. Chilk, Secretary
Nuclear Regulatory Commission
United States Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Docketing and Service Branch

Dear Mr. Chilk:

I write to support the petition before the Nuclear Regulatory Commission submitted by the American College of Nuclear Medicine (PRM-35-10). This petition requests that the NRC considers the need to allow amounts greater than 30 millicuries in diagnostic studies and adds a definition of the term confinement. I believe that this would diminish the cost of care since we could shift to an outpatient setting from an inpatient setting and I believe that this would not create a safety hazard to the public. I urge the NRC to consider adoption of the amendment as proposed.

Sincerely,

H. Murrell, M.D.

H.J. Murrell, M.D., F.A.C.R.
HJM/mp

(33)

Harborview
Medical
Center

NUCLEAR MEDICINE
David H. Lewis, MD
Director
(206) 223-3492
325 9th Ave
Seattle, WA 98104

6/25/92

Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C.
20555

Attention: Docketing and Service Branch

Dear Secretary Chilk,

I wholeheartedly endorse the adoption of 10 CFR Part 35 for the allowance of doses greater than 30 millicuries to be administered to outpatients for the treatment of cancer and thyroid ablation. It is clear from the abstract of Dr. Allen and colleagues from the SNM annual meeting of 1990 that this can be safely done and is certainly much more cost-effective than in-patient treatment. I work at a hospital that has a high rate of un-insured patients who could not pay the hospital bills due to such treatments. Therefore, occasionally, one might be forced to treat patients suboptimally with recurrent 30 millicurie doses rather than the more definitive treatment higher-dose therapies which would cure the patients' disease more assuredly. I think this would be a step forward for American medicine not only in patient care but also in economically sound practice.

Sincerely,

David H. Lewis

David H. Lewis, M.D.
Assistant Professor of Radiology
University of Washington

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

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Department of Public Health

State Office Building
Montgomery, Alabama

Claude Earl Fox, M.D., M.P.H.
State Health Officer

MAILING ADDRESS
434 Monroe Street
Montgomery, Alabama 36130-1701

June 15, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Docket No. PRM-35-10

Dear Sir:

In response to NRC's request for written comments regarding Docket No. PRM-35-10 the following comments are offered.

The State of Alabama Department of Public Health, Radiation Control Division opposes the referenced petition in that it proposes to release from confinement patients whose body burden exceeds 30 millicuries of iodine. This Agency recommends that the standard adhered to by the USNRC and Agreement States of 30 millicuries or 5 millirem per hour at one meter be maintained.

It is my understanding that this petition is the result of a "study" done by Doctor Herbert C. Allen, Jr., Nuclear Medicine Laboratories of Texas, 6411 South Main Street, Texas Medical Center, Houston, Texas. I strongly recommend that a thorough review of this study be made by NRC including discussions with the Staff of Radiation Control of the State of Texas prior to concluding that the petition should be granted.

With the use of iodine over the past many years, a wealth of information should be available from institutional radiation safety officers, particularly of broad major medical institutions.

Thank you for the opportunity to comment.

Sincerely,

Aubrey v. Godwin, Director
Division of Radiation Control
Bureau of Environmental & Health
Service Standards

AVG:KEW:psc

Conference of Radiation Control Program Directors, Inc.
Office of Executive Director 205 Capital Avenue Frankfort, Kentucky 40601 (502) 227-4543

June 16, 1992

Samuel J. Chilk, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Docket Numbers PRM-35-10 and 35-10A

Dear Mr. Chilk:

With respect to these proposed rulemaking petitions referenced above, as submitted by the American College of Nuclear Medicine, the Board of Directors of the Conference of Radiation Control Program Directors, Inc. (CRCPD), based upon recommendations of the CRCPD *Committee on Suggested State Regulations for Control of Radiation - Use of Radionuclides in the Healing Arts*, offers the following comments:

1. The petitioner requests the term "confinement" as used in 10 CFR Part 35, §35.75, be clarified to allow for confinement at home. As written, this regulation does not specify that the patient must be hospitalized. It is our opinion that NRC and Agreement States with the same terminology in equivalent regulations currently have the prerogative to authorize confinement by means other than hospitalization. Therefore, no definition of the term "confinement" is taken to mean hospitalization or other limitations of patient activities to keep radiation exposures to other individuals within allowable limits which are acceptable to the Agency.

2. The petitioner requests the requirement for confinement of patients containing more than 30 millicuries of activity be deleted. It is the recommendation of this Committee that the current release criteria be re-examined and modified to conform to the recommendations in Report Number 37 of the National Council on Radiation Protection and Measurements (NCRP) (Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970). These recommendations provide for release of patients containing radionuclides when the activity in the patient is such that the effective dose equivalent to a hypothetical person one (1) meter from the patient during complete decay of the radionuclide will not exceed the maximum permissible dose to members of the public as specified in 10 CFR Part 20. We believe that this is a more reasoned approach based on available scientific guidance and takes into consideration the administered radionuclide.

3. We wish to reserve further comment on the safety of outpatient radiopharmaceutical therapy in doses up to 400 millicuries of iodine-131 as sodium iodide until these data have been published in peer-reviewed scientific journals, especially in light of the recommendations in NCRP Report Number 37. No references to such publications were included in the petitioner's request.

Thank you for the opportunity to comment on this petition for rulemaking. If you need further information or clarification, please do not hesitate to contact me.

Sincerely,

Aubrey V. Godwin

Aubrey V. Godwin
CRCPD Chairperson

AVG/CMH/sah
cc: Board of Directors
Federal Liaisons
SR-6 Members

30

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, IL 62704
(217) 785-9900

THOMAS W. ORTCIGER
DIRECTOR

JIM EDGAR
GOVERNOR

June 3, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Re: American College of Nuclear Medicine: Receipt of Petition for Rulemaking [Docket No. PRM-35-10] and American College of Nuclear Medicine: Receipt of an Amended Petition for Rulemaking [Docket No. PRM-35-10A]

Gentlemen:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the above-identified petitions for rulemaking. The requests represent changes to NRC's medical rules (10 CFR 35) that would allow release of a patient from hospitalization, but not release from confinement for medical care, any patient containing more than 30 millicuries of activity or having a measured dose rate greater than 5 millirems per hour at one meter.

The Department believes the rules in 10 CFR 35.75(a) are clear enough to allow the release of a patient containing more than 30 millicuries of activity as long as the measured dose rate at one meter is less than 5 millirems per hour, and this is the way the Department interprets these regulations. In instances where a patient is to be released having a measured dose rate greater than 5 millirems per hour, the Department would prefer to review this in the form of a request for an amendment to a license. This would ensure that adequate training is provided and safety precautions are in place for each patient "confined" rather than "hospitalized." The Department does not wish to restrict the practice of medicine, however, the Department is required to protect public health and safety, including family members of patients undergoing radiation therapy treatments on an outpatient basis.

In general, the Department has concerns about implementing "confinement" restrictions outside a hospital setting, especially in light of the request to release patients containing up to 400 mCi of I-131. The proposed definition of "confinement" does not address transport to the confined area, and does not prohibit a patient from taking a bus home, for example. In addition, it is very difficult to control the actions of an ambulatory patient and difficult to assure the patient has remained in confinement. If you have any questions regarding these comments, do not hesitate to call me or Kathy Allen at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

SCC:KAA

cc: B.J. Holt

Preakness
Radiological
Associates, P.A.

Diplomates American Board of Radiology

Armand F. Leone, M.D., F.A.C.R.
Rita F. Girolamo, M.D., F.A.C.R.
George T. Veliath, M.D.
Inwahn Whang, M.D.
Armand Leone, Jr., M.D.
Eileen De Geyter, Business Manager

June 1, 1992

29

Samuel J. Chilk
Secretary of the Commission
U.S. Regulatory Commission
Washington, D. C. 20555
ATTN: Docketing & Service Branch

RE: DOCKET #PRM-35-10

Dear Mr. Chilk:

I acknowledge Mr. Grimsley's letter of March 3, 1992 and the enclosed copy of the Commission's notice of receipt of the American College of Nuclear Medicine Petition for Rule Making.

In discussion with Mr. Michael T. Lesar, Chief, Rules Review Section, I pointed out that the reference on page three (3) of the NRC notice (Section-Petitioner's Request) Item (1) refers to 10 CGR 35.72 (a) (2) which appears to be a typographical error. Insofar as we can determine, the reference should have been as in (2) of the same section of the Commissioner's letter, which refers to Paragraph 35.75 (a) (2).

Attention is also drawn to the need to allow greater than 30 mCi in diagnostic studies, in addition to radioisotope therapy, since such doses are desirable in many of the new Technetium 99m labeled radiopharmaceuticals and can be performed with no hazard to the health and safety of the public or occupational workers.

We have taken the liberty of making changes in the enclosed copy of the Commission's Notice of Receipt of the American College of Nuclear Medicine Petition for Rule Making, reflecting suggestions in this regard and in addition, suggest in the definitions of Section #35.2 as follows: "confinement" means remaining in a hospital or a private residence.

The American College of Nuclear Medicine supports these revisions to the Commission's notice, as attached, and requests that these additions and corrections be published in the Federal Register.

Thank you for your help in this regard and we certainly appreciate your continuing efforts on this change.

Sincerely,

Armand F. Leone, M.D.
AFL/dt

418 Park Avenue Paterson, N.J. 07504 201/881-1300 Fax 201/881-8454 220 Hamburg Turnpike Wayne, N.J. 07470 201/904-0404 Fax 201/904-0423

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County Executive

WESTCHESTER COUNTY
MEDICAL CENTER

MACK L. CARTER, JR.
Commissioner

June 1, 1992

28

Samuel J. Chilk
Secretrary of the Commission
U.S. Regulatory Commission
Washington, D. C. 20555
ATTN: Docketing & Service Branch

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Thank you for your help in this regard and we certainly appreciate your continuing efforts on this change.

Sincerely,

Grace George, M.D.
Nuclear Medicine

Valhalla, New York 10595 • 914-285-

University Radiology Associates, P.C.
New York Medical College
Valhalla, New York 10595

DIAGNOSTIC RADIOLOGY
MICHAEL S. TENNER, M.D., F.A.C.R.
RITA F. GIROLAMO, M.D., F.A.C.R.
ROBERT M. KLEIN, M.D., F.A.C.R.
HOWARD BERMAN, M.D.
JESSICA F. BERKOWITZ, M.D.
ADELE BRUDNICKI, M.D.
SUSAN FREEMAN, M.D.
GRACE GEORGE, M.D.
LOUISE GODINE, M.D.
SUSAN KLEIN, M.D.
DENISE LESLIE, M.D.
ALEX NORMAN, M.D., F.A.C.R.
GRIGORY ROZENBLIT, M.D.
PAUL SANE, M.D.
MICHAEL SWIRSKY, M.D.

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BUSINESS OFFICE 914-347-3589
OP REGISTRATION 914-285-1452
MACY X-RAY 914-285-7341
MUNGER X-RAY 914-993-4377

27

June 1, 1992

Samuel J. Chilk
Secretrary of the Commission
U.S. Regulatory Commission
Washington, D. C. 20555
ATTN: Docketing & Service Branch

RE: DOCKET #PRM-35-10

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The American College of Nuclear Medicine supports these revisions to the Commission's notice, as attached, and requests that these additions and corrections be published in the Federal Register.

Thank you for your help in this regard and we certainly appreciate your continuing efforts on this change.

Sincerely,

Susan Freeman, M.D.

Susan Freeman, M.D.
Director of Nuclear Medicine
SF/AT

(26)

NEW YORK MEDICAL COLLEGE — DEPARTMENT OF RADIOLOGY

Rita F. Girolamo, M.D., F.A.C.R., F.A.C.N.M.
Professor and Vice-Chairman
Department of Radiology
New York Medical College
Valhalla, New York 10595
(914) 285-8995

Westchester County Medical Center
Metropolitan Hospital Center
Coler Memorial Hospital
Lincoln Medical & Mental Health Center

June 1, 1992

Samuel J. Chilk
Secretrary of the Commission
U.S. Regulatory Commission
Washington, D. C. 20555
ATTN: Docketing & Service Branch

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Thank you for your help in this regard and we certainly appreciate your continuing efforts on this change.

Sincerely,

Rita F Girolamo

R. F. Girolamo, M.D.
Director of Nuclear Medicine
RFG/dg

(25)

University Radiology Associates, P.C.
New York Medical College
Valhalla, New York 10595

DIAGNOSTIC RADIOLOGY
MICHAEL S. TENNER, M.D., F.A.C.R.
RITA F. GIROLAMO, M.D., F.A.C.R.
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BUSINESS OFFICE 914-347-3589
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MACY X-RAY 914-285-7341
MUNGER X-RAY 914-993-4377

June 1, 1992

Samuel J. Chilk
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U.S. Regulatory Commission
Washington, D. C. 20555
ATTN: Docketing & Service Branch

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Thank you for your help in this regard and we certainly appreciate your continuing efforts on this change.

Sincerely,

Thomas Juchnewicz,
Deputy Officer/Radiation Safety

Thomas Juchnewicz

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Center for Environmental Health 2 University Place Albany, New York 12203-3399

Lorna McBarnette
Executive Deputy Commissioner

OFFICE OF PUBLIC HEALTH
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Center Director

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May 7, 1992

DOCKET NUMBER PETITION RULE PRM 35-10

(57 FR 8282)

Secretary of The Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch
Docket No. PRM-35-10

Dear Mr. Shilk:

Please accept the following comments on the petition for rulemaking published on p.8282, FR Vol. 57, No. 46, March 9, 1992.

The petitioner requested that NRC revise Part 35 to delete the requirements that patients remain confined for medical care until the residual activity from radiopharmaceuticals is less than 30 millicuries and that dosages to outpatients be allowed to exceed 30 millicuries (up to 400 millicuries of I-131 NaI).

In the opinion of our Radiological Health Advisory Committee the current 30 millicurie limit for outpatient administrations of iodine 131 is too restrictive, and as stated previously in our Committee's comments on the petition submitted December 26, 1990 by Dr. Carol Marcus, it may be interfering with quality medical care. At the other extreme our Committee feels that 400 millicurie administrations should not be permitted outside a hospital. At dosages greater than 150 millicuries nausea and the likelihood of vomiting are more likely and present a risk of extensive contamination. However, dosages on the order of 75 millicuries of iodine 131 are common in the literature for thyroid carcinoma and close to the maximum residual activity of 80 millicuries recommended in NCRP Report No. 37 as a level for which provision should be made for release of the patient from hospital confinement. The NCRP Report then recommends restrictions on patient contact with others until residual activity has decreased to 8 millicuries or less.

It would therefore seem reasonable to establish criteria under which patients could be treated as outpatients or released from hospital confinement with up to 80 millicuries of iodine 131. Criteria should include determining that patients exhibit no nausea or vomiting or other side-effects, are continent, have a high likelihood of compliance, and are followed by the licensee for both clinical effects and radiation protection compliance until this is no longer necessary. For radiation protection purposes this would be the 8 millicurie residual activity level.

Acknowledged by card JUL 16 1992

A checklist could be used to qualify patients and the checklist and instructions to be provided to these discharged patients and outpatients should be approved in advance by the licensing agency.

Very truly yours,

Rita Aldrich

Rita Aldrich, Chief
Radioactive Materials Section
Bureau of Environmental
Radiation Protection

RA:cwd

Two University Place, Room 375, Albany, New York 12203 Tel. 518/458-6485

Texas Department of Health

David R. Smith, M.D.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Radiation Control
(512) 834-6688

Robert A. MacLean, M.D.
Deputy Commissioner

May 8, 1992

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Docket No. PRM-35-10

Attention: Docketing and Service Branch

Dear Mr. Secretary:

In response to a petition for rulemaking published in the Federal Register on March 9, 1992, regarding the proposal that the rule requiring hospitalization of patients receiving greater than 30 millicuries of radiopharmaceuticals be deleted, the Bureau of Radiation Control offers the following comments.

We do not support removal of the requirement for treating patients with therapeutic doses of radiopharmaceuticals in a medical facility where exposures to staff and members of the public, including the patient's family, can be carefully controlled. As stated in the Nuclear Regulatory Commission's (NRC) Statements of Consideration concerning 10 CFR 35.75, dated October 31, 1986, the release criteria are based on those recommended by the National Council on Radiation Protection (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." Because the patient becomes a source of exposure and iodine-131 is the most radiotoxic byproduct material used for medical use, those individuals being treated with radiopharmaceuticals in high doses, and especially with iodine-131, should remain under careful control of the licensee to limit the spread of contamination and radiation exposures to other persons.

This Agency has had experience with an actual case in which a patient received greater than 30 millicuries of a radiopharmaceutical and was not hospitalized. Investigation results confirmed widespread contamination of a private residence. Data provided by the physician further showed that such an operation cannot meet regulatory requirements regarding radiation exposures to the public. Enclosed correspondence from the National Council on Radiation Protection and Measurements to Dr. Edmond Griffin, former Chairman of the Texas Radiation Advisory Board (TRAB), supports Agency findings that contamination and exposures to the public are significant problems when the patient is not hospitalized.

The Texas radiation control program, upon recommendation of TRAB, plans to follow the mandatory hospitalization requirements of the current NRC rule in its rule development and is currently drafting changes to the Texas Regulations for Control of Radiation which will require hospitalization of patients receiving radiopharmaceuticals in amounts greater than 30 millicuries. This rule becomes even more important with the decrease in annual dose limits to members of the general public in 10 CFR Part 20.

Should you need additional data or clarification on our experience with this subject, please contact Mrs. Ruth E. McBurney, C.H.P., Director, Division of Licensing, Registration, and Standards at (512) 834-6688.

Thank you for the opportunity to provide comments.

Yours truly,

David K. Lacker, Chief
Bureau of Radiation Control

Enclosure

NCRP

National Council on Radiation Protection and Measurements

7910 WOODMONT AVENUE, SUITE 1016, BETHESDA, MARYLAND, 20814-3095 AREA CODE (301) 657-2652

WARREN K. SINCLAIR, Ph.D., *President*
S. JAMES ADELSTEIN, M.D., *Vice President*
W. ROGER NEY, J.D., *Executive Director*

September 26, 1983

Edmond E. Griffin, Ph.D
Medical Program Science Administrator
American Heart Association
7320 Greenville Avenue
Dallas, Texas 75231

Dear Dr. Griffin:

This is in response to your request to Dr. Sinclair concerning exemptions to the 30 millicuries requirement prior to release from the hospital. Dr. Sinclair has asked that I respond to you. I am a staff scientist for the NCRP with responsibilty in the medical areas of radiation protection.

Attached is a complimentary copy of NCRP Report No. 37. The philosophy to back up my response to your question is contained in Report 37 and in Report 39 - Basic Radiation Protection Philosophy. The NCRP would recommend against "exemptions" from the standard 30 mCi body content prior to release from the hospital. If anything, in the case of Iodine-131, we would recommend that in the majority of cases the patient should not be released until the total amount in the body is 8 mCi. However that is too restrictive, and, since the number of people receiving therapeutic amounts of radioiodine is not great, the 30 mCi quantity provides adequate radiation protection to members of the family. This, of course, assumes that the members of the family are properly instructed in accordance with the provisions of Section 4.1 of Report 37.

I recommend that anyone responsible for making decisions, such as this one facing your Advisory Board, read all of Report 37 so as to get a full appreciation of the problem. This report was first issued in 1970 and I would add only that, in todays political climate, I would treat all members of the patient's family as under 45 and delete the easing of restrictions for those over 45. Please realize that these restrictions are important for others who may come into contact with the patient. The concern for the patient is that he or she receive the benefit of the procedure and subsequent freedom from the condition being treated.

Contamination is another significant problem especially when iodine is the administered isotope. Everything the patient touches or that is in contact with the patient is contaminated. When I was a radiation safety officer at a large medical center, patients who had been administered iodine

for therapeutic purposes were placed in moderate isolation. They were placed in a private room, were required to wear light cotton gloves whenever using the phone or reading a book, were required to use disposable utensils, were encouraged to collect their own urine in a shielded 10 gallon container kept in their own private bathroom and were fully instructed in procedures which would lessen the exposure of anyone who had to come into the room. Visitors were allowed but they were encouraged not to touch the patient and to sit as far away as possible. Nursing staff were fully trained in proper radiation safety procedures to be followed.

If you have further questions, please don't hesitate to call (301-657-2652) or write. I hope this is helpful to you.

Sincerley,

J. A. Spahn
Staff Assistant

P.S. Our overriding consideration would be that no person in the general population should be exposed to more than 500 mrem per year.

JAS:sat
Enclosures: (1)

American Medical Association

Physicians dedicated to the health of America

James S. Todd, MD
Executive Vice President

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

May 8, 1992

Samuel J. Chilk, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

RE: Docket No. PRM-35-10
Petition of American College of Nuclear Medicine

Dear Mr. Chilk:

The American Medical Association (AMA) supports the petition of the American College of Nuclear Medicine to: 1) revise the Nuclear Regulatory Commission's (NRC) standards for the maximum allowable external radiation exposure of the public, including family members of patients treated with radiopharmaceuticals; and 2) allow an outpatient option for all patients receiving oral or IV radiopharmaceuticals.

The medical use of radiopharmaceuticals has been an effective component of medical practice for over 35 years. More recently, radioactive biologicals such as radiolabeled monoclonal antibodies have been added to the physician's armamentarium. The ability of the physician to administer these materials on an outpatient basis has maintained the accessibility and minimized the costs of such treatments. However, their use often requires the administration of doses in excess of 30 mCi, the maximum total body radiation content with which the release of a patient currently may be authorized, and may require doses as great as 400 mCi.

As such use continues to expand, concern remains over the potential for adverse impact of radiation on the local environment and its occupants. Such concern has prompted the NRC to revise its regulations limiting the maximum allowable external radiation exposure of the public, including the family members of patients treated with radiopharmaceuticals. The sections of the final rule relevant to outpatient treatment with radiopharmaceuticals (10 CFR 35.72(a)(2) and 10 CFR 35.75(a)(2)) would reduce the radiation exposure limit of non-patients from 500 mRem/year to 100 mRem/year, effectively decreasing by 80% the maximum total body radiation content with which the release of a patient may be authorized.

On January 14, 1992, a petition was filed by the American College of Nuclear Medicine requesting the NRC exempt the use of radio-pharmaceuticals from restrictions concerning the radiation exposure limit of non-patients. Their opposition to the current radiation exposure limit results from their interpretation of the revised regulation's implications regarding outpatient medical procedures. Because therapeutically effective doses of radiopharmaceuticals may result in exposure to nonpatients within the immediate surroundings greater than 100 mRem/year, some procedures utilizing radioisotopic materials will no longer be allowable as outpatient procedures. The American College of Nuclear Medicine has concluded that prolongation of hospitalization, necessitated by a decrease in the limit of radiation exposures allowable within a patient's home, will significantly increase the cost of medical care (by as much as $100,000,000/year) and possibly cause the inability of some patients to achieve access to that care.

No evidence has been published demonstrating that an annual external radiation exposure of 500 mRem from radiopharmaceuticals poses any health risk. In addition, little published material is available on the subject of radiation exposure of non-patients in proximity to treated patients, and the possible effects of "second-hand" exposure. When patients were released with total body burdens of 18-43 mCi, family members not entering the confinement area of the home were exposed to 20-80 mRem in 7-8 days. Data has been presented demonstrating that, when I^{131} was used in an outpatient setting with the patient confined to restricted portions of the home within several hours after radioisotope administration, doses of 100-300 mCi resulted in family member exposures averaging only 13 mRem during the first week. Because after 7 days the radiation exposure of a patient's surroundings is usually minimal even after such large doses, it appears that the NRC's assumption that any total body burden greater than 30 mCi at discharge will result in external radiation exposure of family members in excess of 100 mRem/year may not be correct. Consequently, the maximum discharge burden implied by the revised regulation, 30 mCi, may not be well-founded.

Because doses of 30 mCi are substantially below the doses typically used to treat thyroid carcinoma, outpatient treatment of up to 10,000 patients annually with I^{131} will need to be discontinued under the revised regulation, which limits the potential radiation exposure of family members and care providers to amounts 80% lower than those previously allowed. The new lower limit is inconsistent with medical experience and has not been demonstrated to be necessary in order to protect the public from radiation effects. Furthermore, it will limit both early release of patients and the treatment of patients at home, which will in turn impose potentially avoidable hospital inpatient costs and burdens on the health care delivery system.

It would appear that the NRC has been overly cautious on this particular issue, and perhaps insufficiently sensitive to the implications for the patient or the health care system. The NRC may not have considered the therapeutic option of home treatment with radioactive substances.

The current therapeutic uses of radiopharmaceuticals, particularly in outpatient settings, are effective, safe to the public, without hazard to the health of America, and lie well within the bounds of existing regulatory oversight. In addition, adequate home confinement precautions reduce the hazard associated with therapeutic use of radioisotopes to the health and safety of the public sufficiently to eliminate the need for any hospitalization following therapeutic administration of radiopharmaceuticals.

The AMA therefore, urges the NRC to reconsider the revised regulations (10 CFR 35.72 and 35.75) in the context of their potential negative impact on the accessibility of health care, medical practice, and cost containment. The Commission should consider exempting the use of radiopharmaceuticals from mandatory inpatient confinement, and should at least restore the limit for external radiation to individual members of the public of 500 mRem/year unless clear data unequivocally demonstrating the need for a reduction in this limit are obtained. The NRC should also clarify its position specifically on the use of radiopharmaceuticals to treat patients when they are to be released to temporary home confinement.

Sincerely,

James S. Todd MD

James S. Todd, MD

JST/mjz

21

The University of Texas
Health Science Center at San Antonio
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San Antonio Texas 78284-7800

Department of Radiology
Division of Radiological Sciences

(512) 567-5550

May 7, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attn: Docketing and Service Branch
Washington, D. C. 20555

Gentlemen:

I urge the Commission to deny the Petition for Rulemaking submitted by the American College of Nuclear Medicine (Docket No. PRM-35-10) which requests authority to administer radioiodine in quantities of 400mCi or less to outpatients. I respectfully request that the Commission consider the following information:

1. The instantaneous exposure rate immediately after administration of 400 mCi of I-131 to an individual is calculated to be 88 mR/hr at one meter (based on a point source calculation and a specific gamma constant of 2.2 $Rcm^2/mCi\ hr$). Actual measurements taken at the hospitals with which I have been associated for the past 15 years confirm values such as this. Were the patient to retain all of the iodine in his/her body, which is normally not the case, the total exposure to a family member at one meter from the patient for only 8 hours a day during the course of the therapy can be shown to exceed 500 mrem.

Even if the patient retained only 10% of the administered activity, the potential dose equivalent to the patient's family can be shown to be in excess of 500 mrem.

2. Assuming a small retention (i.e., 10%) provides for 360 mCi of the 400 mCi dose to be biologically eliminated from the body contained in urine, saliva, feces, perspiration, semen and as vapor. Any practicing health physicist who has supported a major radioiodine therepy has seen, if swipes were taken, removable contamination of tens of thousands and hundreds of thousands of dpm in the patient's room and lavatory. Such values clearly exceed the widely accepted action levels contained in table N-1, Appendix N, Regulatory Guide 10.8 for removable radio contamination.

3. Of all the radiopharmaceuticals used, radioiodine (I-131) is by far the most hazardous.

4. The petitioner suggests that scientific literature demonstrates that the external exposure to the public, I assume to include the patient's family, would not exceed regulatory limits. I am unaware of any consensus in the literature to support this contention. It is significant to note that the petitioner fails to make a similar statement regarding the ingestion or inhalation of the radioiodine by family members.

Clearly, a burden of proof should be required to be demonstrated by the petitioner.

In conclusion, I urge the Commission to reject this petition in its entirety.

Sincerely,

W.A. Wiatrowski, Ph.D., DABR, CHP
Associate Professor

cf Bureau of Radiation Control
Texas Department of Health
Attn: Mrs. Ruth McBurney
1100 West 49th Street
Austin, Texas 78756

COLORADO
DEPARTMENT
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May 4, 1992

Secretary of the Commission
Docketing and Service Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Docket No. PRM-35-10

This letter is to express my concerns regarding the petition to delete the requirement in 10 CFR 35.75(a)(2) so as to provide the blanket authority to release patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries.

I do not feel this is justified for patients receiving iodine-131 based upon my previous experience as a hospital radiation safety officer. This may be justified for certain other isotopes where the excretion of the isotope is more focused and less diffuse than iodine. Consequently, this should be evaluated on an isotope by isotope basis and on a procedure by procedure basis. With the new 10 CFR 20 dose limits for individual members of the public (10 CFR 20.1301) reflecting a total effective dose equivalent criteria, the issue of dose to family members must be closely examined prior to the release of a patient.

Sincerely,

Robert M. Quillin, Director
Radiation Control Division

RMQ/msm

Clement J. Zablocki
Medical Center

Milwaukee WI 53295

Veterans Administration

(19)

May 3, 1992

In Reply Refer To: 695/00C-S

Secretary of the Commission
Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Docketing and Service Branch RE: Docket No. PRM-35-10

Greetings:

In response to the above, the following comments are submitted by our Radiation Safety Officer, Robert E. Black.

1. The Petitioner is in error for all three points of the resolution dated September 24, 1991, as follows:

A. The outpatient treatment of certain thyroid disorders and other malignancies with large doses of I-131 exceeding 30 mCi is in violation of NRC regulations. It can easily be calculated (see attachment) that a body burden of 30 mCi of I-131 in an outpatient could cause a family member to receive a dose to the whole body of 0.5 rem in one calendar year. To cause an outpatient to have a body burden in excess of 30 mCi of I-131 would also likely cause a family member to receive more than the regulatory limit of 0.5 rem and would be a violation of 10CFR20.105(a).

B. The licensee must possess, use, and transfer licensed material in such a manner that radiation levels in unrestricted areas do not exceed two millirems in one hour, or 100 millirems in seven days (10CFR20.105[b]). Confinement of radiation patients is one way of meeting this regulatory requirement.

C. The legal limit of the amount of I-131 that can be given on an outpatient basis would often be less than 30 mCi in order to meet the requirements of 10CFR20.105 (see attached calculation). If this regulation was strictly enforced, the nuclear medicine physician would have to ask the health physicist to measure the biological half life of I-131 for each outpatient, and calculate the maximum permissible body burden. But the physician is allowed to follow the less rigorous rule in 10CFR35.75, even though members of the general public might receive doses greater than 0.5 rem thereby. The general public includes the outpatient's relatives who are young children or who are pregnant.

2. If outpatients were given 100 mCi, or 200 mCi, or 400 mCi of I-131, their family members would receive radiation exposures of from one to ten rem. No article published in Health Physics in the last eight years has even suggested that this would be a risk-free proposition.

3. Finally, there is a large body of health physicists, with collective experience in radiation protection since 1942, qualified to ensure the protection of the health and safety of the public. We are confident these people will agree that this petition is harmful and should be denied.

4. If there are any further questions, please contact the institution's Radiation Safety Officer, Mr. Robert E. Black, at (414)384-2000, extension 2631.

Sincerely,

R. E. STRUBLE
Medical Center Director

Enclosure

Calculation of Radiation Exposure From Outpatients with Various Body Burdens of I-131

Consider an outpatient with an initial body burden of one mCi of I-131. The radiation exposure rate R at a distance of one meter will be 0.22 mR hr^{-1} (from Table I of NCRP Report No. 37). This radiation exposure rate will decrease as the body burden of I-131 decreases because of radioactive decay and excretion from the patient's body.

The total radiation exposure, E, can be defined as

$$E = \int R(t)dt \tag{1}$$

where R(t) is the function describing the change of the radiation exposure rate with time. That is,

$$R(t) = R_o\, e^{-\lambda(eff)t} \tag{2}$$

where R_o is the initial exposure rate when the I-131 is ingested by the patient, t is the time after ingestion, and λ (eff) is the effective decay constant for the decrease of the I-131 body burden due to both radioactive decay and excretion. Combining (1) and (2) yields:

$$E = \int R_o\, e^{-\lambda(eff)t}\, dt \tag{3}$$

Since R_o and (eff) are constants, preparing (3) for integration between limits yields

$$E = -\frac{R_o}{\lambda(eff)} \int_0^t e^{-\lambda(eff)t}[-\lambda(eff)dt] \tag{4}$$

Integrating results in

$$E = -\frac{R_o}{\lambda(eff)} \left[e^{-\lambda(eff)t} \right]_0^t \tag{5}$$

The family of an outpatient will always be exposed to radiation from whatever I-131 remains in the patients body. This requires that the exposure E shall be evaluated from the moment the patient ingests the I-131, when t=0, until the I-131 is all gone, when t is infinite (about three weeks, in this example). When these limits are substituted into (5), E becomes

$$E = -\frac{R_o}{\lambda(eff)} \left[e^{-\lambda(eff)t} \right]_0^\infty = -\frac{R_o}{\lambda(eff)} (0 - 1) \tag{6}$$

$$E = \frac{R_o}{\lambda(eff)} \tag{7}$$

In reality R_o would be measured when the I-131 is given to the outpatient. But for these feasibility calculations it will be estimated from Table I of NCRP 37.

The value of λ(eff) may be different for different patients, depending on how much thyroid tissue or thyroid cancer tissue is present. Patients who have had their cancerous thyroids completely removed may excrete 90% of their I-131 medication in 24 hours. Others who have large masses of cancerous thyroid tissue remaining may retain large amounts of I-131 for days. My experience has included a few patients with both extremely fast and extremely slow excretion rates. One may reasonably expect many patients to excrete half of the I-131 in about two days. Therefore, we shall assume the biological half-life to be 50 hours. Then

$$\lambda(\text{eff}) = \frac{.693}{50 \text{ hrs}} = .01386 \text{ hrs}^{-1} \tag{8}$$

When 30 mCi of I-131 are given to an outpatient, the radiation exposure to family members at a nominal distance of one meter will be

$$E = \frac{30 \text{ mCi} \times .22 \text{ mR hr}^{-1} \text{ mCi}^{-1}}{.01386 \text{ hr}^{-1}} \tag{9}$$

$$E = 476 \text{ mR} \tag{10}$$

Since rems are equivalent to roentgens for moderate energy x and gamma rays,

$$E = 476 \text{ mrem} \tag{11}$$

If the outpatient receives 100 mCi of I-131, the radiation exposure to family members will be

$$E = \frac{100 \text{ mCi} \times .22 \text{ mR hr}^{-1} \text{ mCi}^{-1}}{.01386 \text{ hr}^{-1}} \tag{12}$$

$$E = 1587 \text{ mR} \equiv 1587 \text{ mrem} \tag{13}$$

For 200 mCi or 400 mCi of I-131, exposure to family members would be 3175 mrem and 6349 mrem, respectively.

Implicit in these calculations is the assumption that the I-131 is excreted continuously by the patient. Actually the external radiation exposure rate decreases slowly until the patient urinates, and then the rate drops in a step function whose magnitude is related to the amount of I-131 that was excreted. For the present purpose, this effect can be ignored, for it is less important than the different biological half-lives for I-131 that will be characteristic of different outpatients.

If the patient has considerable amounts of thyroid tissue, either normal or cancerous, then the biological half-life may be longer. In this event a body burden of 30 mCi of I-131 could give a member of the general public a radiation exposure greater than 500 mrem. The patient's biological half-life easily could be 75 hours. Then

$$\lambda_{(eff)} = \frac{.693}{75 \text{ hrs}} = .00924 \text{ hrs}^{-1} \qquad (14)$$

and the exposure would be

$$E = \frac{30 \text{ mCi} \times .22 \text{ mR hr}^{-1} \text{ mCi}^{-1}}{.00924 \text{ hr}^{-1}} \qquad (15)$$

$$E = 714 \text{ mR} \cong 714 \text{ mrem} \qquad (16)$$

This patient should be confined to comply with 10CFR20.105, but 10CFR35.75 provides a liberal exception to the general regulation and permits the nuclear medicine physician to release the patient.

Robert E. Black

State of Alabama
Department of Public Health

Claude Earl Fox, M.D., M.P.H.
State Health Officer

State Office Building
Montgomery, Alabama

May 6, 1992

MAILING ADDRESS
434 Monroe Street
Montgomery, Alabama 36130-1701

(18)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Docket No. PRM-35-10

Dear Sir:

In response to NRC's request for written comments regarding Docket No. PRM-35-10, as it appeared in Federal Register, Monday, March 9, 1992, the following comments are offered.

1. I support the petition to a point and agree that NRC broadened its interpretation of the "greater than 30 millicurie" confinement criteria to cover "all" radiopharmaceuticals as opposed to specific radiopharmaceuticals such as iodine 131 as sodium iodide. In discussion of the development of revisions to 10 CFR 35, I do not personally recall the release criteria ever being discussed as applying to all radiopharmaceuticals. In my opinion this was "understood" to mean certain radiopharmaceuticals only. However, as it was not carefully worded, reviewers not involved in the original work interpreted it to apply to all radiopharmaceuticals for which such is not warranted.

2. I am opposed to the petition in that it supports release of patients from hospital (institution) confinement whose body burden of iodine exceeds 30 millicuries, even as high as 400 millicuries. In the ACNM's resolution of September 24, 1991, the following statement appears:

> "To the contrary, scientific research and professional published data has shown that external radiation exposure to the public in this application is considerably below the acceptable limits....."

ACNM has informed me that the basis for this statement is a study performed by Doctor Herbert C. Allen, Jr., Nuclear Medicine Laboratories of Texas, 6411 South Main Street, Texas Medical Center, Houston, Texas. Doctor Allen has kindly furnished me with copies of abstracts of his work which are attached to this letter. Please note that the abstract relates exposures to occupational workers, not members of the public and to standards which existed prior to 10CFR20 revisions.

Without having seen the results of Doctor Allen's work I am not in a position of passing judgement on his work. However, it has been my experience that patients having been administered therapeutic quantities (greater than 30 millicuries) of iodine 131 pose a concern that warrants strict control and care.

I encourage NRC Staff to secure copies of and evaluate the work of Doctor Allen in this matter prior to making a final decision.

Further information and studies related to this matter should also be included. A source of such information and first hand experience would be major university hospitals involved in such work.

In conclusion, as submitted, with the release of patients who contain greater than 30 millicuries of iodine 131, I am personally opposed to the petition for rulemaking.

Thank you for the opportunity to comment on this petition for rulemaking.

Sincerely,

Kirksey E. Whatley

Kirksey E. Whatley, Director
Radioactive Materials Licensing
Division of Radiation Control
Bureau of Environmental & Health
Service Standards

KEW:psc

Attachment

(5)

AMERICAN COLLEGE OF NUCLEAR MEDICINE

OFFICE OF THE PRESIDENT

April 28, 1992

Kirksey E. Whatley
Radioactive Materials Licensing
Division of Radiation Control
Bureau of Environmental & Health Service Standards
434 Monroe Street
Montgomery, AL 36130-1701

Dear Mr. Whatley:

I am responding to your letter to Dr. Wetzel of April 7, Since the "Guard" has changed. I appreciate your support for the petition by the College to NRC concerning 10CFR 35.75, Release from Confinement.

With regard for the safety of the public in cases where Patients receiving more than 30 mCi I 131, I have watched this issue for forty years with interest as a Radiation Physicist and have wondered. However in the absence of data, This has been speculation. One of our members has been doing this for many years and has convinced me that the procedure is safe, even for Cancer Therapy. The key to this lies in the degree and effectiveness of confinement to the patient's home.

Dr. Herbert Allen has done over 600 cancer treatments under this regime with very careful monitoring and surveillance and reports no incidence of untoward exposure to the family or the public. By transmission of your letter and my response, I will ask Dr. Allen to share his experience with you.

Thank you for your support.

Best wishes,

Sincerely,

John U. Hidalgo, CMNP
President,
American College of Nuclear Medicine

1209 Lair Ave.
Metairie, LA 70003

(6)

NUCLEAR MEDICINE
Laboratories
OF TEXAS

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April 29, 1992

Kirksey E. Whatley
Radioactive Materials Licensing
Division of Radiation Control
Bureau of Environmental & Health Services Standards
434 Monroe Street
Montgomery, AL 36130-1701

Dear Director Whatley:

The current President of the American College of Nuclear Medicine, John U. Hidalgo, has referred your letter of April 7, 1992 to me for further amplification.

Since I will be out of the office for approximately one week, I am sending you the abstract of the paper we presented before the Society of Nuclear Medicine, Washington, D.C., June 19-22, 1990. In addition, we presented a similar paper before the Third Conference on Radiation Protection and Dosimetry, Orlando Florida Oct. 21-24, 1991.

Since I am leaving the office today, I have asked the secretary to enclose the 1990 abstract published in The Journal of Nuclear Medicine, Vol. 31, Number 5, May 1990, Proceedings of the 37th Annual Meeting, Washington, D.C. Upon my return to my office, I will be happy to supply any additional information.

We are in the process of submitting the paper for publication.

Thank you very much for your interest in the NRC Petition regarding 10 CFR 35.75.

Sincerely,

Herbert C Allen Jr. M.D. by MB

Herbert C. Allen, Jr. M.D.,FACNM
Historian -- AMERICAN COLLEGE OF NUCLEAR MEDICINE

cc: John U. Hidalgo, President,
Richard Wetzel, M.D., Past President
Thomas Johnson, Jr., Executive Director

HCA:mb

Enc.

HERBERT C. ALLEN, JR., M.D., F.A.C.N.M.
DIRECTOR

1990 Abstract Form for Scientific Papers, Scientific Exhibits and Works-in-Progress

The Society of Nuclear Medicine 37th Annual Meeting
Washington Convention Center—Washington, DC.
Tuesday, June 19 – Friday, June 22, 1990

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(7)

№ 16443

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430 NON-HOSPITALIZED THYROID CANCER PATIENTS TREATED WITH SINGLE DOSES 50-400 mCi, H.C. Allen, Jr., J.D. Zielinski. Nuclear Medicine Labs of Texas; Texas Medical Center; Houston, Tx.

A preliminary report on a prospective study beginning 35 years ago during which more than 600 thyroid cancer patients have been evaluated for: (1) Rads delivered to the thyroid gland and (2) determining the advisability of private office treatment followed by confinement in their home without exposing the family and general public to harmful radiation levels.

For 30 years, with official approval of the Texas State Department of Health (TRCA), 430 ambulatory patients were confined in their homes until the total body burden declined to < 30 mCi.

46 treated patients were studied with specific emphasis on determining the potential radiation hazard to household members and general public. Leak/wipes of pertinent household areas were assayed for radiation contamination. The entire house was surveyed during confinement and prior to release. No violation of regulations was found. Radiation exposure to family members met NRC/TRCA regs. Thyroid burden studies of family members attending ablated patients was determined.

Data indicated: (1) there was no health hazard to family members or general public when ambulatory non-hospitalized patients were treated with > 30 mCi and confined to their home; (2) outpatient treatment with home confinement has proven cost effective; (3) prevailing regulations are unnecessarily too restrictive and over-regulatory as currently being applied; and (4) this method of treatment should be recognized by the regulatory authority as a legitimate, safe and sound form of therapy for the patient's benefit.

List the name, address, & telephone number of the principal author who should receive all correspondence.

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Division or Dept. Nuclear Medicine

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For Scientific Papers: Abstracts must be received (not postmarked) by Thursday, January 11, 1990.
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Supplemental Data ⊕ (8)

430 NON-HOSPITALIZED THYROID CANCER PATIENTS TREATED WITH SINGLE DOSES 50-400 mCi I-131. H. C. Allen, Jr., J.D. Zielinski. Nuclear Medicine Lab. of Texas. Texas Medical Center, Houston, TX.

A preliminary report on a prospective study began 35 years ago (1953) concerning the treatment of thyroid cancer in over 600 patients.

570 patients received single large oral doses, ranging from 50 to 400 mCi, 83% received greater than 150 mCi. 89% of patients treated showed an absence of thyroid tissue after a single dose. 93% were followed annually at least 5 years; 26% at least 25 years. Pre- and post-ablation uptakes, EHL's, and weight of thyroid tissue were determined. Absorbed rads delivered to 73 patients selected at random receiving a mean dose of 189 mCi -- 78,258 rads (414 rads per mCi). The absorbed rads determination is the subject of a subsequent publication.

This paper conentrates on the feasibility and praticality of ambulatory patients with single doses of I-131 greater than 30 mCi and followed by home confinement until the total body burden is less than 30 mCi. 430 thyroid cancer patients have been treated with single doses I-131 > 30 mCi followed by home confinement until the total body burden < 30 mCi.

46 ambulatory patients were studied with specific emphasis on determining the potential radiation hazard to household members and general public. Film badges were placed inside the designated confinement area and throughout the remainder of the home. Household members (30) of 21 patients wore film badges during the patients' home confinement.

Mobile and stationery film badge monitors were routinely located throughout the "confinement" bedroom and bathroom, as well as the entire home. Radiation exposure did not exceed maximum permissible levels published in the TRCR (Regulations). Mannequin studies revealed that radiation received by an adjacent "bed fellow" also did not exceed the millirem exposure allowed occupational workers (per quarter). External radiation exposure to family members were 34.7% of that permitted by NRC/TRCR. Thyroid burden studies of family members attending the ablated patients revealed a mean level of 0.0064 uCi when the mean ablation dose was 190 mCi. Family members, therefore, received 16% of the maximum permissible dose allowed (0.04 uCi) occupational workers.

Permission for this prospective study of thyroid cancer with ablative doses greater than 30 mCi, not requiring hospitalization, was done with the full cooperation of the Texas Bureau of Radiation Control, Texas State Department of Health.

neglected. In the present work Monte Carlo codes were used to investigate the effect of topology of the CB and RM interface on the backscatter dose to the RM. Planar, cylindrical and spherical geometries were included. For the planar geometry, a maximum dose increase of 9 ± 1 (S.E.)% was obtained in the region within 12 mg/cm^2 from the interface due to a semi-infinite source of electrons with energy greater than 0.5 MeV. Averaged over the region of RM imbedding electron sources between two planar CB/RM interfaces 1000 microns apart, no dose enhancement was predicted for electron energies from 0.1 to 1.75 MeV. For the cylindrical interface with 500 micron radius of curvature, the maximum dose increase averaged over the whole cylinder due to an imbedded source of monoenergetic electrons was 12 ± 1 (S.E.)%. This occurred at 0.75 MeV. For the spherical interface with 500 micron radius of curvature, the maximum dose increase in the region within 20 microns (2.1 mg/cm^2) from the interface due to an imbedded source of monoenergetic electrons was as high as 21 ± 1 (S.E.)%. This occurred at about 0.5 MeV. The dose increase, averaged over the whole sphere, was 12 ± 0.6 (S.E.)%. This provides an estimate of the maximum dose enhancement to the RM due to electron backscatter.

No. 320

THREE-DIMENSIONAL DOSE COMPUTATION FOR HEPATIC MICROSPHERE THERAPY. P.L. Roberson, R.K. Ten Haken, D.L. McShan, P.E. McKeever, K.M. Pillai, W.D. Ensminger. University of Michigan Medical Center, Ann Arbor, MI.

Three-dimensional dose distributions have been developed for liver for the VX2 rabbit model treated with hepatic arterial administration of Y-90 glass microspheres (Y90 MS). Colored, plastic, nonradioactive spheres were administered by hepatic arterial injection in order to mimic the treatment deposition of Y90 MS. Sample blocks of treated liver were serially sectioned (200 um thickness), fixed and photographed showing the position of the microspheres. The slide photographs were projected on a vertically mounted digitizer to enter the sphere positions into the University of Michigan 3-D treatment planning system. A published point dose kernel for Y-90 (*) was used to perform dose calculations for each sphere. Doses were summed to produce 3-D dose distributions. Because the dimensions of the sampled sections were less then the range of the Y-90 beta particles, the dose to the sampled volume due to the surrounding tissue was estimated by placing sphere distributions representative of the sample in the surrounding tissue. Dose volume histograms were derived from the dose distribution. The minimum calculated dose to a representative volume is approximately one-half of the MIRD calculated (or average) dose. Significantly higher doses were calculated for small volumes due to clustering of the microspheres. Dose distributions and dose-volume histograms will be shown and compared to the MIRD-type dose calculations.

* Prestwich, WV, Nunes, J, Kwok, CS J Nucl Med 30:1036, 1989 and J Nucl Med 30:1739, 1989.

No. 321

QUANTITATION IN RADIOIODINE THERAPY OF METASTATIC THYROID CANCER: COMPARISON OF PROJECTED AND ACTUAL TUMOR ABSORBED DOSES. PB Zanzonico, JR Hurley, and DV Becker, New York Hospital-Cornell Medical Center, New York, NY.

In order to more rationally plan and monitor radioiodine (I131-iodide) therapy of metastatic differentiated thyroid cancer, we now perform serial measurements of tumor activity (as well as blood activity concentration and total body activity) following both tracer (~5 mCi) and therapy (>100 mCi) administrations and calculate the resulting tumor (as well as blood and total body) absorbed doses. Tumor activity is measured (±20%) using planar ("conjugate view") and SPECT imaging methods and tumor mass is calculated using the tumor dimensions on planar gamma camera images. Cumulated activity is calculated by numerical integration and absorbed dose is calculated as the sum of the mean beta-ray absorbed dose (assuming complete local absorption) and the mean total body photon absorbed dose ("g factor" method). For 8 metastases in 4 patients receiving 120 to 359 mCi I131-iodide (corresponding to a maximum "safe" absorbed dose of 200 rad to blood), the projected (from tracer) and the actual therapy individual tumor absorbed doses ranged from 2,400 to 85,000 rad and from 1,900 to 29,000 rad, respectively. In 7 of 8 tumors, the actual tumor absorbed dose was 38 to 73% (average: 53%) less than the projected tumor absorbed dose; in 1 site (in the neck and therefore possibly residual thyroid), it was 45% greater. Although the absolute absorbed doses are somewhat uncertain, due primarily to inaccuracies in tumor mass estimates, the projected and actual tumor absorbed doses should be similar. However, since acute radiation damage and resulting accelerated radioiodine turnover in tumor often follow large therapy administrations, an overstimation (based on the tracer) of the actual tumor absorbed dose is not unexpected, but should be systematically considered in rational radioiodine therapy of thyroid cancer.

No. 322

430 NON-HOSPITALIZED THYROID CANCER PATIENTS TREATED WITH SINGLE DOSES 50-400 mCi, H.C. Allen, Jr., J.D. Zielinski. Nuclear Medicine Labs of Texas; Texas Medical Center; Houston, Tx.

A preliminary report on a prospective study beginning 35 years ago during which more than 600 thyroid cancer patients have been evaluated for: (1) Rads delivered to the thyroid gland and (2) determining the advisability of private office treatment followed by confinement in their home without exposing the family and general public to harmful radiation levels.

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46 treated patients were studied with specific emphasis on determining the potential radiation hazard to household members and general public. Leak/wipes of pertinent household areas were assayed for radiation contamination. The entire house was surveyed during confinement and prior to release. No violation of regulations was found. Radiation exposure to family members met NRC/TRCA regs. Thyroid burden studies of family members attending ablated patients was determined.

Data indicated: (1) there was no health hazard to family members or general public when ambulatory non-hospitalized patients were treated with > 30 mCi and confined to their home; (2) outpatient treatment with home confinement has proven cost effective; (3) prevailing regulations are unnecessarily too restrictive and over-regulatory as currently being applied; and (4) this method of treatment should be recognized by the regulatory authority as a legitimate, safe and sound form of therapy for the patient's benefit.

Cardiovascular Basic III: Myocardial Perfusion and Metabolism

10:30-12:00 **Session 55** **Room 31**

Moderator: George A. Beller, MD
Comoderator: Randolph E. Patterson, MD

No. 323

QUANTITATIVE ISONITRILE IMAGING FOR RISK AREA DETERMINATION FOLLOWING TRANSIENT CORONARY OCCLUSION. J.D. Bergin, A.J. Sinusas, W.H. Smith, N.C. Edwards, D.D. Watson, H. Ruiz, and G.A. Beller. University of Virginia, Charlottesville, VA.

We have previously shown that Tc-99m labeled methoxy-isobutyl isonitrile (MIBI) delineates anatomic risk area (RA) in a model of myocardial infarction. However, redistribution (RD) of MIBI has been noted by some following transient coronary occlusion (OCC). To evaluate the

(17)

GREATER NEW YORK CHAPTER
HEALTH PHYSICS SOCIETY, INC.

May 8, 1992

DENNIS M. QUINN
Executive Secretary
(914) 736-8410
NY Power Authority
P.O. Box 215
Buchanan, NY 10511

Secretary of the Commission
U.S. NRC
Washington, D.C. 20555
Re: Docket Number PRM-35-10

Gentlemen,

On behalf of the Greater New York Chapter of the Health Physics Society I would like to submit the following comments regarding recent petition by the ACNM to amend the regulations relative to the confinement, safety instructions and precautions used for patients receiving radiopharmaceutical therapy in amounts exceeding 30 millicuries.

While we understand and sympatize with some arguments expressed by the ACNM, we strongly object the lack of control that the proposed approach would cause:
1) Radiation exposures of members to general public, present near these patients could easily exceed permissible limits - the NCRP Report No. 37, Table 2, 1973);
2) Contamination in areas of common use (Wiatrowski et al., "Radiocontamination in medical centers from diagnostic nuclear medicine procedures", 1984, Health Physics, 47, 297-298), exceeding regulatory levels would NOT be controlled;
3) Radwaste generated by these patients may not be trivial, depending on specifics of the procedure.

Basically, we find the current NRC regulation on the subject to be sound and practical as it provides adequate controls and flexibility.

Sincerely,
Jadwiga Strzelczyk
JadwigaStrzelczyk,
President, GNYCHPS

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Wesley G. Farnsley, M.D.
George H. Zenger, M.D.
P.O. Box 17097
Louisville, KY 40217
(502) 636-7251

Humana Hospital Audubon
Radiation Therapy
Nuclear Medicine

5 May 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing & Service Branch

RE: Docket #PRM-35-10

Gentlemen:

In regards to the petition submitted by the American College of Nuclear Medicine pertaining to 10 CFR Part 35 (Docket #PRM-35-10), I wish to comment.

I'm greatly surprised and dismayed that the American College of Nuclear Medicine would submit a proposal such as this. Thirty millicurie body burden would expose a visitor or family member to 5 MR per hour at bedside. 120 millicurie dose yields somewhat greater than 60 MR per hour at bedside.

I have been in Nuclear Medicine for over 30 years and practiced clinical medicine for 37 years. One cannot rely upon patients at home to carry out orders or instructions whether it be taking medication or keeping visitors out of the room or at a sufficient distance to avoid unnecessary radiation exposure. Furthermore, we have the risk of contamination of the bathroom, bed and floor in the patient's home. I see no way that a radiation safety officer would tolerate this in the hospital and certainly no way it would be tolerated in a patient's home devoid of any monitoring or being certain that instructions are carried out.

Therefore I wholeheartedly recommend that hospitalization be required for ambulatory patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries.

From the Federal Register, I note that the petitioner states that there are published scientific papers that attest to the safety of outpatient radiopharmaceutical therapy in doses of up to 400 millicuries of I-131. I'm sure they are relatively safe to the patient but not to those in close proximity to the patient.

Sincerely,

George H. Zenger

George H. Zenger, M.D.

GHZ/kb
cc: Vicki Jeffs - Cabinet for Human Resources
Commonwealth of Kentucky

FAIRFAX HOSPITAL
FAIRFAX HOSPITAL SYSTEM

3300 Gallows Road
Falls Church, Virginia 22046
703 698-3705
703 698-3394

Department of Medical Physics/Radiation Safety
James A. Deye, Ph.D, Director

(15)

5/4/92

TO: Secretary of the Commission, US NRC
ATTN: Docketing and Service Branch

FROM: James A. Deye, Ph.D., Radiation Safety Officer

re: Jan. 14, 1992 petition to allow patients to receive > 30 mCi of ^{131}I on an outpatient basis. **Docket No. PRM-35-10**

This is to express my disagreement that this petition is in the public's best interest. Though there may be reason to allow patient's receiving monoclonal therapy to be treated on an oupatient basis, it is not at all clear that this reasoning can be extended to "radiopharmaceutical therapy in doses of up to 400 millicuries of I-131 NaI" ! Data in our own and other hospitals, routinely demonstrate exposure rates above 10 mR/hr at one meter from 131-I NaI therapy patients and significant contamination around the patient's room. I am not aware of any evidence which indicates that these potential doses are inconsequential to the family members and general public. In a worse case senerio, the contamination and potential doses could be very high, if the patient were to leave the dosing facility an then vomit a large fraction of the therapy dose (100 mCi ?) in an area where some unaware member of the public may

have to deal with it. Such occurances are not that uncommon.

The data on monoclonal antibody therapy are not as clear and there may be some reason to handle this type of administered dose differently due to the difference in the metabolism and incorporation within the cells. However there can still be an appreciable fraction of the isotope which is not taken up and is therefore excreted. Since no data were presented with the published Federal Register notice, it is difficult to adequately access this situation.

As the petition is currently stated, it would require a significant reassessment of the NRC's regulations in many areas beyond 10CFR35 as they are based on risk estimates to the public. These would be far exceeded by the potential (almost probable) doses from a therapeutic 131-I NaI patient who is not cared for by well trained and monitored staff for the first few days after administration.

(14)

1670 Clermont Street
Denver, CO 80220

April 30, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Re: Petition for Rulemaking No. PRM-35-10, American College of Nuclear Medicine

Dear Sirs;

As a health physicist with some fourteen years' experience in medical and biomedical research-related health physics, I feel compelled to comment on the above petition for rulemaking. To release patients containing greater than 30 mCi of radioactive material to an environment without institutionally supervised formal radiation protection controls, including patients containing up to several hundred mCi of ^{131}I, one of the most radiotoxic beta/gamma emitters in use, is a truly amazing proposition. Considering only the obvious case of ^{131}I, such patients may be sources of gamma radiation that could exceed, by a factor of thirty or forty, the gamma dose rate at one meter that is allowable in an uncontrolled area "in an hour." Such patients might be excreting over a hundred mCi per day of ^{131}I immediately after dose administration, representing a daily excretion of more than one million times the allowable action level for ^{131}I in the thyroid of radiation workers, with such releases occurring in an environment occupied by members of the general public, including children.

The unrestricted release of patients containing up to 30 mCi of activity is already a point of embarassing philosophical inconsistency to those of us in the radiation safety field, who must daily quibble with radioactive materials users about wastes and contaminated areas that may contain only sub-microCurie amounts of licensed materials. To increase this limit, in effect, by a factor of ten or more, would make a patent mockery of the entire radiation safety programs of licensed institutions. If, in fact, untrained and unsupervised persons containing hundreds of milliCuries of highly radiotoxic material in unsealed form are not a threat to the health and welfare of the general public, then the NRC and Agreement State agencies should eliminate the vast majority of their byproduct materials licensing activities, and most persons in the health physics profession should forsake their current livelihoods and stop wasting public monies on the unnecessary control of harmless sources of radiation.

Sincerely,
Harry M. Cullings
Harry M. Cullings

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

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Marshall Brucer MD FACNM FABSNM
5335 N. Via Celeste Tucson, Arizona 85718 (602) 299-6288

(13)

April 23, 1992

Samuel J Shilk
Secretary of the Commission
Nuclear Regulatory Commission
Docketing & Service Branch, Docket #PRM-35-10
Washington DC 20555

Mr Secretary

This letter is in support of the resolution of the American College of Nuclear Medicine to delete the mandated hospitalization of patients undergoing radioiodine therapy with more than 30mCi (now, if you follow regulations, properly writtten 1.11GBq) for certain thyroid diseases.

The old dose limit provision was inserted into the old 1956 AEC regulations by the late Edith Quimby, a Columbia Ph D radiation physicist who ran AECs Subcommittee on Human Use. I knew most of the members of the Subhuman committee, and the MD members objected to its insertion; not because of the "dose" it established, but because no government committee should be allowed to practice medicine. Establishing a dose is the practice of medicine.

If you object that the NRCs rule did not "establish a dose" then survey the doses commonly given to ablate the thyroid, it is usually 1 GBq (or 29.9 mCi in your old fashioned language). Why? Because the patient is already being overcharged for the radioiodine and doesn't need to let the hospital to get in on the rape. Of course, some patients may need a second dose because of this stupid limit, but comming back is cheaper than a few days totally unnecessary hospitalization.

It is true that in the 1950s, even to 1975 when your group took over all the mistakes of the AEC, most committee members were scared stiff of radiation. But this frenzy has changed. Nuclear Medicine is now one of the most highly trained specialties, working in the most thoroughly researched science in history: radiobiology. We know that low dose radiation (e.g. nuclides in the diagnostic range) is hormetic, actually beneficial. An NRC (in the medical field) is no longer necessary. We no longer use health physicists to protect us, and our patients from radiation; we now hire "Radiation Regulatory Compliance Physicists" to protect us from NRC harassment.

If NRC won't do the honorable thing and disband completely (See my letter to NRC 10/26/89), I suggest that you give up your practice of medicine by rescinding the rule mandating hospitalization of patients who are not sick.

Copies: HCA,AMA

Marshall Brucer MD

ACNP
1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036
(202) 429-5120 Fax (202) 223-4579
SNM
American College of Nuclear Physicians
The Society of Nuclear Medicine

April 24, 1992

Samuel Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch (PRM-35-10)

Dear Secretary Chilk:

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) wish to formally respond to the American College of Nuclear Medicine (ACNM) petition docketed January 14, 1992.

The petitioner's first request proposed the deletion of 10 CFR Part 35.72(a)(2). This issue is already under consideration by the NRC according to a previous petition (docket number PRM-20-20). ACNP and SNM wrote in support of the previous petition on July 15, 1991. We still maintain that this action is necessary and strongly urge the NRC to resolve this issue by deleting Part 35.72(a)(2) immediately. In order to support regulation to ensure safety, we recommended substitution of NCRP no. 37 for 35.72 (a)(2).

The petitioner's second request addressed mandated hospitalization and confinement. ACNP and SNM believe that NRC regulation is silent on the issue of mandated hospitalization and that the real issue is adequate confinement. Our interpretation of NRC's regulations regarding confinement does not mandate hospitalization for patients receiving radioactive treatments. The regulations state that until the measured dose rate falls to acceptable levels, the patient must be under medical care, not necessarily hospital care. Nuclear medicine's and the NRC's objective is to ensure safety efficiently and effectively. The rationale for establishing an alternative protected environment for patients receiving very high doses is unclear, since there are unlikely to be economic benefits. In either case, a regulatory change should not be necessary.

In summary, ACNP and SNM urge NRC to expedite a resolution on the ACNM petition and its predecessor (PRM-20-20).

Sincerely,

Robert J. Lull, M.D.
President
American College of Nuclear Physicians

Leon S. Malmud, M.D.
President
Society of Nuclear Medicine

Beaumont®
William Beaumont Hospital Nuclear Medicine

Cheryl Culver, M.S.

(11)

April 20, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Docketing and Service Branch

SUBJECT: Comments Supporting Petition for Rulemaking - Docket No. PRM-35-10

The NRC should revise 10 CFR 35.75 (a) (2) to allow certain patients to be treated as outpatients instead of mandating hospitalization for patients receiving oral and IV radiopharmaceuticals in amounts greater than 30 millicuries. The regulation is unclear and unscientifically supported. "Confinement for medical care" could be interpreted beyond the scope of hospitalization to include confinement in a patient's home. Low energy gammas and betas pose no external safety hazard to the public in doses greater than 30 millicuries, yet no distinction is made for the type or energy of the radionuclide. Diagnostic doses should be clearly excluded from 10 CFR 35.75 (a) (2). Any confinement regulations for diagnostic doses should be carefully researched and specific to the physical characteristics of the radiopharmaceutical.

Temporary home confinement is in the best interest of patients who live alone and those requiring access to affordable medical care.

At a minimum, NRC should permit exceptions to hospital confinement on a case-by-case basis by order of the authorized physician (with concurrence of the Radiation Safety Officer and/or Radiation Safety Committee). Written instructions detailing precautions and terms of home confinement should be required and carefully reviewed with the patient and the patient's family and/or roommates prior to administration of therapy doses. This is the current practice for treatment of outpatients with radioiodine for hyperthyroidism. With the rising cost of health care more radionuclide therapy treatments should be offered on an outpatient basis.

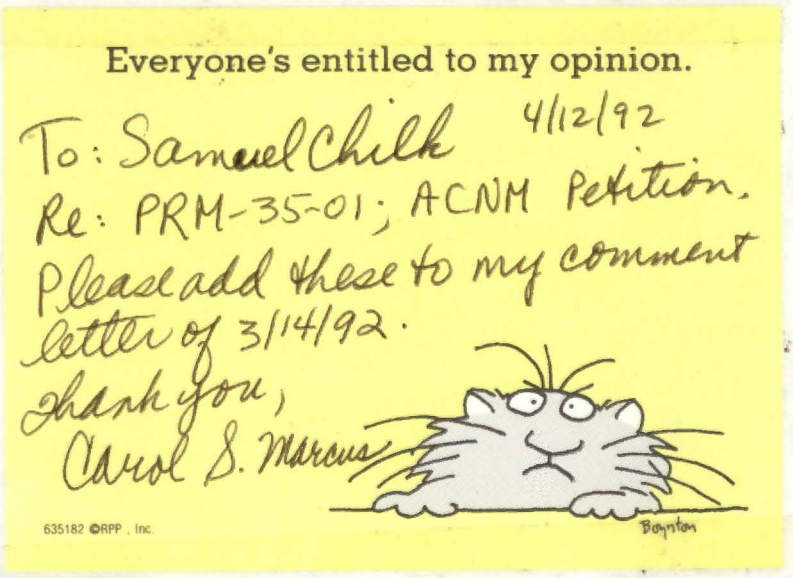
Sincerely,

Cheryl Culver

Cheryl Culver, M.S.
Certified Medical Physicist

CC/jrw

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769 (313) 551-4100 Fax No. (313) 551-0768



*Supplement to Comment Number 1 on Docket PRM-35-10

Contamination of the Home Environment by Patients Treated with Iodine-131: Initial Results

A. P. JACOBSON, PHD, P. A. PLATO, PHD, AND D. TOEROEK, MS

Abstract: We have employed twin sodium iodide radiation detectors to analyze iodine-131 transfer from thyroid patients to their families. Unlike previous studies of this problem, we measure thyroid radioiodine activity directly and are able to detect as little as 92 pCi of iodine 131 in adult thyroids. As in previous studies, we have also measured direct radiation exposures of family members with wristband thermoluminescent dosimeters. Thus far, we have studied seven families with 17 persons. Eleven of these are children under age 16. Direct radiation exposure of family persons from proximity of these radioactive patients ranged from 0.17 to 126 mR per day (natural background radiation amounts to approximately 0.35 mR per day). The maximum activity of iodine-131 in family thyroids ranged from less than 92 pCi to as high as 110,000 pCi and resulted in thyroid dose equivalents of 4 to 1330 mrem. Based on recent estimates of thyroid cancer, the latter dose equivalent could possibly double the risk of thyroid malignancy in children over what is expected normally. Such a risk implies the addition of 10 induced cases to the 10 naturally occurring cases per million people per year. (Am. J. Public Health 68:225–230, 1978)

Introduction

In 1966, there were an estimated 9.2 medical radioisotope administrations per thousand persons in the United States.[1] Klement[2] suggests from available data that the largest radiation exposure from these radiopharmaceuticals is due to administration of iodine-131. An independent survey of 400 hospitals in the United States found that about 700,000 thyroid diagnoses were performed with iodine-131 in 1974.[3] Sales data for radiopharmaceuticals indicate an increase of 25 per cent per year.[4] Klement[2] estimates that the thyroid dose equivalent per procedure is about 5 to 15 rem for a function test and 50 to 150 rem for a thyroid scan. These dose equivalents depend on the activity given, on the size of the thyroid gland, and on its relative iodine uptake.

These relatively large dose equivalents* received by patients are justifiable on a risk-benefit basis. However, because such patients are released from hospitals while they still contain radioactive materials, some attention should be given to the radiation exposures to nonpatients by this route. Previous studies suggest that radiation exposures of individual family members by radioactive patients are relatively small (see below). However, the large number of such exposures raises some questions about risks to health. The true extent of this problem at the moment is unknown, and much guesswork is applied to questions about health risks to a patient's family. Undue concern, as well as apathy with regard to radiation hazards, are considered detrimental to the interests of public health.

For protection of the public, the Nuclear Regulatory Commission requires that patients receiving radioactive materials remain hospitalized until their content of radioactivity is less than 30 mCi. However, the National Council on Radiation Protection and Measurements (NCRP) believes that since exposure rates and half lives of various radionuclides differ markedly, a more useful basis for release from hospitals is the degree of radiation exposure to other individuals with whom the patients associate.[5]

Radioactivity levels for discharge of radioiodine patients from hospitals with regard to the age of persons likely to be exposed are summarized in Table 1 for iodine-131 (reference 5, p. 18). The NCRP believes that there are unusual situations where it is necessary to send patients home in spite of their carrying a thyroid burden that could result in a dose equivalent to others in excess of 0.5 rem to the whole body. Such cases are permitted, as exceptions, provided that:

> "(1) No person under 45 years shall be permitted to receive more than 0.5 rem in a year.
> "(2) No person over 45 years shall be permitted to receive more than 5 rems in a year."

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*To distinguish between a "dose" of radiation and a "dose" of administered radioactivity, we use the term *dose equivalent* with units of rem for radiation dose where: dose equivalent (rem) = absorbed dose (rad) x quality factor (QF). Throughout this paper we assume QF = 1. Administered radioactivity has the units of millicuries (mCi).

TABLE 1—Radioactivity Levels for Discharge of Radioactive Patients from Hospitals.[5]

	No Restrictions*	Family Persons over 45 years	Family Persons under 45 years
Activity at Discharge	8 mCi	80 mCi	50 mCi
Exposure Rate at 1 meter	1.8 mR/hr	18 mR/hr	11 mR/hr

* Restrictions with regard to babies and young people are discussed in NCRP, 1970, pages 19 and 20.[5]

Previous studies offer some assistance in determining health risks to families of radioactive patients, but for the most part the studies are superficial. Harbert and Wells[6] have measured dose equivalents to immediate family members of patients treated with iodine-131 for thyroid carcinoma or thyroid ablation. Total whole body dose equivalents to relatives of 11 patients did not exceed 130 mrem as determined by film badges. Although patients were asked to judge the faithfulness with which relatives wore their film badges, results were not presented. Harbert and Wells concluded that the discharge limit of 30 mCi of iodine-131 in patients' thyroids is adequate to insure public safety.

Buchan and Brindle[7] estimated thyroid radioiodine activity in 39 subjects who were associated with patients treated for hyperthyroidism. On the basis of one measurement per subject, they conclude that, ". . . except where very young children are involved, precautions to minimize contamination should be abandoned." They further suggest that there need be no upper limit of iodine-131 activity for outpatients insofar as contamination hazards are concerned. We agree with the rebuttal of this study made by Chandra and Marshall: "More data are needed before deciding that present out-patient limits are satisfactory, unsatisfactory, or unduly restrictive."[8]

In further efforts to support their earlier conclusion, Buchan and Brindle[9] employed thermoluminescent dosimeters (TLDs) to determine dose equivalents to 54 subjects who were members of the households of outpatients undergoing iodine-131 therapy for thyrotoxicosis. These authors point out that their measurements of dose equivalents apply to the TLD powder and not to the whole body, but return to their earlier conclusion that precuations are unnecessary. We submit such conclusions are premature.

At best, we feel these studies leave many questions unasked and some unanswered. We are examining in detail the problem of environmental spread of iodine-131 by patients. This paper reports our initial findings on seven patients and their families.

Methods

Instrument construction and calibration have been described elsewhere.[10] Measurement of iodine-131 activity within a thyroid is made with a pair of 7.62 cm diameter by 4.45 cm thick NaI(Tl) crystals positioned above the neck between the clavicles and the thyroid cartilage. Each detector is sheathed in a 0.64 cm thick lead cylinder, which decreases the background count rate in the primary iodine-131 photopeak region (0.364 MeV) to 50 per cent of the unshielded count rate. Additional shadow shielding is effected by the placement of lead bricks under the detectors in the plane of the mounting baseplate. The detectors and their lead housings are mounted in aluminum collars which are connected to the steel elbows. We use a 256 channel pulse-height analyzer and punched paper tape to produce a permanent copy of each gamma-ray spectrum.

For children, the counting efficiency was between 3.3 and 4.0 per cent. For adults, the counting efficiency was between 3.0 and 3.3 per cent. For a 30 minute counting time, our calculated minimum detectable thyroid activity for iodine-131 is 92 pCi. We have dealt with uncertainties of dose equivalents calculated from our activity measurements thoroughly elsewhere.[10]

Procedure

Each patient in this study had at least one person under 18 years of age living in the household. Following the iodine-131 administration, the patients were advised to avoid close contact with young children, if possible, for three weeks. If the patients had young children to care for, they were told to avoid holding them close to the neck. It was explained to patients and their families that TLD wristbands must be worn for the length of the study (approximately two months), thyroid radioactivity measurements would be made on family members periodically, breath and saliva samples from the patient would be collected periodically, smear samples of the home would be collected, and an air sampling pump would be placed in the home for five days.

At least one member of each family was provided with thermoluminescent dosimeters (TLDs) placed in a wristband obtained from Eberline Instrument Corporation, Santa Fe, New Mexico. Each wristband contained 3 TLD-100 LiF chips manufactured by Harshaw Chemical Company, Solon, Ohio. Two chips for measuring whole body dose equivalents were behind 285 mg/cm^2 aluminum shielding and the third chip for skin dose equivalents was behind 10 mg/cm^2 plastic shielding. All chips were read on a Harshaw TLD Reader System, Model 2000, and the Emory University method for reading low-level doses was employed.[11]

Air pumps by WISA-International, Model 120, were used to move 4.5 liters per minute of air through filter cartridges made by Scott Aviation Company, South Haven, Michigan, and which contained carbon impregnated with TEDA (triethylenediamine) for the specific absorption of iodine in the air stream. Each filter cartridge was counted on a gamma-ray spectrometer.

Samples of the patients' breath were obtained by having

the patient breathe through a tube of KI-impregnated charcoal until an attached plastic bag was fully inflated. This way, each sample represented an equal volume (3791 cm^3) of breath. Charcoal to a depth of 5.5 cm was loaded into a polyethylene tube 3.5 cm diameter and 6.5 cm long. The cartridges are counted on the gamma-ray spectrometer, and data are reported as activity per cubic centimeter of air exhaled.

Saliva samplers consist of two cotton-tipped swabs in a pre-weighed glass vial with stopper. The patient thoroughly saturated the swabs with saliva, returned them to the vial, and replaced the stopper. Since these samples were usually of high activity, counting times were only 300 to 800 seconds. Data are reported as activity per gram of saliva.

Surfaces in the home were monitored for iodine-131 by wiping surfaces with Nu-Con Smears (Nu-Con Products Company, Hartford, CT). These cloth discs of 4.45 cm diameter were placed in labeled envelopes to prevent cross contamination. The smears were counted in a low-background beta counter (Beckman Low Beta II). Iodine-131 activity was confirmed by gamma-ray spectrometry. A count per minute reading was calculated for each smear, so that areas of high and low iodine-131 activities around the home could be identified.

Results

In this paper, we report only whole body and skin exposures and thyroid dose equivalents. Data on home smears, air, breath, and saliva samples will be furnished in a subsequent paper. Our data are presented in Table 2.

Figures 1 to 4 are selected samples from the seven families studied and present thyroid activity as a function of time. The error bars shown for each data point in these figures represent two standard deviations and include uncertainties in each count rate, the positioning of the radiation detectors, the uncertainties associated with the depth, mass, and location of a thyroid, and counting errors. The multiphasic shapes of most of these curves suggest repeated episodes of radioiodine transfer between patient and family. The accumulated thyroid dose equivalents to each subject were determined by integrating the area under each curve with a planimeter. The areas under curves in Figures 1 to 4 were then used in the following equation:

$$D = \frac{1.02 \times 10^{-2} \epsilon A}{m} \qquad \text{(Eq. 1)}$$

where

D = integrated dose equivalent to thyroid (mrem)
A = planimeter reading (pCi·day)
m = thyroid mass (g)

$$\epsilon = \text{effective energy} \left(\frac{\text{MeV·rem}}{\text{disintegration·rad}} \right)$$

= 0.23 for adults
= 0.21 for children

The thyroid mass of each adult (18+ years) was assumed to be 20 g.

The thyroid mass of each child to age 13 was calculated by the method of Kay[12]:

$$m = 1.63 + 0.04t + 0.0001t^2 \qquad \text{(Eq. 2)}$$

where
m = thyroid mass (g)
t = age (months)

TABLE 2—Data from Seven Families and 17 Subjects. (Figures for external direct exposure represent the mean of two TLD readings for whole body exposures and single TLD readings for skin exposures. We assume a quality factor of unity in determining dose equivalents.)

Family No. Iodine-131 Administered	Subject Status	Age (years)	Thyroid Mass (Grams)	Internal Thyroid Dose Equivalent ± 2σ (mrem)	External Direct Exposure	
					whole body (mrem)	skin (mrem)
1	Husband	25	20	124 ± 40	7.1	8.7
(8 mCi)	Son	8	6	210 ± 53	No TLD Issued	
	Son	6	5	276 ± 64	No TLD Issued	
2	Husband	64	20	7 ± 3	19.1	52.1
(150 mCi)	Son	24	20	12 ± 4	36.5	38.2
	Husband	40	20	11 ± 3	143.0	213.0
	Son	12	10	28 ± 5	No TLD Issued	
3	Son	11	9	15 ± 3	No TLD Issued	
(13.7 mCi)	Daughter	13	10	4 ± 2	11.3	24.8
	Daughter	8	6	9 ± 2	15.6	31.3
4	Daughter	13	10	15 ± 5	5.9	46.9
(19.7 mCi)	Daughter	11	9	47 ± 17	16.2	43.6
5	Daughter	11	9	8 ± 2	Lost Wristband	
(17.9 mCi)						
6	Husband	28	20	32 ± 11	156.6	204.0
(17.5 mCi)	Daughter	0.33	2	1330 ± 275	Too Young for Wristband	
7	Husband	27	20	30 ± 9	2220.0	3390.0
(13.5 mCi)	Son	3	3	612 ± 150	No TLD Issued	

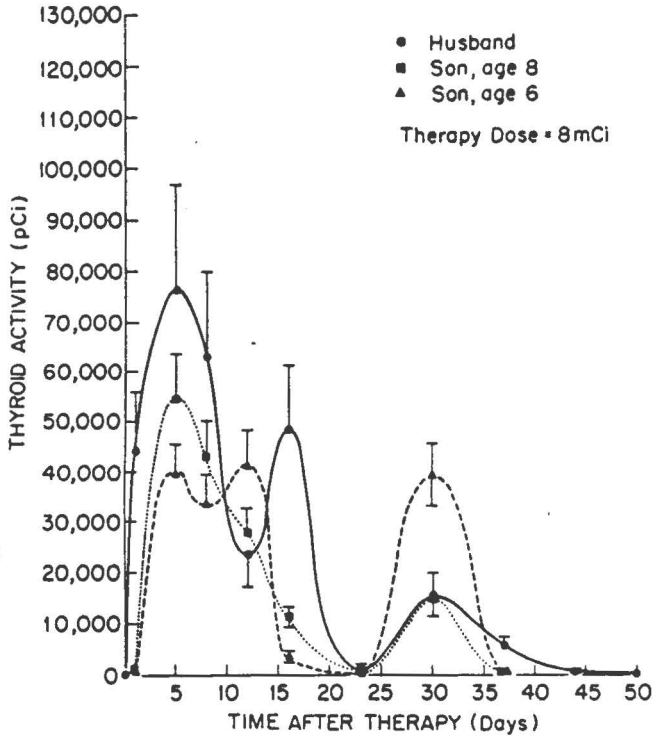

FIGURE 1—Family No. 1. Therapy Activity Administered Was 8 mCi.

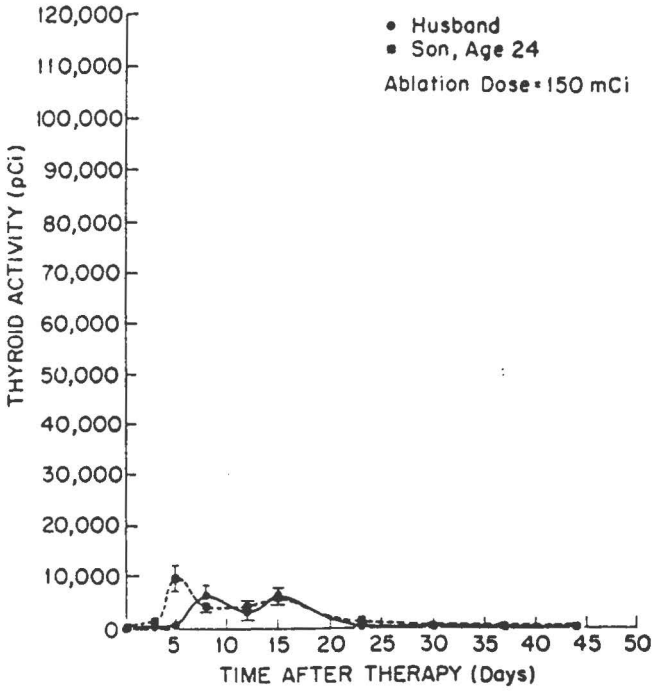

FIGURE 2—Family No. 2. Ablation Activity Administered Was 150 mCi.

Discussion

Our data tend to confirm the NCRP suggestion that the degree of direct radiation exposure of individuals from radioactive patients is a more useful basis for hospital discharge than the body content of radioactivity.[5] Inspection of Table 2 shows that, in a majority of cases, external exposures to individuals exceed internal thyroid dose equivalents quite substantially. In Family 7, the difference is a factor of 113 between skin and thyroid dose equivalents. Only two subjects had thyroid dose equivalents larger than external exposures to skin or whole body.

In spite of uncertainties of thyroid mass and depth of overlying tissues, the uncertainty associated with direct thyroid counting is low compared to alternative methods such as wristbands.[10] In some cases, use of wristband dosimeters is impractical or impossible. Some children refused to wear them (Families 1 and 3). Other dosimeters were lost or suffered severe tooth damage. The 4-month old daughter of Family 6 was too young to wear a dosimeter. However, her age presented no problem with direct thyroid counting which showed substantial uptake of iodine-131.

All individuals in proximity to radioiodine thyroid patients in this study received small but measurable dose equivalents to thyroid tissue. This raises questions about risks of radiogenic thyroid cancer from such doses. Although thyroid tissue seems to be relatively resistant to destruction by radiation, studies have demonstrated its susceptibility to neoplastic lesions of both benign and malignant types. To assess the degree of this risk, several considerations are important: 1) X rays are assumed[13] to be more effective in producing neoplastic change than iodine-131; 2) for X rays, the dose-response relation for thyroid neoplasms is known to be linear down to about 20 rem, less is known about this relation for radioiodine exposures and for dose equivalents below 20 rem[14]; most of the useful data for assessing risk was obtained from X ray exposures[15]; 4) for chromosomal damage, iodine-131 seems to be as effective as X rays.[16]

The last point is important since the mechanism for pathogenesis of thyroid cancer seems to involve chromosomal damage as a primary event. In rats, Furth[17] reports that the neoplastic process after irradiation progresses from cellular hyperplasia to benign neoplasia ultimately to malignant transformation. Further, studies of chromosomal damage seem to dominate the list of radiobiological effects from low and very low dose equivalents of radiation.[18] It is now quite certain that thyroid cancer was increased among those atomic bomb survivors who were proximally located to the hypocenter at the time of blast.[1] Among some 13,000 persons examined, 39 thyroid cancer cases were histologically confirmed. In addition, 386 individuals showed other thyroid abnormalities, a majority of which were nontoxic goitres. Thus, the risk for induction of thyroid cancer in the range of 25 to 200 rem is 1 to 2 cases per million Japanese per year per rem for males; for females, the risk is a factor of two higher than for males. For Marshall Islanders exposed to radioactive fallout in 1964, the group that received the highest dose equivalents consisted of children less than 10 years. This group showed 89.5 per cent with thyroid lesions in contrast to the absence of lesions in people of the same age in the less exposed and non-exposed groups. [redacted] it is estimated that the risk of thyroid nodularity approximates

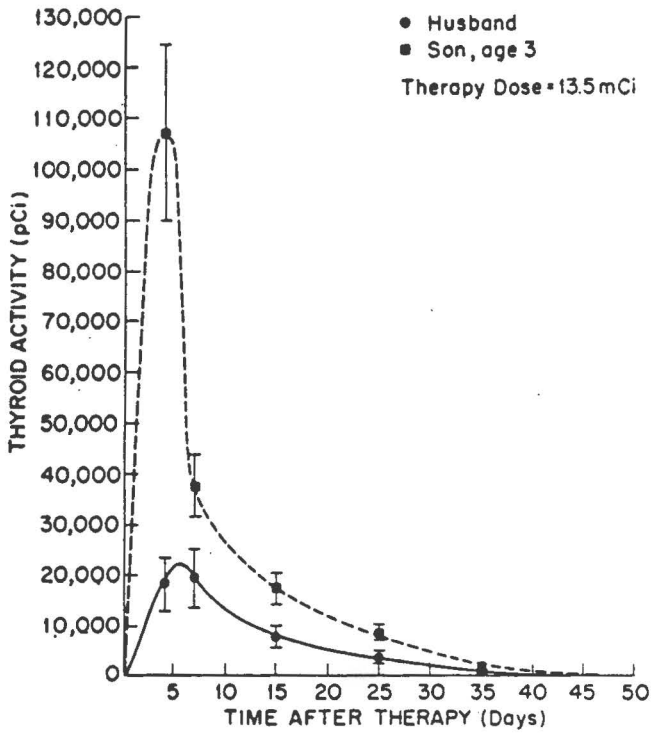

FIGURE 3—Family No. 6. Therapy Activity Administered Was 13.5 mCi.

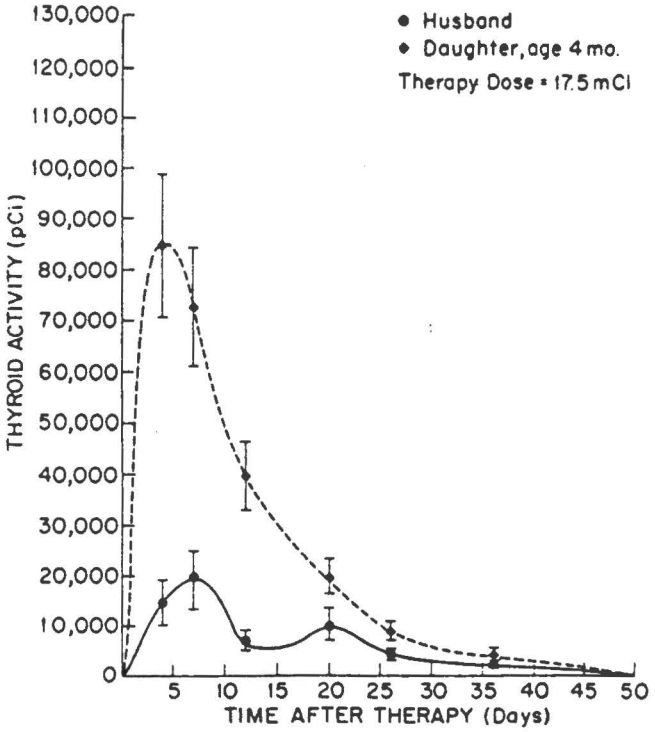

FIGURE 4—Family No. 7. Therapy Activity Administered Was 17.5 mCi.

50 cases per million persons per year per rem in the range between 500 to 1400 rems. The risk of thyroid carcinoma here was estimated at 10 cases per million per year per rem.[1]

In further attempts to estimate the degree of radiogenic thyroid cancer, the BEIR Committee[14] assumes a linear dose response in the low dose equivalent range and suggests the risk to be between 1.6 and 9.3 cases per million persons per year per rem. These figures apply to exposed children, followed for 25 to 35 years.

The absolute risk factors for thyroid cancer and thyroid nodularity as determined by the BEIR[14] and UNSCEAR[1] Committees attempt to estimate the extent of such risks on a "per rem" basis. To do this requires the guesswork of extrapolation downward from studies of persons exposed at high dose rates and high doses, usually above 20 to 50 rem. The uncertainties of extrapolation are emphasized when one considers thyroid carcinoma in Japanese atomic bomb casualties. For example, in Japan the prevalence rate for thyroid carcinoma was significantly higher among those exposed to 50 rem or more compared to those exposed to less than 50 rem. The 50+ rem group had a 41 per cent excess and the 1 to 49 rem group had only a 5 per cent excess over the non-exposed group.[19]

The annual incidence rate for thyroid cancer in the U.S. population under 40 years age is approximately 10 cases per million.[20] If the upper limit of the BEIR estimate for absolute thyroid cancer risk is used, one can calculate that the maximum dose equivalent for this study (1.33 rem, infant, Family 6, Table 2) could possibly double the risk of thyroid cancer. Equivalent exposures of older persons would constitute less risk due to the influence of age and increased thyroid size. If our data are used by others to estimate a per-rem risk of thyroid cancer, the internal thyroid dose equivalents of Table 2 should be added to the external direct exposure dose equivalents. However, we caution against such estimates since extrapolation is required.

Figures 1 through 4 are representative examples of thyroid activity of subjects throughout the time of this study, approximately two months. The number of peaks in the subjects of Figure 1 suggest multiple transfers of iodine-131 from the patient. Figure 4 for Family 7 shows no such repeats, although the son's thyroid activity exceeded 100,000 pCi. Transfer of iodine-131 between Patient 2 and her family was very small in spite of the large activity administered to the patient (Figure 2). This patient, however, was not released from the hospital until her thyroid activity was below 30 mCi.

It appears certain from our study of these subjects that, for spouses, there is a relation between thyroid activity and intimacy. Of the 12 husbands and wives questioned to the present time, none were willing to adjust living habits with their spouses because of the radiation therapy. Most, however, are concerned for their children and are willing to listen to suggestions which minimize exposure to their children. The two principal factors are proximity between patient and children and the relatively high radioiodine activity of body fluids. Surveys of the home are showing interesting trends. Some surfaces are about a factor of two higher than background beta activity. Bathroom fixtures, patient's toothbrushes, and bed linens were all about five to 13 times back-

ground levels. Consistently, the telephone mouthpiece was the surface highest in beta activity: 13 to 300 times background. Saliva activities were high during our study period of two months.

We expect to discuss the relation between thyroid activity and family behavior in a subsequent paper. However, some interesting data are beginning to appear. For example, the several peaks in Figure 1 are attributed to repeated episodes of closeness. Patient No. 6 was careful not to hold, feed, or bathe the child unless necessary. When the husband was away, the patient did attend the child who was always home with the patient. This necessary proximity between patient and child could account for the child's high thyroid dose equivalent. The relatively large thyroid dose equivalent to the child of patient No. 7 likely is due to her not following any special precautions. She did refrain from mouth contact with the son or his food. This patient frequently held the child very closely. Unfortunately the child would not wear a wristband dosimeter. Additionally, this family spent two weeks on vacation during the study. Confinement in a closed automobile may account for the relatively high thyroid dose and the high wristband readings of the spouse. From Figure 4 it appears that most of the radioiodine transfer occurred soon after treatment with imperceptible or no transfers later.

Patients Nos. 2, 4, and 5 kept contact with family minimal even to the extent that the children were rarely indoors. Inspection of Table 2 shows this behavior to be relatively successful in keeping internal exposures as well as external exposures low. It is interesting that exposure rates and transfer to thyroid were kept small in Family 2 in spite of a very large administration of radioiodine. This is evidence of our belief that such transfers and exposures can be kept minimal by determining the most significant routes of transfer and by careful patient briefing before release by the physician. Patient No. 3 employed usual precautions given her by the attending physicians. She rarely touched the children and attempted to remain at one meter distance from them whenever possible. The relatively low exposure rates and thyroid dose equivalents seem to reflect this precautionary behavior.

Conclusions

Our analyses of thyroid doses to patients' children and the associated risk of thyroid disease lead us to conclude such risk is small (a maximum of 10 induced cases in addition to 10 natural cases per million people per year) even if the upper limit of the BEIR estimate for absolute thyroid cancer is used. However, current philosophy of radiation protection suggests that all unwarranted radiation exposures be eliminated. To that end, we are beginning to identify the significant routes of radioiodine transfer between patient and family and expect to be able to suggest methods to reduce such transfers without unreasonable changes in family behavior patterns and certainly without requiring longer hospitalization than currently practiced.

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Radiation Safety Considerations for Post-Iodine-131 Hyperthyroid Therapy

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The purpose of this study was to develop guidelines based on patient measurements as to when iodine-131- (^{131}I) treated hyperthyroid patients may resume close personal contact. External exposure rates were measured on 59 patients using an ionization survey meter in the upright position. The initial measurement was recorded within 20 min post-dose administration at one meter. Exposure rates were measured 2–11 days post-dose administration at 1, 0.6, and 0.3 meters from the patient's thyroid. In the administered dose range of 3 to less than 12 mCi of ^{131}I, all 40 patients measured ≤ 2.0 mR/hr at one meter on Day 0, and 25 patients (25/29) were ≤2.0 mR/hr at 0.6 meter on Days 2–4. Guidelines can be prepared based on the administered dose that are rational and in conformity with existing radiologic health standards.

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Radioactive iodine therapy (^{131}I) is the treatment of choice for most adult patients with Graves' disease (*1*). The ^{131}I treatment dose (up to 30 mCi) is almost always given on an outpatient basis, and patients continue with their daily routine. While the radioactive iodine is indicated for these patients, there are precautions patients may take to avoid radiation exposure to their families and to other people with whom they come into contact.

Following administration of therapeutic doses, contamination from excretion of radioiodine in urine, perspiration, and saliva can be associated with internal accumulation of radioiodine by family members or those who come in contact with the patient (*2*). Patients carefully instructed in personal hygiene, eating habits, and contamination control can minimize the internal radiation exposure to others (*3*).

The ^{131}I present in the patient also poses an external source of radiation exposure to individuals who come into close contact with the patient. The external radiation exposure can be minimized by reducing the duration of time spent in close proximity to others and by increasing the distance. Previous studies suggest that the external exposures often exceed the internal thyroid dose equivalent in family members of therapy patients (*3,4*).

Recommendations for minimizing the external exposure were published in NCRP Report #37 in 1970 (*5*). The report recommended that children and persons under 45 yr of age avoid being in the same room or at a distance of less than 2.7 meters for more than a few minutes from a patient who had received therapeutic doses of ^{131}I, until the measured exposure rate fell below 1.8 mR/hr at 1 meter. Since it is impractical, in most cases, to monitor a patient's external exposure rates, physicians may base recommendations on other published guidelines for resuming close contact. The Society of Nuclear Medicine recommends that the treated patient sleep alone for the first few days after the treatment (up to 30 mCi ^{131}I) (*6*). The Society suggests that if caring for a baby, the patient should minimize the amount of time spent in close proximity with the infant during the first two days after treatment. It also recommends that the patient try to minimize the time spent with pregnant women and young children for 2–5 days after treatment. In another published guidebook for thyroid patients, the patient is encouraged to have someone else care for their infant for 2 wk after having received radioiodine therapy, if possible (*7*). It suggests that patients avoid contact with pregnant women at home and at the workplace.

This study was, therefore, undertaken to derive more specific guidelines as to when ^{131}I-treated hyperthyroid patients may resume close contact with their children, spouses, and co-workers post-therapy.

MATERIALS AND METHODS

Fifty-nine patients treated with ^{131}I for hyperthyroidism (53 with Graves' disease and 6 with Plummer's disease) volunteered to participate in this study. The ages ranged from 27–83 yr with a mean value of 47.7. Forty-four of the patients were females and 15 were males. All patients had ^{131}I thyroid uptake measured prior to treatment. All patients had external exposure rates measured at one meter initially within 20 min post-therapy dose administration (PDA). With the patient sitting, the exposure rate at one meter from the patient's waist up to their neck was measured. The maximum exposure rate

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was recorded for each patient. All patients were asked to return three times following their ^{131}I therapy dose. Whenever possible, the time intervals were scheduled at 3, 7, and 10 days PDA. To accommodate weekends and patient's convenience, however, the time intervals were extended to 2–4 days, 5–7 days, and 8–11 days. The date and time of the return visits were recorded on an appointment card and the patients were asked to call and reschedule their appointments if necessary. No attempt was made to call the "no show" patients. At each return appointment, the patients' external exposure rates were measured at distances of 1 meter, 0.6 meter, and 0.3 meter from their thyroid gland. The patients sat and held a meter stick parallel to the floor with the end placed midway between their cricoid cartilage and the suprasternal notch for each measurement.

The ionization survey meter (Victoreen 470A, Cleveland, OH) was calibrated semi-annually on two points of each scale using a calibrated cesium-137 (^{137}Cs) source, traceable to the National Bureau of Standards (accuracy ± 3%) (8). The energy response of the meter is 0.97 for ^{131}I and 0.96 for ^{137}Cs.

CRITERIA FOR RESTRICTING CONTACT

NCRP Report No. 37 (5) states that 1.8 mR/hr is the initial exposure rate, which results in a total integrated exposure of 0.5 R at 1 meter during complete decay of ^{131}I. The recommended maximum permissible dose equivalent for persons not occupationally exposed is 500 mrem per year. The report recommended that patients measuring less than 1.8 mR/hr at 1 meter be released from hospital care with no restrictions.

The Nuclear Regulatory Commission describes an unrestricted area as one in which the radiation exposure to an individual is less than 2 mrems in any one hour (9). The Nuclear Regulatory Commission states that a licensee may authorize release of a patient containing radiopharmaceuticals if the measured dose rate is less than 5 mrem/hr at a distance of one meter. (10). The licensee must provide the patient with radiation safety guidance to minimize radiation dose to household members and the public (11). On the basis of these references, the radiation exposure level of less than 2 mR/hr was selected as our criterion for resuming contact.

Statistical Analysis

The results are presented as mean ± standard error of the mean. Linear regressions were calculated by the least-square's method. Statistical significance was determined by applying the Student's t-test. A p value < 0.05 was considered statistically significant.

RESULTS

Positive correlation between exposure rate and percent thyroid uptake was significant only for the initial (within 20 min PDA) measurement at one meter ($r = 0.50$, $n = 59$, $p < 0.001$). Significant positive correlations between dose administered and exposure rate were found throughout the series of measurements.

The initial exposure rates measured at 1 meter within 20 min PDA are shown in Figure 1A. All patients receiving less than 12 mCi (40 of 59) had initial exposure rates ≤ 2 mR/hr at one meter. Of the patients receiving a dose ≥ 12 mCi (19 of 59), all but one had

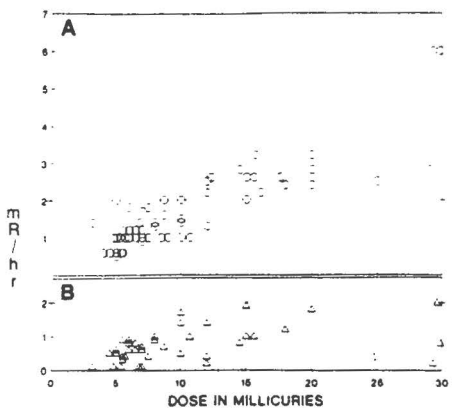

FIGURE 1
Exposure rate versus administered dose of ^{131}I at one meter. The criterion for restricting contact, 2 mR/hr, is represented by the dotted line. (A) Within 20 min PDA, circles, ($r = 0.86$, $p < 0.001$, $n = 59$, slope = 0.14, intercept = 0.22). (B) 2–4 days PDA, triangles, ($r = 0.48$, $p < 0.001$, $n = 41$, slope = 0.04, intercept = 0.37).

an initial exposure rate ≥ 2 mR/hr at one meter. The subsequent exposure rates measured at 2–11 days PDA were, therefore, placed in two groups (Table 1): Group L (low dose) for the patients receiving 3 to less than 12 mCi and Group H (high dose) for those who received 12–30 mCi of ^{131}I.

Patient exposure rates at one meter measured 2–4 days PDA are shown in Figure 1B. Forty of 41 patients had exposure rates ≤ 2 mR/hr at one meter.

Patient exposure rates at 0.6 meter measured 2–4 days, 5–7 days, and 8–11 days PDA are shown in Figure 2 (A, B, C, respectively). For Group L patients, the average exposure of 29 patients (29/41) was 1.6 ± 0.6 mR/hr (range 0.7–3.4) at 2–4 days PDA. Seventy-nine percent of the patients (25/29) had exposure rates ≤2 mR/hr (Fig. 2A). For Group H patients, the average exposure of 12 patients (12/41) was 2.8 ± 1.6 mR/hr (range 0.9 – 6.0) at 2–4 days PDA. Forty-two percent of the patients (5/12) recorded readings ≤ 2 mR/hr (Fig. 2A). At 5–7 days PDA, the average exposure of 11 patients (11/31) was 1.8 ± 0.9 mR/hr (range 0.30–3.80). Seventy-two percent of patients (8/11) were ≤ 2 mR/hr (Fig. 2B). At 8–11 days PDA, the average exposure of 6 patients (6/15) was 1.3 ± 0.4 mR/hr. All patients (6/6) were less than 2 mR/hr at 0.6 meter (Fig. 2C).

Patient exposure rates at 0.3 meter measured 2–4 days, 5–7 days, and 8–11 days PDA are shown in Figure 3 (A, B, C, respectively). For Group L patients, the average exposure of 29 patients (29/41) was 5.5 ± 2.5 mR/hr (range 2.1–15.0) at 2–4 days PDA (Fig. 3A). The average exposure of 22 patients (22/33) was 3.4 ± 1.7 mR/hr (range 1.2 – 9.3) at 5–7 days PDA. Eighteen percent of the patients (4/22) were ≤ 2 mR/hr (Fig. 3B). At 8–11 days PDA, the average exposure of nine

TABLE 1
Measured External Exposure Rates (mR/hr)*

Distance days	0 day	2–4 days	5–7 days	8–11 days
Group L (3 to <12 mCi)				
1.0 m	1.2 ± 0.4	0.6 ± 0.4	0.4 ± 0.2	
0.6 m		1.6 ± 0.6	1.0 ± 0.6	0.8 ± 0.5
0.3 m		5.5 ± 2.5	3.4 ± 1.7	2.7 ± 1.8
N	40	29	22	9
Group H (12–30 mCi)				
1.0 m	2.9 ± 1.2	1.1 ± 0.7	0.7 ± 0.4	
0.6 m		2.8 ± 1.6	1.8 ± 0.9	1.3 ± 0.4
0.3 m		8.9 ± 5.1	6.1 ± 2.6	4.4 ± 1.5
N	19	12	11	6

* Mean mR/hr ± s.d.

patients (9/15) was 2.7 ± 1.8 mR/hr (range 0.2–6.8). Twenty-two percent of patients (2/9) were ≤ 2 mR/hr (Fig. 3C).

For Group H patients, the average exposure of 12 patients (12/41) was 8.9 ± 5.1 mR/hr (range 1.3–18.0) at 2–4 days PDA (Fig. 3A). The average exposure of 11 patients (11/33) was 6.1 ± 3.6 mR/hr (range 1.0–13.0) at 5–7 days PDA. One of the patients (1/11) was ≤ 2 mR/hr (Fig. 3B). At 8–11 days PDA, the average exposure of six patients (6/15) was 4.4 ± 1.5 mR/hr (range 2.6–6.0) (Fig. 3C).

DISCUSSION

There is no evidence suggesting that small amounts of radiation from ^{131}I-treated patients cause any problem to others; nonetheless, guidelines developed from the reported data (when properly applied) could reduce unnecessary radiation exposure to others. The groups of people at greatest risk from the external radiation exposure to ^{131}I-treated hyperthyroid patients are embryos, fetuses, infants, and children. The younger the child, the greater the sensitivity to ionizing radiation

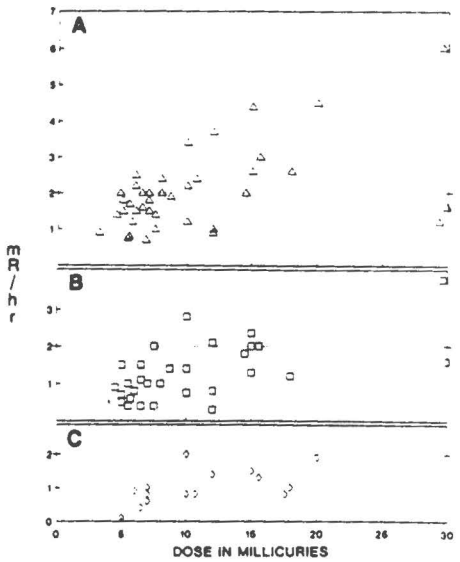

FIGURE 2
Exposure rate versus administered dose of ^{131}I at 0.6 meter. The criterion for restricting contact, 2 mR/hr, is represented by the dotted line. (A) 2–4 days PDA, triangles ($r = 0.51$, $p < 0.001$, $n = 41$, slope = 0.08, intercept = 1.14). (B) 5–7 days PDA, squares ($r = 0.64$, $p < 0.001$, $n = 33$, slope = 0.08, intercept = 0.44). (C) 8–11 days PDA, diamonds ($r = 0.57$, $p < 0.05$, $n = 15$, slope = 0.06, intercept = 0.34).

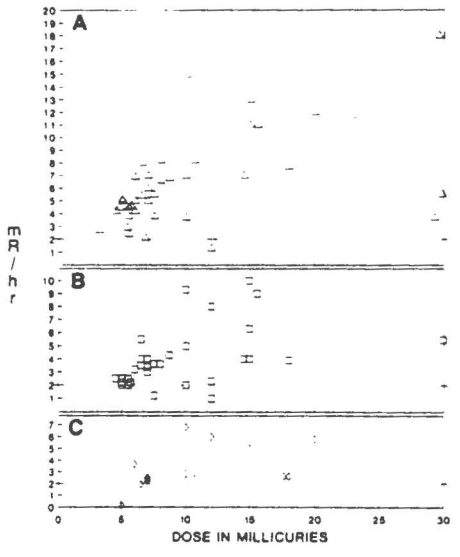

FIGURE 3
Exposure rate versus administered dose of ^{131}I at 0.3 meter. The criterion for restricting contact, 2 mR/hr, is represented by the dotted line. (A) 2–4 days PDA, triangles ($r = 0.47$, $p < 0.01$, $n = 41$, slope = 0.25, intercept = 3.89). (B) 5–7 days PDA, squares ($r = 0.62$, $p < 0.001$, $n = 33$, slope = 0.27, intercept = 1.48). (C) 8–11 days PDA, diamonds ($r = 0.47$, $p < 0.051$, $n = 15$, slope = 0.06, intercept = 1.47).

TABLE 2
Suggested Guidelines for Resuming Close Contact Post-Iodine-131 Hyperthyroid Therapy

	0.3 meter		0.6 meter		1 meter	
Days (PDA)	<12 mCi	≥12 mCi	<12 mCi	≥12 mCi	<12 mCi	≥12 mCi
0–1	Restrict amount of time	Restrict amount of time	Some restrictions for contact with small children and pregnant women	Restrict amount of time	No restrictions	Some restrictions for contact with small children and pregnant women
2–4	Restrict amount of time	Restrict amount of time	No restrictions	Some restrictions for contact with small children and pregnant women	No restrictions	No restrictions
5–7	Restrict amount of time	Restrict amount of time	No restrictions	No restrictions	No restrictions	No restrictions
8–11	Some restrictions for contact with small children and pregnant women	Restrict amount of time	No restrictions	No restrictions	No restrictions	No restrictions

(*12*). A group of 10,902 Jewish children whose scalps were irradiated for treatment of tinea capitis were reported to have a sixfold increase in incidence of thyroid cancer even though the average dose to the thyroid was estimated to be 6.5 rads. The risk of developing childhood cancer and leukemia from in utero exposure to low-dose radiation is estimated to be 250 cases of leukemia and 300 cases of fatal cancer per million fetuses exposed per rad. The estimated risk of induction of leukemia in a young adult (age 20) is 100 times less: 2.5 cases per million persons per rad. The NCRP (*14*) recommends that family members of a radioactive patient receive less than 0.5 rem in any one year; and that fertile women with respect to the fetus receive less than 0.5 rem in the gestation period. Using the maximum external dose rates measured at 0.3 meters from all patients at 2–4 days, 5–7 days, and 8–11 days PDA (18 mR/hr, 10 mR/hr, and 7 mR/hr, respectively) and estimating the exposure rate from 30 mCi of activity at 0.3 meter for Days 0 and 1 PDA, a person continuously exposed (24 h/day for 11 days) at 0.3 meters would receive 6.0 rads. A person exposed to these dose rates for 2 hr per day would receive 0.5 rads in 11 days.

TABLE 3
Distance Zones Common to Americans

Zone	Description	Distance range
Intimate distance	Close phase (lovemaking, comforting, protecting)	0–0.15 meter
	Far phase (not used by Americans in public)	0.15–0.46 meter
Personal distance	Close phase (proximity used between husbands and wives)	0.46–0.76 meter
	Far phase (arms length)	0.76–1.22 meters
Social distance	Close phase (personal business, social gatherings)	1.22–2.13 meters
	Far phase (formal business)	2.13–3.66 meters

Guidelines for when patients may resume contact to within certain distances are shown in Table 2. The criterion for removing restrictions is when the average exposure rate measures 2 mR/hr at that distance. A person continuously exposed to 2 mrem/hr (i.e., 24 hr/day) for 10 days would have a cumulative dose of 0.48 rem, which is less than the 0.5 rem recommended as the dose limit for the general public. Average exposure rates between 2 mR/hr and 3 mR/hr were considered borderline, when applied to estimation of adult radiation risks.

To make practical use of this data as presented, one should understand the daily pattern of distances separating two persons. Anthropologists have described distinct distances human beings use in social situations or in work environments (Table 3) (*15*). The results obtained at one meter, therefore, provide the basis for conservative recommendations for when a patient may return to work or resume normal social interactions.

In the context of more personal space at 0.6–1 meter, the results provide guidance for patients who are caring for children and infants: whether to sleep alone and for how long; and how long to avoid close personal contact with pregnant women.

Close contact to within 0.3 meter almost always involves physical contact. Proximity to the thyroid is a

consideration here. An adult patient holding an infant on their lap may be guided by recommendations for contact at 0.6 meter, as opposed to a patient holding an infant near their shoulder. A patient embracing a pregnant woman may have a brief proximity of 0.5–0.6 meter between their thyroid and the fetus.

Other radiation safety considerations are contamination resulting from radioiodine excreted in urine, perspiration, saliva, and breath of the patient and radiation dose to the thyroid gland, especially the dose effect on fetal and infant thyroid from internal uptake of radioiodine from the patient. Patients should be carefully instructed to prevent significant transfer and uptake of radioiodine by others (*16*). A woman receiving any dose of ^{131}I (sodium iodide) should be instructed not to resume breast feeding for a period of at least 8 wk (*17*). Prior to resuming nursing, a patient treated with ^{131}I for hyperthyroidism should have the breast milk activity measured to ensure that only background activity is present.

ACKNOWLEDGMENTS

The authors thank Nena Collier, Maureen Rotarius, and Nancy Sawyer for their valuable help in preparing this manuscript.

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The Mercy Hospital of Pittsburgh
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412-232-

Mercy Hospital

April 22, 1992

(10)

The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

Re: Docket No. PRM-35-10

Sir,

Regarding the petition for rulemaking filed by the American College of Nuclear Medicine (ACNM) in treating patients with doses of I-131 in excess of 30 millicuries on an outpatient basis, we have several concerns. While treating patients on an outpatient basis will be cost effective, it would have the potential for creating serious radiation hazard to the general public. Our concerns and comments are as follows:

1. Patient Vomitus

After a dose of I-131 is administered to a patient orally, there does exist a possibility that within the next two hours following the administration of the dose the patient may vomit. Under such circumstances, the vomit still contains a significant fraction of the administered I-131 dose. If the patient is immediately discharged following the administration of the dose, such vomitus could cause serious contamination of the property and persons surrounding the patient at the time. In view of this possibility, we would like to suggest that if the patient is treated on an outpatient basis, the patient be kept for observation in the Nuclear Medicine Department for at least two hours following administration to allow sufficient time for the I-131 dose to be absorbed from the gastrointestinal system before being discharged from the Nuclear Medicine Department.

2. Use of Personal Items by the Patient

We have seen from our experience that patients treated with doses exceeding 30 millicuries create varying amounts of radioactive contamination in the private rooms prepared for them in the hospital. The amounts of radioactive contamination vary depending on such factors as administered dose, duration of stay, and personal habits. Radioactive contamination can be present on any surfaces which the patient may come in contact with, i.e., linens and towels, fixtures and switches, appliances, floor, telephone, etc. as well as

any surfaces which may come in contact with the patients body fluids, i.e., toilet, bath tub, and sink. This contamination can vary from quite mild to very serious. Unless some type of restrictions are placed on the outpatient to limit their contact with other people, as well as to confine them to prevent the spread of contamination, we feel we will be creating a considerable hazard of radioactive contamination to the general public and especially those people who will come in close contact with the patient.

3. Emergency Surgery or Death of the Radioactive Patient

If a patient who has received a high dose of I-131 on an outpatient basis dies or is involved in a fatal accident or needs emergency surgery, there must be a system required by regulations to warn first responders and health care personnel and funeral homes of the potential radiation hazard if proper precautions are not taken in treating the patient.

We feel the existing rules limiting the treatment of patients with I-131 doses in excess of 30 millicuries are adequate and do not require any change. In view of the current radiation protection philosophy as reflected in the latest revision of Title 10 of the Code of Federal Regulations, Part 20, which reduces the dose limits to the general public, the proposal by the ACNM is contrary to this philosophy.

Sincerely yours,

Jagdish P. Bhatnagar, Sc.D

Jagdish P. Bhatnagar, Sc.D.
Radiation Safety Officer

and Jeffrey M. Gluckson
Assistant Radiation Safety Officer

Mercy Hospital, Pittsburgh, PA

NRC2.txt

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Radiation Protection
P.O. Box 27687 • Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

Dayne H. Brown, Director
Telephone 919/733-4283

9

April 22, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington DC 20555

RE: Docket No. PRM-35-10

Dear Commissioners:

The petition before the Commission that requests radioactive patients be allowed outpatient treatment regardless of the quantity of radioactivity administered should be denied. The current limit of 30 millicuries may unnecessarily require the hospitalization of certain patients, and it may be preferable to repeal it, but some provision must remain for guaranteeing the safety of the public.

Patients administered therapeutic quantities of radiopharmaceuticals can present a radiation hazard to their family members, coworkers and other persons they encounter. For example a typical patient being treated for thyroid cancer with iodine-131 will have associated radiation levels of 10 to 50 mrem/hr at one meter following treatment. The associated radioactive contamination of everyday items like telephones, bathrooms, dishes, bed linens and furniture will typically be in the tens of thousands of dpm. These patients are often otherwise healthy, and if not for the current restrictions could continue normal activities, including returning to work, following treatment. Releasing such patients with the expectation that they will go home and lock themselves in a room for two or three days with limited contact with family and friends is not realistic.

The 30 millicurie limit is indeed arbitrary in that it has been generically applied to all radiopharmaceuticals without regard to their physical or metabolic characteristics. With the advent of

new procedures like radiolabelling of monoclonal antibodies, consideration needs to be given to the suitability of the current limit. Allowing for case by case institutional review in accordance with approved procedures and criteria may be an alternative.

However, with regard to the petitioner's statement that patients receiving 400 millicuries of iodine-131 can be safely treated as outpatients, I cannot imagine a situation where it would be suitable to release such a patient immediately following administration of the radioactivity. Someone standing within 30 centimeters of the patient for 10 minutes would receive 100 mrem (the allowable dose for a member of the public) from the external gamma exposure alone. Depending upon the biological retention of the radiopharmaceutical and the route(s) of excretion, the internal dose resulting from inhaled iodine-131 could also be very significant for members of the patient's household.

Sincerely,

Allen Mabry,
Health Physics Supervisor

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April 22, 1992

8

Mr. Samuel J. Chilk
Secretary of the Commission USNRC
Washington, DC 20555

ATTENTION: DOCKETING AND SERVICE BRANCH P.R.M.-35-01

Dear Mr. Chilk:

I am writing in response to the publication in the Federal register dealing with a petitioner's request that 10 CFR 35.72 (a) (2) be deleted. The petitioner representing the American College of Nuclear Medicine has presented this issue to the House of Delegates of the American Medical Association now on two (2) past occasions. As Delegate to the House of Delegates representing the American College of Nuclear Physicians, and as a member of the Society of Nuclear Medicine as well as a member of the Section Council on Nuclear Medicine of the American Medical Association, I have been aware of this issue for more than a year. The AMA through the Council on Scientific Affairs' guidance together with discussions with the many representatives to the AMA who have expertise in Nuclear Medicine has developed a position which urges the NRC to bring good safe practices judgements to bear on issues such as this.

As a former member of the Medical Advisory Committee to the NRC on medical use of isotopes I am not certain that the most desirable expertise on radiation physics/safety has been evident on NRC staff in recent years. I fear here as a result that a portion of the petitioner's request might be inappropriately implemented. My concern is in regard to the second request in American College of Nuclear Medicine petition to permit an out-patient option instead of hospitalization when therapeutic doses of radioactive pharmaceuticals at levels greater than 30 millicurie are instituted in the patient care program. It seems to me that I recall some discussions on just this issue several years prior to my termination of services on the ACMUI. As I recall, the Nuclear Regulatory Commission stated that the use of the word "confinement" was intended to permit a non-hospital option for the management of patients who contained relatively large quantities of radioactive material attendant to their therapy. As I recall, there was concern raised about the mechanisms for approval of such non-hospital containment sites including expressions of concern that a treatment patient might be permitted to return to the homesetting in a housing development or condominium resulting in outright fear on behalf of other tenants, neighbors, and local news media. I must say parenthetically that at that time the

state-of-the-art of Nuclear Medicine therapeutic applications had not reached the monoclonal antibody stage to make the possibility for radioactive doses in the range of 400 millicuries as petitioner has claimed to be considered for an out-patient administration. I know of no data which would support this arguement at this time. NRC in the interests of assisting in cost containment might direct some of its attention with appropriate physics expertise to developing a plan for such diversion of confinement from the expensive hospital scene.

May I call to your attention the NCRP report #37 which has its basis in sound physics with regard to radiation protection. Furthermore, the NRC could seek the NCRP's assistance in generating a publication which has the quality of soundly-based science as has characterized NRC reports in the past. Then make this publication appliciable to the issues of levels of radioactivity contained in the human body that require confinement and also present a comprehensive program for safe confinement in facilities other than expensive acute care hospitals.

I wish to express concern that the NRC take some appropriate carefully guided action in a timely fashion in response to the petitioner's requests for I feel safe in assuring your that this issue will not drop from the scene for a lack of persistence on the part of the American College of Nuclear Medicine.

Respectfully submitted,

J. K. Goodrich, M.D.

JKG/jml

Texas Radiation Advisory Board

Jack S. Krohmer, Ph.D.
Chairman

1100 West 49th Street
Austin, Texas 78756-3189
(512) 834-6688

April 25, 1992

(7)

Mr. Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

Re: Docket No. PRM-35-10

Dear Mr. Chilk:

The eighteen member governor appointed Texas Radiation Advisory Board (TRAB) is charged by the Texas Legislature to review and evaluate radiation policies of the state. The board has studied the radiation safety for patients who have received greater than thirty millicuries of a radiopharmaceutical and offers comments regarding the petition of the referenced docket number.

The TRAB supports maintenance and enforcement of the rule requiring hospitalization of patients treated with greater than thirty millicuries and so voted unanimously in its meeting of November 17, 1991. The board has advised the state to follow the mandatory hospitalization requirements of the current Nuclear Regulatory Commission rule.

The Medical Committee of the TRAB has reviewed and evaluated scientific papers described in the petition and the investigation results of an actual patient case which resulted in widespread contamination of a private residence as discovered by the state's regulatory agency. The TRAB concluded that the degree and extent of contamination found indicates that this type of operation cannot meet regulatory requirements regarding radiation exposures to the public.

Over the years, the TRAB's Medical Committee researched institutions nationwide regarding this policy and current health physics practices. The board believes there is compelling evidence for denial of the petition to amend the requirement for mandatory hospitalization of patients receiving greater than thirty millicuries of a radiopharmaceutical.

If TRAB can share other information from its research into this topic, please contact me or Mrs. Margaret Henderson, the board's special assistant in all matters.

Best personal regards,

FJ Bonte

Frederick J. Bonte, M.D.
Chairman, Medical Committee

State of Kansas
Joan Finney, *Governor*

Department of Health and Environment
Azzie Young, Ph.D., *Secretary*

Reply to: (913) 296-1564

April 16, 1992

SECRETARY OF THE COMMISSION
DOCKETING AND SERVICE BRANCH
U S NRC
WASHINGTON DC 20555

6

re: KDHE COMMENTS ON 10 CFR PART 35 [DOCKET # PRM-35-10]

Dear Secretary of the Commission:

The petitioner states that 20 CFR 35 be revised to allow patients that are treated with radiopharmaceuticals be released from medical confinement when their levels are greater than 30 millicuries. The petitioner claims that scientific studies support that treating patients on an outbasis with pharmaceuticals in doses greater than 30 millicuries would not create a safety hazard to the public.

KDHE's position is based upon the NCRP Report # 37 "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides - March 15, 1978." To paraphrase some of the pertinent comments:

"For nonoccupational exposure

> The radiation or radioactive material outside a controlled area, attributable to normal operations within the controlled area, shall be at such a level that it is improbable that any individual will receive a dose equivalent of more than 0.5 rem in any one year from external radiation.

In the present state of our knowledge, it is considered wise to avoid all unnecessary irradiation. An individual who has received a therapeutic dose of a radionuclide may be a source of undesirable radiation to other persons. In this report, it is recommended that exposure rate rather than activity constitute the basis for patient release. Exceptions to this are provided when it appears likely that the release of the patient will not result in radiation exposure to members of the household, or others, greater than that permitted for members of the general public. The recommendations given in this report are designed to ensure that exposure to anyone concerned with a radioactive patient shall not exceed the levels recommended above. Protection is of special concern for the immediate family, doctor, nurse, pathologist and other hospital personnel who may repeatedly have to care for patients undergoing therapy with radionuclides. It is important for such persons to appreciate the existence and the extent of this problem in order to deal with it appropriately."

U.S. NUCLEAR REGULATORY COMMISSION
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KDHE's recommendation: that the petitioner request an amendment to his/her license to use monoclonal antibodies for therapeutic use as opposed to changes in the current statute. There are instances where the doctors and patients best interest would be served best by using ALARA techniques on a case by case basis for early release, as opposed to revision of the regulation.

If the petitioner is successful in revising 10 CFR 35, Mr. Secretary, then it follows that regulations 10 CFR 20.105; 20.1003; 20.1301; 20.1302; 10 CFR 35.75; and others would all need to be revised.

These changes would have an impact on the effectiveness of KDHE staff in the areas of regulatory compatibility, review, surveys and enforcement actions.

Sincerely,

James A. Johnson
Radiation Control Inspector
Bureau of Environmental Health Services
Radiation Control Program

JAJ/psw

KRISTINE M. GEBBIE
Secretary

DOCKET NUMBER
PETITION RULE PRM 35-10
(57FR8282)

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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

April 10, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: DOCKETING AND SERVICE BRANCH

Dear Sirs:

This is in reference to docket number PRM-35-10; notice of a petition for rulemaking from the American College of Nuclear Medicine. The comment period for this petition for rulemaking ends May 8, 1992. This action potentially impacts Agreement States as well as states directly under NRC control. While individual states may be able to review this petition in a timely but disjointed fashion, a thorough, methodical, and cooperative review will be delayed.

I request that the comment period be extended through June 8, 1992 to allow the states to collectively evaluate this petition at the annual meeting of the Conference of Radiation Control Program Directors (CRCPD) to be held May 17-21, 1992. More specifically the CRCPD's SR-6 Committee on the use of radionuclides in the healing arts of which I am the chair will meet in conjunction with the CRCPD's annual meeting and this will be on our agenda. This is a scheduled meeting and the subject of the petition is well within our charge from the CRCPD. It would be most appropriate for us to comment on the petition and since we are not able to move up our meeting date I therefore request the extension of the comment period.

Sincerely,

Terry C. Frazee

Terry C. Frazee, Supervisor
Radioactive Materials Section
State of Washington &
Chair, SR-6 Committee, CRCPD

TCF:amw

CC: Chuck Hardin, Executive Director, CRCPD
Aubrey Godwin, Chair-Elect, CRCPD
Members, Resource Persons, and Advisors, SR-6 Committee, CRCPD

David A. Parker, M.D.

5322 Rymoor Drive Sylvania, Ohio 43560-1852 (419) 882-5226

April 11, 1992

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Dear Sirs:

As an active Nuclear Medicine Physician, I am writing in support of the ACNP petition for rulemaking (Docket No. PRM-35-10). Mandating hospitalization for therapies in excess of 30 millicuries is wasteful of our scarce healthcare dollars and does not increase public safety.

Sincerely,

David A Parker

David A. Parker, M.D.

MEDICAL COLLEGE OF WISCONSIN

Department of Radiation Oncology

J. Frank Wilson, M.D., FACR
Chairman

Roger W. Byhardt, M.D.
Beth A. Erickson, M.D.
Maurice Greenberg, M.D., FACR
Colleen A. Lawton, M.D.
Kevin J. Murray, M.D.
Laird E. Olson, M.D.
Maddie Sharma, M.D.
Christopher J. Schultz, M.D.

Medical Radiation Physics
Michael T. Gillin, Ph.D.
Daniel F. Grimm, M.S.
Katherine Sherwood, M.S.
Darwin L. Zellmer, Ph.D.

...ation Biology
John E. Moulder, Ph.D.
Jeffrey Shadley, Ph.D.

(4)

April 7, 1992

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Attention: Docketing and Service Branch

Dear Sir:

The purpose of this letter is to support the request of the American College of Nuclear Medicine for modification of 10 CFR 35.75 (A) (2). This petition requests an amendment to allow an outpatient option for patients who contain more than 30 mCi. In my professional opinion adoption of this request would permit medical costs to be minimized and provide efficient care. I also believe this rule would not increase risk to the public at large.

Thank you very much for consideration of my opinions.

Best Wishes,

Michael T. Gillin, Ph.D
Associate Professor

MG/keo

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 257-5636

The Williamsport Hospital & Medical Center

RICHARD W. DeWALD
Chairman of the Board

DONALD R. CREAMER
President

777 Rural Avenue Williamsport, PA 17701-3198 • 717/321-1000

TIN # 24-0795508

(3)

April 6, 1992

U.S. Nuclear Regulatory Commission
Secretary of the Commission
Docketing and Service Branch
Washington, DC 20555

Dear Sirs,

I am writing to support the American College of Nuclear Medicine petition to delete the requirement in 10 CFR 35.75(a)(2) that licensees may not authorize release from confinement for medical care any patient administered a radiopharmaceutical greater than 30 millicuries.

At our hospital we admit a number of patients for ablation of remnant thyroid tissue following diagnosis of thyroid carcinoma. The dose given is 100 mCi of iodine and generally the patients require 2 days of hospitalization until their body iodine content drops below the 30 mCi range. In view of the fact that the patients must be hospitalized in a private room, the expense clearly exceeds $1000 per admission. Our ability to isolate these patients is no greater than the isolation which we can usually achieve in their own home. In addition, we vacate the patient rooms surrounding the room in use for iodine therapy which decreases the rooms available for patients who need them in the community.

We hope that you will look favorably upon this change since it is cost effective without increasing the risk to the general population.

Sincerely yours,

Judith A. Gouldin, M.D.

JAG/ma

St. Anthony's Medical Center

10010 Kennerly Road St. Louis, Missouri 63128

DIVISION OF RADIATION THERAPY
DEPARTMENT OF RADIOLOGY
ST. ANTHONY'S CANCER CENTER

Bruce J. Walz, M.D., F.A.C.R.
Radiation Oncologist

Fred Abrath, Ph.D.
Radiological Physicist

March 30, 1992

(2)

Samuel J. Shilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
ATTN: Docketing and Service Branch

CONCERNING: Proposed Rule Change 10 CFR 35.75 (A) (2), Outpatient Treatment With Radioisotopes

Dear Secretary Shilk:

The purpose of this letter is to comment upon the proposed rule change which would permit outpatient treatment with radioisotopes such as I-131, in doses greater than 30 millicuries. This proposed rule change to allow outpatient treatment makes a great deal of sense from a medical standpoint, a standpoint of public health, and cost saving. Most of the patients who require large doses of I-131 are ambulatory, and in the short run quite healthy, and thus able to care for themselves and dispose of urine and other bodily fluids.

With the usual counselling to stay away from small children, and avoid close exposure to people of childbearing age, good radiation safety can be prescribed at home. For instance, when we treat patients with radioiodine, whether they are in or outpatients, we routinely counsel them not to hold small children on their lap, that is close to the bladder, nor near the region of the thyroid. They are also routinely instructed to flush the toilet twice after use, though we permit our patients to sleep in the same bed with their spouse, providing the spouse is beyond childbearing. In fact, when we keep the patients in the hospital, this presents a certain radiation hazard for hospital personnel, many of whom are young females, and occasionally we have a nurse or aide that is pregnant, and we have to reassign them.

We support changing the rule to allow treatment of patients with radioiodine up to 400 millicuries, in an outpatient setting.

Sincerely yours,

Bruce Walz, MD

Bruce J. Walz, M.D.
Director, Radiation Therapy,
St. Anthony's Medical Center
President, Missouri
Radiological Society

Fred Abrath

Fred Abrath, Ph.D.
Radiation Safety Officer,
St. Anthony's Medical Center
Past President, Missouri Chapter
of Physicists in Medicine

pb

Fax # (314) 525-1689
Telephone: (314) 525-1688
In Emergency: (314) 525-1000

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-10]

American College of Nuclear Medicine; Receipt of Petition for Rulemaking; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Notice of receipt, Correction.

SUMMARY: This document corrects a notice appearing in the Federal Register on March 9, 1992 (57 FR 8282). This action is necessary to correct a typographical error.

DATE: Submit comments by (60 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write: Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration,

U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-7758 or Toll Free: 800-368-5642.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

On page 8282, in the second column, in the second line of paragraph (1) under the heading "Petitioner's Request," the citation "10 CFR 35.72(a)(2)" should read "10 CFR 35.75(a)(2)."

Dated at Bethesda, Maryland, this 18th day of March, 1992.

For the Nuclear Regulatory Commission.

Donnie H. Grimsley

Donnie H. Grimsley, Director
Division of Freedom of Information
and Publications Services
Office of Administration

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

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UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

(1)

March 14, 1992

Samuel J. Chilk
Secretary of the Commission USNRC
Washington, DC 20555

Attention: Docketing and Service Branch
PRM-35-01

Dear Mr. Chilk:

As a member of the American College of Nuclear Physicians (not related to the American College of Nuclear Medicine), the Society of Nuclear Medicine, and NRC's Advisory Committee on Medical Uses of Isotopes, I wish to respond to the ACNM Petition docketed 14 Jan. 92.

One of the petitioner's requests is that 10 CFR 35.72(a)(2) be deleted. You may recall that I submitted a petition dated 26 Dec. 90 in which the identical request was made. I pointed out that the physics is incorrect, and wished to substitute NCRP no. 37 and the methodology described therein in order to evaluate when patients may be released from confinement, and indeed whether they required confinement at all. In the State of California, 10 CFR 35.72(a)(2) is not honored. Instead, each licensee is bound to NCRP no. 37. The only improvement to this document that I can suggest is to refine the very conservative and simplistic equation of appendix one so that it might be more clinically relevant. California licensees are free to do so, but perhaps NRC would request that NCRP issue a Commentary with helpful information and calculations so that individual licensees may have the convenience of a publication with high quality advice and therefore not have to bother with the calculations themselves. If the NRC has failed to resolve this issue since it was first raised, in August, 1988, and after it was finally raised in a petition nearly 15 months ago, it is obvious that NRC is still having difficulty with it and perhaps needs to ask its advisors or the NCRP for help or assign it a higher priority.

The NRC was first asked to fix its error when Mr. Cunningham requested a petition from ACNP/SNM, which was eventually submitted in June, 1989. When the repair of 35.75(a)(2) was to be included, I was told by the leader of the Medical Section that NRC found this to be embarrassing and wished to fix it themselves, rather than have it publicly pointed out by physicians. It was therefore omitted. When NRC failed to fix the problem, I included it in my petition of 26 Dec. 90.

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

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Lesar

This point has now been formally raised in two petitions and nearly in a third. This issue requires only very elementary knowledge of radiation protection and health physics. Hopefully NRC will resolve it very soon.

The second request in the ACNM petition is to permit an outpatient option instead of hospitalization. This point was raised in California in 1989 because NCRP no. 37 assumes hospitalization as the only option for monitoring. It is interesting that the leader of the Medical Section at NRC stated at the time that the term "confinement" was used to provide for a non-hospital option, assuming adequate monitoring. I therefore wrote to Warren Sinclair, then President of NCRP, to ask whether NCRP could substitute the more flexible term "confinement" for "hospitalization". His answer is appended. Apparently both NCRP and NRC are flexible in the matter, and one only has to make a convincing case that adequate monitoring is in place. I therefore question whether the second request of ACNM even has to be made at all. As of 1987, NRC had already provided the flexibility. Has NRC changed its interpretation? As a practical matter, it is often rather difficult to arrange for adequate monitoring in a cost-effective manner outside a hospital setting, and I think that it is important to realize that although this option exists (or appears to exist), it is not that simple to accomplish.

The one aspect of the petition that causes me some concern is the claim of safety of an outpatient dose of 400 mCi. I have not reviewed data supporting this argument and would appreciate the opportunity to do so. Although I'm sure that safety could be satisfied, it would appear to require some very specific circumstances.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

CSM:sfd

Proposed Rules

FYI, we should comment, I think.

Federal Register
Vol. 57, No. 46
Monday, March 9, 1992

DOCKETED USNRC '92 MAR 20 P3:25

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-10]

American College of Nuclear Medicine; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Notice of receipt.

SUMMARY: The Commission is publishing for public comment a notice of receipt of a petition for rulemaking which was filed with the Commission by the American College of Nuclear Medicine. The petition was docketed by the Commission on January 14, 1992, and has been assigned Docket No. PRM-35-10. The petitioner requests that the Commission amend its regulations regarding confinement, safety instructions, and precautions used for patients receiving radiopharmaceutical therapy in amounts greater than 30 millicuries.

DATES: Submit comments by May 8, 1992. Comments received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write: Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-7758 or Toll Free: 800-368-5642.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW., (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background

On January 14, 1992, the Nuclear Regulatory Commission (NRC) docketed a petition for rulemaking submitted by the American College of Nuclear Medicine. The petitioner requested amendments to 10 CFR part 35 by deleting the requirement for mandated hospitalization for ambulatory patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries and allowing patients the option to be treated on an outpatient basis if they qualify medically.

The petitioner states that the requested amendment is in the best interest of patients who require access to affordable quality care and that scientific published data support the changes requested by the petition as consistent with protection of the public as stated in 10 CFR part 35.

Petitioner's Request

The petitioner requests the NRC to revise 10 CFR part 35 to—

(1) Delete the requirement in 10 CFR 35.72(a)(2) that licensees may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until the activity in the patient is less than 30 millicuries;

(2) Amend § 35.75(a)(2) to allow for an outpatient option instead of mandating hospitalization for patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries.

Reasons for Petition

Section 35.75 prohibits an NRC medical use licensee from releasing from confinement for medical care any patient administered a radiopharmaceutical until certain criteria are met. One of the criteria is that the activity in the patient is less than 30 millicuries. The petitioner believes that the regulation should be changed to allow for temporary home confinement instead of mandating hospitalization. The petitioner claims that with the advent of monoclonal radiolabelled antibodies for diagnosis and treatment, outpatient therapy would provide efficient care and allow costs to be minimized without increased risk to the public. The petitioner also states that published scientific papers attest to the safety of outpatient radiopharmaceutical therapy in doses of up to 400 millicuries of I-131 NaI.

Conclusion

The petitioner states that, if this petition is granted, it would benefit patients by giving them affordable quality care while allowing them to be treated on an outpatient basis instead of being confined to a hospital. The petitioner claims that scientific studies support the finding that treating patients on an outpatient basis with radiopharmaceuticals in doses greater than 30 millicuries would not create a safety hazard to the public.

Dated at Rockville, Maryland, this 3d day of March, 1992.

For the Nuclear Regulatory Commission.

Samuel J. Shilk,

Secretary of the Commission.

[FR Doc. 92-5406 Filed 3-6-92; 8:45 am]

BILLING CODE 7590-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Regulatory Review

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Request for comment.

SUMMARY: The Federal Deposit Insurance Corporation ("FDIC") is soliciting public comment on which of its regulations and programs impose unnecessary or excessive costs or burdens and what changes can be made to reduce those costs or burdens. This action is being taken to comply with President Bush's request that Federal regulatory agencies evaluate existing regulations and programs and identify and accelerate action on initiatives that will eliminate any unnecessary regulatory burden.

DATES: Written comments must be received on or before April 8, 1992.

Acknowledged by card JUL 16 1992

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

BERKELEY · DAVIS · IRVINE · LOS ANGELES · RIVERSIDE · SAN DIEGO · SAN FRANCISCO SANTA BARBARA · SANTA CRUZ

UCLA SCHOOL OF MEDICINE
HARBOR — UCLA MEDICAL CENTER
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

May 2, 1989

Warren K. Sinclair, Ph.D.
President, NCRP
7910 Woodmont Ave.
Bethesda, MD 20814

Dear Dr. Sinclair:

I am writing to you to request an interpretation of a point in NCRP #37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," published in 1970.

Throughout the report, it is assumed that patients are either in the hospital or home; there is no consideration of the possibility that patients may be confined and medically supervised in a different physical entity. In the case of patients who have no medical reason for hospitalization, but who are hospitalized because they are hazardous radiation sources, it might be much less expensive to house them in a secluded facility with appropriate radiation safety personnel and medical and nursing personnel available. As long as the radiation safety recommendations of NCRP #37 are strictly adhered to, couldn't we substitute "seclusion in an appropriately monitored facility" for "hospitalization"?

This issue has been raised in the State of California, where medical licensees are tied to NCRP #37. Before we contact our Chief of Radiologic Health for a variance, we would like your comments.

It may be of interest to you that when NRC revised its medical use regulations in 1987, they used the term "confinement" rather than "hospitalization". A copy of 10CFR 35.75 is attached for your convenience.

Thank you for your attention and consideration.

Very truly yours,

Carol Marcus

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Medicine Outpt. Clinic
Bldg. A-13
and
Assoc. Prof. of Radiological Sciences, UCLA
Ph: (213) 533-2845

CSM:dt
cc: Robert F. Carretta, M.D.
Gerald L. DeNardo, M.D.
Encl:

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§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

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

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

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

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

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

§ 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.301 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives;

(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

NCRP

National Council on Radiation Protection and Measurements

7910 WOODMONT AVENUE, SUITE 800, BETHESDA, MARYLAND 20814-3095 AREA CODE (301) 657-2652

WARREN K. SINCLAIR, Ph.D., *President*
S. JAMES ADELSTEIN, M.D., *Vice President*
W. ROGER NEY, J.D., *Executive Director*

May 17, 1989

Dr. Carol S. Marcus
Director
Nuclear Medicine Outpatient Clinic
Building A-13
University of California, Los Angeles
UCLA School of Medicine
Harbor - UCLA Medical Center
1000 Carson Street
Torrance, California 90509

Dear Dr. Marcus:

Dr. Sinclair has asked that I respond to your request for guidance on the wording in NCRP Report No. 37. The important point in these NCRP recommendations is that no member of the public be exposed to a source or sources of radiation in such a way that the total dose equivalent exceeds 500 mrem in any year and that no person occupationally exposed receives a dose equivalent that exceeds 5 rem in any year. These numbers need to be tempered by the recommendations of NCRP Report No. 91, "Recommendations on Limits for Exposure to Ionizing Radiation". The guidance presented there is that 1) cumulative exposures should not exceed the age of the worker in years x 1 rem, 2) in the exposure of pregnant women under occupational conditions, the limit for the fetus (500 mrem) should not be received at a rate greater than 50 mrem per month and 3) all limits include the sum of external and internal exposures.

With regard to what you call the place where treatment is conducted, the intent of the recommendations is that provisions are made for the protection of the patient, the workers and any members of the public. This implies that personnel administering care to the patient have been trained and fully comprehend the procedures and the reason for the procedures.

I very much appreciate your consulting with us before you proceed further. We are not usually given the opportunity to counsel on the interpretation of our recommendations.

Yours sincerely,

James A. Spahn, Jr.
Staff Scientist

UNIVERSITY OF CALIFORNIA, LOS ANGELES

UCLA

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SANTA BARBARA · SANTA CRUZ

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

Dec. 26, 1990

Samuel J. Chilk
Secretary, U.S. Nuclear Regulatory
Commission
11555 Rockville Pike
Rockville, MD 20852

Attn: Chief, Docketing and Service Branch

Dear Mr. Chilk:

This Petition is being submitted pursuant to 10 CFR Part 20.301(c) in order to authorize operating up to an annual dose to individual members of the public of 5 mSv (500 mrem). This has been undertaken after conferring with Mr. Hal Peterson of NRC. This Petition also requests a change in the present 10 CFR Part 35.75 because there is a closely related problem which merits being addressed. Last, this Petition requests deletion of 10 CFR 20.301(d), which could lead to absurd situations.

This Petition is being submitted by me personally in my capacity as an advisor to the NRC, because I see a potential problem. It is not being submitted on behalf of any organization or group. The fact that organizations to which I belong may support this Petition shall in no way be interpreted to mean that I am acting in any capacity as their agent. This is my idea and my work and I have not a priori requested their opinion or support.

The subject of this Petition is the radiation absorbed dose to members of the general public from patients receiving radiopharmaceuticals for diagnosis or therapy. At present, members of the general public are permitted absorbed doses of up to 5 mSv/y. When the new Part 20 goes into effect, the level of absorbed dose permitted will be reduced to 1 mSv/y. If members of the public who are closest to the patient may not receive more than 1 mSv/y, patients who are now hospitalized would require hospitalization for appropriately longer times than they are now and many outpatients would have to be made inpatients. This would be extremely expensive. It is difficult to imagine any benefit to the public by reducing dose to 1 mSv, as no one has demonstrated any risk from chronic doses of 5 mSv/y. Indeed, residents of portions of Colorado, who receive 2.5 mSv/y, and those in higher background areas, have never shown any adverse effects from these low levels of radiation. The new Part 20 continues to permit the fetus of a declared pregnant woman to accrue a dose of 5 mSv/9 mo.; it would be scientifically consistent to permit certain members of the general public to do the same.

The new Part 20.903 appears to have retained the concept of the 1110 MBq (30 mCi) limit, which is expressed in 35.75(a)(2). It is as though NRC omitted consideration of the basis of the 1110 MBq limit when the new Part 20 was written, because it is not at present scientifically consistent with the Part 20 absorbed dose change. In addition, 35.75(a)(2) is not scientifically sound

either, because it refers to all radionuclides instead of just I-131, for which the 1110 MBq activity limit was originally intended.

I propose to retain the 1110 MBq limit for I-131, vary the maximum activity of other radionuclides consistent with the calculation methodology employed in NCRP no. 37, and continue to permit members of the public to receive up to 5 mSv from patients. I wish 10 CFR 20.301(d) to be deleted because EPA's radionuclide NESHAPS will be a national standard on 19 May 91 and its more restrictive nature nullifies the present Part 20 standards. For Part 20 to hold us to EPA which nullifies Part 20, is an example of colossal regulatory absurdity.

ECONOMIC IMPACT

In 1989, there were approximately 150,000 administrations of NaI-131. Of these, about 100,000 were 3.7 MBq or less, and of no consequence in terms of public radiation absorbed dose. There were about 35,000 hyperthyroid treatments, 10,000 metastatic surveys, and 5000 remnant ablation and thyroid cancer therapy doses. Nearly all the hyperthyroid treatment and metastatic survey doses were administered to outpatients. About 40,000 of these patients would become inpatients, as the I-131 limit for administered activity to comply with a 1 mSv public dose would be dropped to 1110 MBq/5 = 222 MBq (6 mCi). Assuming that the typical dose for hyperthyroidism is 444-555 MBq, and the uptake is about 70% and the effective halflife about 4.3 days, the average patient would require hospitalization for 4 days:

$0.7 \times 500 = 350$ MBq in gland after 1 day.

$$\frac{222}{350} = e^{-\frac{0.693(t)}{4.3}}$$

$$0.634 = e^{-0.16\ t}$$

$$-0.456 = -0.16\ t$$

$$t = {}^{0.456}/_{0.16} = 2.85d$$

$1 + 2.85 = 3.85 \approx 4$ days

Assuming that half the metastatic survey patients receive 370 MBq, 5000 patients would require 1 day of inpatient admission.

Assuming that the 5000 thyroid remnant ablation and thyroid cancer therapy doses are 3700-7400 MBq and that it takes 1-2 days to get to the 1110 MBq level now, it would take another 1-2 days to drop another 80% to 222 MBq, or an average of 1.5 days extra.

It costs about $500/day in a private room for these radioactive patients.

The new Part 20 would therefore cost:

$[35,000(4) + 5000(1) + 5000(1.5)]\ 500 =$

152,500 (500) = $76,250,000/year for NaI-131 patients.

Assuming that the number of outpatients receiving over 1110 MBq Tc-99m in various forms by Jan., 1993 is about 600,000 (using 1989 numbers), and that each requires 1 day as an inpatient, we have another 600,000(1)(500) = $300,000,000/y.

The above calculation assumes that the maximum administered activity for an outpatient stated in 35.75(a)(2) will not go down by a factor of 5; if it did, an extra 3,500,000 patients a year would become inpatients, at about $1,750,000,000/y.....!

In summary then, the new Part 20 as it stands will cost $76,250,000/y for NaI-131 patients. The old 35.75(a)(2) will cost, within 2 years, $300,000,000/y. If the old 35.75(a)(2) were upgraded to reflect the Part 20 philosophy, it would cost an additional $1,750,000,000/y.

If NRC requires us to accept EPA standards, that amounts to well over $100,000,000/y (CIRRPC Report of June 26, 1990).

<u>If this Petition is granted, there will be zero additional costs.</u>

We may still have additional costs if EPA decides that NRC standards are not high enough to assure public health and safety and we have dual regulation. For NRC to capitulate without firing single torpedo (20.301(d)) is sad indeed.

35.75(a)(2): CALCULATIONS FOR TC-99m

In order to calculate the actual activity of Tc-99m inside a patient that will result in excessive radiation absorbed dose to members of the public in close contact with the patient, I will use the NCRP no. 37 model:

$$D(t) = \frac{34.6\ \Gamma Q_O\ T_{1/2}\ (1-e^{-\ 0.693t/T_{1/2}})}{r^2}$$

Where D(t) = accumulated exposure at time t, in roentgens.

Γ = specific gamma-ray constant for a point source (R/mCi-h at 1 cm). In its use, no account is taken of scattering or absorption of the gamma-rays in the body of the patient.

Q_O = initial activity of the point source in millicuries.

$T_{1/2}$ = physical halflife in days.

r = distance from the point source to the point of interest, in cm.

t = exposure time, in days.

The model assumes that a member of the public remains 1 meter from the patient continuously until total radionuclide decay. It assumes that there is no excretion of the radionuclide from the patient.

Γ for Tc-99m = 0.8; $T_{1/2}$ = 6.02h = 0.25d

r = 1 meter = 100 cm

$t = \infty$

D = 0.5R

$$0.5 = \frac{34.6\ (0.8)(Q_o)(0.25)(1-e^{-0.693(\infty)/0.25}}{10{,}000}$$

$$0.5 = \frac{6.92\ Q_o}{10{,}000}$$

$$Q_o = \frac{0.5(10{,}000)}{6.92} = 722 \text{ mCi}$$

In other words, a member of the public standing 1 m from a patient containing 722(37) = 26,700 MBq of Tc-99m would receive 5 mSv radiation absorbed dose.

The corresponding number for I-131 is 8 mCi; the NRC limit of 30 mCi recognized the fact that one need not spend full time next to the patient. Using the factor of 30/8 = 3.75 for Tc-99m, the patient could have 722(3.75) = 2710 mCi = 100,000 MBq inside him. That is a lot more than the present limit of 1110 MBq.

The present limit for Tc-99m is roughly 2 orders of magnitude too low. No one is going to give more than about 2200 MBq to a patient. We don't need a published limit. You just need to change 35.75 to refer to I-131 only or to set the limit at that which gives an absorbed dose of 5 mSv to a member of the public.

20.301(c) REQUIREMENTS/ANSWERS

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section.

The need has been demonstrated. The duration is indefinite.

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit.

Patients given 1110 MBq of I-131 or more will be hospitalized and released in accordance with NCRP no. 37 guidelines. The more a patient can reasonably be expected to stay away from others, the more I-131 he may leave with. It would be rare for a member of the public to be exposed more than once a year to patients containing high activities of I-131. Should that be expected to occur, the licensee would keep the patient in the hospital longer.

(3) The procedures to be followed to maintain doses as low as is reasonably achievable.

Education of patient and care-giver to minimize time and contamination and maximize distance.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Medicine Outpt. Clinic
Bldg. A-13
and
Assoc. Prof. of Radiological Sciences, UCLA

CSM:dt

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-10]

American College of Nuclear Medicine;

Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Notice of receipt.

SUMMARY: The Commission is publishing for public comment a notice of receipt of a petition for rulemaking which was filed with the Commission by the American College of Nuclear Medicine. The petition was docketed by the Commission on January 14, 1992, and has been assigned Docket No. PRM-35-10. The petitioner requests that the Commission amend its regulations regarding confinement, safety instructions, and precautions used for patients receiving radiopharmaceutical therapy in amounts greater than 30 millicuries.

5/8/92

DATE: Submit comments by (60 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so but the Commission is able

Pub. 3/9/92

to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition, write: Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-7758 or Toll Free: 800-368-5642.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background

On January 14, 1992, the Nuclear Regulatory Commission (NRC)

docketed a petition for rulemaking submitted by the American College of Nuclear Medicine. The petitioner requested amendments to 10 CFR Part 35 by deleting the requirement for mandated hospitalization for ambulatory patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries and allowing patients the option to be treated on an outpatient basis if they qualify medically.

The petitioner states that the requested amendment is in the best interest of patients who require access to affordable quality care and that scientific published data support the changes requested by the petition as consistent with protection of the public as stated in 10 CFR Part 35.

Petitioner's Request

The petitioner requests the NRC to revise 10 CFR Part 35 to-

(1) Delete the requirement in 10 CFR 35.72(a)(2) that licensees may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until the activity in the patient is less than 30 millicuries;

(2) Amend §35.75 (a)(2) to allow for an outpatient option instead of mandating hospitalization for patients receiving oral or IV radiopharmaceuticals in amounts greater than 30 millicuries.

Reasons for Petition

Section 35.75 prohibits an NRC medical use licensee from releasing from confinement for medical care any patient administered a radiopharmaceutical until certain criteria are met. One of the criteria is that the activity in the patient is less than 30 millicuries. The petitioner believes that the regulation should be changed to allow for temporary home confinement instead of mandating hospitalization. The petitioner claims that with the advent of monoclonal radiolabelled antibodies for diagnosis and treatment, outpatient therapy would provide efficient care and allow costs to be minimized without increased risk to the public. The petitioner also states that published scientific papers attest to the safety of outpatient radiopharmaceutical therapy in doses of up to 400 millicuries of I-131 NaI.

Conclusion

The petitioner states that, if this petition is granted, it would benefit patients by giving them affordable quality care while allowing them to be treated on an outpatient basis instead of being confined to a hospital. The petitioner claims that scientific studies support the finding that treating patients on an outpatient basis with radiopharmaceuticals in doses greater

than 30 millicuries would not create a safety hazard to the public.

Dated at Rockville, Maryland, this 3d day of MARCH, 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

AMERICAN COLLEGE OF NUCLEAR MEDICINE

OFFICE OF THE PRESIDENT

October 5, 1991

Mr. Samuel J. Chilk
Secretary
U. S. Nuclear Regulatory Commission
Washington, D. C.

Dear Mr. Chilk:

The enclosed resolution of the American College of Nuclear Medicien is hereby transmitted to be considered as a petition for rule making under Title 10, part 35 and part 20, Code of Federal Regulation.

Please be assured the American College of Nuclear Medicine believes this petition is in the best interests of patients who require access to affordable quality care and that scientific published data support our petition as consistent with protection of the public embodied in the U. S. Nuclear Regulatory Commission Regulations Title 10, Code of Federal Regulations, but there is need for the NRC to clarify 35.75 by making a positive statement that 35.75 does not mandate hospitalization for otherwise ambulatory patients receiving oral or IV radiopharmaceuticals in amounts > 30 mCi.

Part 35.75 refers to release from CONFINEMENT while paragraphs 35.310 and 35.315 refer to safety instructions and safety precautions used for "patients receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75." Though intent may have been otherwise, the NRC has over-reacted by codifying what years ago was a reasonable suggestion from physicists, but which now represents an over cautious regulatory view since it has been demonstrated scientifically that there is no risk to patient families or the public at large whatsoever in managed home outpatient care.

Even at present, 35.75 seems to mandate hospitalization as the sole site for such treatment and overlooks merits of a necessary option, temporary home confinement for outpatient radiopharmaceutical therapy at levels exceeding 30 mCi for cancer and metabolic conditions. With advent of monoclonal radiolabelled antibodies for diagnosis and treatment, outpatient therapy will provide efficient care, allow costs to be minimized and no increased risk to the public will develop; published scientific papers attest to the safety of outpatient radiopharmaceutical therapy in doses to 400 mCi of I-131 NaI.

Mandated hospitalization should be deleted from part 35.75 and the outpatient option made available to patients who medically qualify. Home confinement accomplishes effective public protection. Mandated hospitalization interferes with the practice of medicine; an outpatient's medical and economic requirements are more effectively met. Simultaneously, scarce and expensive hospital space becomes available for someone else in need.

Thank you for placing this formal petition before the Nuclear Regulatory Commissioners.

Sincerely Yours,

Richard A. Wetzel M.D.

Richard A. Wetzel, M. D. FACP, FACNM
President, American College of Nuclear Medicine

Encl (1)

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

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AMERICAN COLLEGE OF NUCLEAR MEDICINE
P.O. Box 175, Landisville, PA 17538
(717) 898-6006

September 24, 1991

The resolution of ACNM follows:

"Resolved,. That the American College of Nuclear Medicine petition the Nuclear Regulatory Commission (NRC) to:

1. Recognize that the outpatient treatment of certain thyroid disorders and other malignancies (which can be treated with large doses of I-131 exceeding 30 mCi) is an acceptable legitimate policy not in violation of NRC regulations; and

2. Recognize that no regulation requires confinement when large amounts greater than 30 mCi I-131 are to be administered to a patient provided there is no hazard to the health and safety of the public or occupational worker; and

3. Recognize that there is no legal limit of an amount of I-131 or other radiopharmaceutical that can be administered to a patient by a licensed nuclear medical physician and the treatment of patients on an outpatient basis (not hospitalized) is not in violation of NRC regulations."

Support for this resolution in the view of the American College of Nuclear Medicine derives from the following considerations:

Radioactive inorganic sodium Iodide-131 has been used for the treatment of certain thyroid disorders since 1946. Other radioactive biologicals (i.e. monoclonal antibodies) have been labelled with radioactive Iodine-131 and used in the treatment of other malignant disorders. Adequate radiation cancer therapy involves administering large doses greater than 30 millicuries (mCi) per patient (100 - 200 mCi).

There is no scientific evidence that external radiation exposure to the public in this application will exceed the limitations published in 10 CFR 20.105 when treated on an outpatient basis. To the contrary, scientific research and professional published data has shown that external radiation exposure to the public in this application is considerably below the acceptable levels as published in the U. S. Nuclear Regulatory Commission Regulations Title 10, Code of Federal regulations, Section 20(10 CFR 20).

The health and safety of the public is not compromised by outpatient treatment with large doses greater than 30 mCi I-131 followed by patient confinement in his/her home.

There is a large body of experienced and licensed nuclear physicians and scientists qualified to ensure protection of the health and safety of the public that did not exist in 1946 or even when current regulations were promulgated in 1957.