ADAMS Template: SECY-067

DOCUMENT DATE: 10/02/1987

TITLE: PR-035 - 52FR36942 - BASIC QUALITY ASSURANCE IN RADIATION THERAPY

CASE REFERENCE: PR-035

52FR36942

KEY WORD: RULEMAKING COMMENTS

Document Sensitivity: Non-sensitive - SUNSI Review Complete

STATUS OF RULEMAKING

PROPOSED RULE: PR-035 OPEN ITEM (Y/N) N

RULE NAME: BASIC QUALITY ASSURANCE IN RADIATION THERAPY

PROPOSED RULE FED REG CITE: 52FR36942

PROPOSED RULE PUBLICATION DATE: 10/02/87 NUMBER OF COMMENTS: 72

ORIGINAL DATE FOR COMMENTS: 12/01/87 EXTENSION DATE: / /

FINAL RULE FED. REG. CITE: FINAL RULE PUBLICATION DATE: / /

NOTES ON: PERFORMANCE BASED RULE DEVELOPED. REVIEWED TERM MISADMINISTRATION
STATUS : (PR-35, 55FR01439) VS THIS PRESCRIPTIVE RULE. SEE SECY 89-269 & SR
OF RULE : M 10/20/89. (10/3/87 - 2/19/88). PR WITHDRAWN (63FR66496, 12/2/98)

HISTORY OF THE RULE

PART AFFECTED: PR-035

RULE TITLE: BASIC QUALITY ASSURANCE IN RADIATION THERAPY

PROPOSED RULE SECY PAPER: 87-029A	PROPOSED RULE SRM DATE: 09/02/87	DATE PROPOSED RULE SIGNED BY SECRETARY: 09/27/87
FINAL RULE SECY PAPER:	FINAL RULE SRM DATE: / /	DATE FINAL RULE SIGNED BY SECRETARY: / /

STAFF CONTACTS ON THE RULE

CONTACT1: ANTHONY N. TSE	MAIL STOP: NL-007	PHONE: 427-4108
CONTACT2: JAYNE M. MCCAUSLAND	MAIL STOP: T-9F31	PHONE: 415-6219

DOCKET NO. PR-035
(52FR36942)

In the Matter of

BASIC QUALITY ASSURANCE IN RADIATION THERAPY

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
10/02/87	09/29/87	FEDERAL REGISTER NOTICE - PROPOSED RULE
10/26/87	10/19/87	COMMENT OF UNIVERSITY OF CALIFORNIA, LOS ANGELES SCH OF MED (CAROL S. MARCUS) (17)
10/30/87	10/26/87	COMMENT OF UNIVERSITY OF CINCINNATI, MEDICAL CENTER (HARRY R. MAXON, III) (1)
11/02/87	10/30/87	COMMENT OF CENTRAL MAINE MEDICAL CENTER (JOHN W. CARRIER) (2)
11/02/87	10/22/87	COMMENT OF UNIVERSITY OF IOWA, HOSPITALS AND CLINICS (JAMES A. PONTO) (3)
11/04/87	10/30/87	COMMENT OF UNIVERSITY OF TEXAS, MEDICAL BRANCH/GALVESTON (ANTHONY R. BENDETTO) (4)
11/06/87	10/30/87	COMMENT OF DANBURY HOSPITAL (HERBERT W. MOWER) (5)
11/09/87	11/04/87	COMMENT OF VICTOREEN NUCLEAR ASSOCIATES (H. GLASSER) (6)
11/10/87	11/05/87	COMMENT OF UNIVERSITY OF WISCONSIN, CLINICAL SCIENCE CENTER (MICHAEL A. WILSON) (7)
11/10/87	11/03/87	COMMENT OF WM. S. MIDDLETON MEMORIAL VETERANS' HOSP (RICHARD J. HAMMES) (8)
11/10/87	11/04/87	COMMENT OF RICHARD L. COLE, JR., MD (9)
11/10/87	11/05/87	COMMENT OF SAINT JOHN'S HOSPITAL (RAY CAPESTRAIN) (10)
11/13/87	11/09/87	COMMENT OF VICTOREEN NUCLEAR ASSOCIATES (H. GLASSER) (11)
11/13/87	11/09/87	COMMENT OF YALE UNIVERSITY, SCHOOL OF MEDICINE (PAUL B. HOFFER) (12)
11/13/87	11/05/87	COMMENT OF MADIGAN ARMY MEDICAL CENTER (JOSEPH P. HELLMAN) (13)

DOCKET NO. PR-035 (52FR36942)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
11/17/87	11/13/87	COMMENT OF IOWA, DEPARTMENT OF PUBLIC HEALTH (JOHN A. EURE) (14)
11/17/87	11/13/87	COMMENT OF HUMANA HOSPITAL AUDUBON (GEORGE H. ZENGER) (15)
11/17/87	11/13/87	COMMENT OF WASHINGTON UNIVERSITY, MEDICAL CENTER (BARRY A. SIEGEL) (16)
11/18/87	01/23/87	COMMENT OF AMERICAN COLLEGE OF RADIOLOGY (WILLIAM T. MOSS) (18)
11/23/87	11/18/87	COMMENT OF SAINT AGNES HOSPITAL (JOHN F. WOCHOS) (19)
11/23/87	11/05/87	COMMENT OF SOUTH CAROLINA DEPT HEALTH & ENVIRONMENTAL CONTROL (HEYWARD G. SHEALY) (20)
11/24/87	11/18/87	COMMENT OF VIRGINIA MEDICAL CENTER - MIAMI, FL (DARRELL O. POOLE) (21)
11/24/87	11/12/87	COMMENT OF WILLIAM BEAUMONT HOSPITAL (WILLIAM C. PORTER) (22)
11/27/87	11/25/87	LTR AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AND SOCIETY OF NUCLEAR MEDICINE (BROWN) REQUESTING EXTENSION OF COMMENT PERIOD DEADLINE
11/27/87	11/24/87	COMMENT OF MEMBER OF LOUISIANA MEDICAL ADVISORY BD (CARL MERLIN) (23)
11/27/87	11/25/87	COMMENT OF AMERICAN COLLEGE OF RADIOLOGY (OTHA W. LINTON) (24)
11/27/87	11/12/87	COMMENT OF MEDTHODIST HOSPITAL OF INDIANA, INC (LARRY L. HECK) (25)
11/27/87	11/25/87	COMMENT OF WALTER REED ARMY MEDICAL CENTER (GERALD M. CONNOCK) (26)
11/27/87	11/19/87	COMMENT OF VIRGINIA MEDICAL CENTER - SAN DIEGO, CA (GILBERT GREENSPAN) (27)
11/27/87	11/19/87	COMMENT OF VIRGINIA MEDICAL CENTER - SAN DIEGO, CA (SAMUEL E. HALPERN) (28)
11/30/87	11/25/87	COMMENT OF NORTHERN NEW MEXICO NUCLEAR SERVICES (J.R. DAMRON) (29)
11/30/87	11/24/87	COMMENT OF UNIVERSITY OF TEXAS, MEDICAL BRANCH AT GALVESTON (RICHARD G. LANE) (30)

DOCKET NO. PR-035 (52FR36942)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
11/30/87	11/25/87	COMMENT OF MAYO CLINIC (MANUEL L. BROWN) (31)
11/30/87	11/23/87	COMMENT OF INDIANA UNIVERSITY MEDICAL CENTER (MACK L. RICHARD) (32)
11/30/87	11/25/87	COMMENT OF ECOLOGY ALERT (E. NEMETHY) (33)
11/30/87	11/27/87	COMMENT OF DAVID L. LAVEN, CRPH, FASCP (34)
11/30/87	11/19/87	COMMENT OF RICHARD L. COLE, JR., M.D. (35)
11/30/87	11/19/87	COMMENT OF TRI-CITY MEDICAL CENTER (SAMUEL L. KIPPER) (36)
11/30/87	11/19/87	COMMENT OF MICHAEL S. KIPPER, M.D. (37)
11/30/87	11/20/87	COMMENT OF MALLINCKRODT INSTITUTE OF RADIOLOGY (CARLOS A. PEREZ) (38)
11/30/87	11/27/87	COMMENT OF SAINT JOHN MEDICAL CENTER (KEITH M. JONES) (39)
11/30/87	11/27/87	COMMENT OF DOCTORS MERLIN AND HAYMAN (CARL S. MERLIN) (40)
11/30/87	11/25/87	COMMENT OF LEXINGTON RADIATION THERAPY CENTER (OSCAR A. MENDIONDO) (41)
11/30/87	11/24/87	COMMENT OF MAYO CLINIC (RICHARD J. VETER - GLENN S. FORBES) (42)
11/30/87	11/24/87	COMMENT OF YALE NEW HAVEN HOSPITAL (EUGENE A. CORNELIUS) (43)
11/30/87	11/23/87	COMMENT OF INTERSTITIAL COLLABORATIVE WORKING GROUP (SANDRA ZINK) (44)
12/01/87	11/19/87	COMMENT OF WEST COAST CANCER FOUNDATION (MARY LOUISE MEURK/DEVORAH H. NOVAK) (45)
12/03/87	11/25/87	COMMENT OF THERAPY ASSOCIATES, INC (ARNOLD SORENSEN) (46)
12/03/87	11/30/87	COMMENT OF AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE (PAUL L. CARSON) (47)
12/03/87	12/01/87	COMMENT OF COLLEGE OF AMERICAN PATHOLOGISTS (WILLIAM B. ZEILER) (48)
12/03/87	11/26/87	COMMENT OF JACK WAKLEY (49)

DOCKET NO. PR-035 (52FR36942)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
12/03/87	11/24/87	COMMENT OF AMERICAN COLLEGE OF MEDICAL PHYSICS (PETER R. ALMOND) (50)
12/04/87	11/25/87	COMMENT OF TEXAS, DEPARTMENT OF HEALTH (DAVID K. LACKER) (51)
12/04/87	11/28/87	COMMENT OF HOWARD V. KAVANAUGH (52)
12/04/87	11/19/87	COMMENT OF KAISER FOUNDATION HOSPITAL - SCPMG (DENNIS L. HEMINGWAY) (53)
12/04/87	11/30/87	COMMENT OF NATIONAL COUNCIL ON RADIATION PROTECTION MEASURMNT (WARREN K. SINCLAIR) (54)
12/08/87	12/04/87	COMMENT OF BIO-MED ASSOCIATES, INC (JACK J. MERKIN) (55)
12/08/87	12/04/87	COMMENT OF BANNOCK REGIONAL MEDICAL CENTER (ERIC B. BIELINSKI) (56)
12/08/87	11/19/87	COMMENT OF KAISER PERMANENTE MEDICAL CENTER (DAVID ROSSMAN) (57)
12/08/87	12/04/87	COMMENT OF S.V. HILTS (58)
12/08/87	12/03/87	COMMENT OF GEORGIA, DEPARTMENT OF HUMAN RESOURCES (THOMAS E. HILL) (59)
12/08/87	11/30/87	COMMENT OF MONTEFIORE HOSPITAL (ROBERT SPECHT) (60)
12/11/87	12/10/87	COMMENT OF ACNP/SNM (MELISSA P. BROWN) (61)
12/14/87	12/01/87	COMMENT OF SAINT FRANCIS HOSPITAL (JOSEPH D. CALANDRA) (62)
12/18/87	12/15/87	COMMENT OF DEPT OF NAVY (R.H. RICE, JR.) (63)
12/21/87	12/16/87	COMMENT OF SAINT ELIZABETH HOSPITAL (STANLEY A. REED) (64)
12/28/87	12/18/87	COMMENT OF WORCESTER MEMORIAL HOSPITAL (PETER B. SCHNEIDER) (65)
12/28/87	12/22/87	COMMENT OF VETERANS ADMINISTRATION, MEDICAL CENTER (K.K.N. CHARYULU) (66)
12/28/87	12/18/87	COMMENT OF DIVISION OF RADIATION ONCOLOGY (LARRY W. HENRY, M.D.) (82)
12/29/87	12/21/87	COMMENT OF MONTEFIORE HOSPITAL (IRWIN GOLDBERG) (67)

DOCKET NO. PR-035 (52FR36942)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
12/30/87	12/15/87	COMMENT OF OLYMPIA RADIOLOGICAL ASSOCIATES, LTD (LARRY W. HENRY) (68)
01/04/88	12/30/87	COMMENT OF JAMES A. HALEY VETERANS HOSPITAL (IAN B. TYSON) (69)
01/05/88	12/30/87	CORRECTION TO ACNP/SNM COMMENTS (M.P. BROWN)
02/16/88	02/09/88	COMMENT OF TACOMA RADIATION CENTER (HOWARD H. WONG/RICHARD A. HORN) (71)
02/19/88	02/09/88	COMMENT OF AMERICAN ENDOCURIETHERAPY SOCIETY (KAREN K. FU) (70)
03/14/88	02/09/88	COMMENT OF UNIVERSITY OF CONNECTICUT, HEALTH CENTER (RICHARD P SPENCER) (72)
01/12/89	01/11/89	NOTICE OF WORKSHOP TO BE HELD ON JANUARY 30, 1989.
11/27/98	11/24/98	FEDERAL REGISTER NOTICE - ADVANCE NOTICE OF PROPOSED RULEMAKING: WITHDRAWAL
01/11/99	12/10/98	FEDERAL REGISTER NOTICE - ADVANCE NOTICE OF PROPOSED RULEMAKING: WITHDRAWAL; CORRECTION

7590-01-P

Nuclear Regulatory Commission

10 CFR Part 35

RIN 3150-AC42

Comprehensive Quality Assurance in Medical Use and a Standard of Care; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal; Correction.

SUMMARY: This document corrects a notice appearing in the Federal Register on December 2, 1998 (63 FR 66496), that withdraws an advance notice of proposed rulemaking that requested public comments on questions related to comprehensive quality assurance and a standard of care in medical uses of byproduct material. This action is necessary to correct an erroneous telephone number.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, telephone (301) 415-7162.

Pub. on 12/15/98
at 63FR69026

SUPPLEMENTARY INFORMATION:

On page 66496, in the center column, under the ADDRESSES section, the telephone number, "(202) 512-2249" is corrected to read "(202) 634-3273."

Dated at Rockville, Maryland, this 10th day of December 1998.

For the Nuclear Regulatory Commission.

David L. Meyer, Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150 - AC42

Comprehensive Quality Assurance in

Medical Use and a Standard of Care

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPRM) that requested public comments on questions related to comprehensive quality assurance and a standard of care in medical uses of byproduct material. The Commission has decided to withdraw this ANPRM because of the effective implementation of the "Quality Management Program and Misadministrations" rule and the NRC's current efforts in revising the existing regulation for medical uses of byproduct material into a more risk-informed and performance-based regulation.

ADDRESSES: The Commission paper, the staff requirement memoranda (SRM), and associated documents are available for public inspection, and copying for a fee, at the NRC Public Document Room located at 2120 L Street NW. (Lower Level), Washington, DC 20012-7082, telephone: (202) 512-2249.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6219, e-mail jmm2@nrc.gov.

SUPPLEMENTARY INFORMATION:

On October 2, 1987, the Commission published two notices in the Federal Register regarding medical use of byproduct material. The first notice was the proposed rulemaking entitled "Basic Quality Assurance in Radiation Therapy" (52 FR 36942), that proposed a requirement for medical use licensees to implement some specific basic quality assurance practices to reduce the number of therapy misadministrations involving byproduct material. The second notice was an ANPRM entitled "Comprehensive Quality Assurance in Medical Use and a Standard of Care" (52 FR 36949), that requested public comments on the extent to which a comprehensive quality assurance program requirement was needed. The NRC believed that this two-pronged approach to the misadministrations problem would provide the best balance between assuring public health and safety and avoiding inadvertent interference in the delivery of quality medical care.

On July 25, 1991 (56 FR 34104), the NRC published a final rule entitled "Quality Management Program and Misadministrations" (the QM Rule) which was based on the above-mentioned 1987 proposed rule. During the implementation of the final rule, the NRC decided to assess the effectiveness of the rule and, based on the results of the assessment, to determine the need for a rulemaking on comprehensive quality management.

Subsequently, a Commission SRM on SECY-97-115 dated June 30, 1997, approved subsuming several Part 35 rulemakings into one major revision to 10 CFR Part 35 rulemaking activity. The proposed rulemaking entitled "Medical Use of Byproduct Material," was published in the Federal Register (RIN 3150-AF74) (August 13, 1998; 63 FR 43516). The NRC is in the process of developing the final rule governing medical use of byproduct material into a more risk-informed and performance-based regulation. This overall revision includes a consideration as to whether or not the regulation on the quality management program should be revised to become more risk-informed and performance-based. For this reason, the Commission is withdrawing the ANPRM.

Dated at Rockville, Maryland, this 24th day of November, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Quality Assurance in the Medical Use of Byproduct Material; Meeting Notice

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of meeting

SUMMARY: The Nuclear Regulatory Commission (NRC) has planned a public workshop with medical use licensees to discuss working drafts of a proposed rule and a regulatory guide concerning quality assurance in the medical use of byproduct material.

DATES: The workshop will be held Monday, January 30, 1989 (for quality assurance related to the use of radiopharmaceuticals); and Tuesday, January 31, 1989 (for quality assurance related to the use of sealed sources for teletherapy and brachytherapy). The workshop will begin each day at 9:00 am and end about 5:00 pm.

ADDRESS: U.S. Nuclear Regulatory Commission, Room 4B11, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Regulation Development Branch, NL/S-129, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3797.

SUPPLEMENTARY INFORMATION: The NRC is proposing to amend its regulations to require its medical use licensees to develop and implement quality assurance programs designed to prevent, detect, and correct the cause of errors in the administration of byproduct material for medical use.

A proposed rule was published in the Federal Register on October 2, 1987 (52 FR 36942) which prescribed certain quality assurance procedures that the NRC believed should be incorporated in each medical use program to prevent most human errors in the administration of byproduct material. Public comments suggested that the prescriptive rule lacked flexibility, and might interfere with the delivery of medical care. Instead, a performance-based rule was recommended.

Based on consideration of public comments to date, the NRC has prepared a working draft of a performance-based proposed rule. The NRC has also prepared a working draft of a regulatory guide that contains specific quality assurance procedures to meet the performance-based rule.

The purpose of the workshop is to obtain input from and have a round-table discussion with the medical use licensees on the working drafts of the performance-based rule and the regulatory guide.

The working drafts of the performance-based rule and the regulatory guide are available for inspection, and copying for a fee, at the NRC Public Document Room, 2120 L Street, Lower Level, NW., Washington, DC. The transcript of the workshop will be available by about March 1, 1989 at the NRC Public Document Room.

CONDUCT OF THE MEETING: The workshop will be co-chaired by Mr. John L. Telford, Section Leader, Rulemaking Section, Regulation Development Branch, Office of Nuclear Regulatory Research, and Dr. John H. Austin, Acting Chief, Medical, Academic and Commercial Use Safety Branch, Office of Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. The meeting will be conducted in a manner that will facilitate the orderly conduct of business.

The following procedures apply to public participation in the meeting:

1. At the meeting, questions or statements from attendees other than participants (i.e., medical use licensees and NRC staff) will be entertained as time permits.

2. Seating for the public will be on a first come-first served basis.

Dated at Rockville MD, this 11 th day of January, 1989.

For the Nuclear Regulatory Commission.

Bill M. Morris

Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

Department of Nuclear Medicine
Farmington, Connecticut 06032
(203) 679-3120

Mr. Norman McElroy
Chief, Medical Section
Nuclear Material Safety & Safeguards
U.S.N.R.C.
Washington, D.C. 20555

February 9, 1988

Dear Mr. McElroy:

We seek your assistance in resolving an issue that has grown out of the NRC proposed guidelines for reducing therapy misadministration. In brief, a supplier of radioiodide stock and therapy solutions, Syncor, has stated that they will not release a therapeutic dose until they have the patient's name. The justification they use is under p.36948, Federal Register, vol. 52, No. 191, Friday, Oct. 2, 1987. Proposed rules. 35.39. "Prescriptions for these byproduct materials must be in writing, and must include the patient's name..." Was the intent to supply a prescription to the outside supplier or radiopharmacy, or was it intended for internal use?

I am enclosing a copy of comments by Vincent Penikas, PhD, our Radiation Safety Officer. I believe the following points emerge.

1. The rules are proposed and are not yet in effect. However, Syncor has activated the proposals (at least in their own interpretation).
2. Syncor has inferred that they are a radiopharmacy and not a primary supplier, and hence can require that the patient's name be supplied.
3. We are concerned about patient's confidentiality. When a prescription is given to a patient for filling in an outside pharmacy, the patient has a choice of pharmacies and can be assured of the professional discretion of the pharmacist. The patient has fewer safeguards, when we release his/her name to an outside supplier.

Hence, we would appreciate your comments on the handling of this issue. Your assistance is appreciated.

Sincerely,

Richard P. Spencer, M.D., PhD
Professor & Chairman
Department of Nuclear Medicine

Enclosure
cc: Dr. V. Penikas

NRC (~~Hawe~~ Howe)
1
2
RIDS, TSC

THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

Radiation Safety Office
Farmington, Connecticut 06032
(203) 679-2250

February 3, 1988

TO: Dr. Richard Spencer
Director, Department of Nuclear Medicine

FROM: Vincent T. Penikas, Ph.D.
Radiation Safety Officer

SUBJECT: SYNCOR

As you are aware, Syncor requires the name of the patient who will be receiving therapeutic radioiodine that is being ordered from them. They have stated that they cannot dispense a therapeutic amount of radioiodine without having the patient's name. They claim this is required by regulations. I am not aware of such a regulation so I requested they provide us with a copy of the regulation. After some delay, they finally sent the attached extract from the Federal Register. The attachment is a copy of rules being proposed by the Nuclear Regulatory Commission to implement quality assurance steps that will reduce the chance of therapy misadministrations.

I cannot find in these proposed rules anything that specifically requires the patient's name be provided to the radiopharmacy. Ordering, prescribing, and administering certain radiopharmaceuticals are covered in Section 35.39 of 10CFR35. Refer to page 36948 of the attachment. You will note that paragraph 35.39(b) requires that prescriptions for the administration of a radiopharmaceutical for therapy must be in writing and must include the patient's name, the radiopharmaceutical, dosage, and route of administration. I believe this is the section of the proposed rules that Syncor has interpreted as requiring that they be provided with the name of the patient. It is not clear whether this section refers only to the ordering of a nuclear medicine procedure by a physician or if it includes the actual ordering of the radiopharmaceutical from the supplier.

I consulted with Larry Spitznagle to get his reaction to this problem. He was not aware of any requirement to provide the patient's name to a supplier. However, he understood a radiopharmacy's desire to have such information for completeness of records and their own protection. He also understood the problem of maintaining patient confidentiality.

At the present time the regulations referred to by Syncor are proposed rules and have not been finalized as regulations. If Snycor continues to insist upon having the patient's name and the Health Center is concerned about patient confidentiality, then you may have to use another vendor. Has this problem been referred to an appropriate level of the Society of Nuclear Medicine?

VTP:lf

Attachment

VSO 7-10
Add: 1
Norman Nkeel

Tacoma Radiation Center

314 South "K" Street, Room 11 • Tacoma, Washington 98405 • (206) 627-6172

HOWARD H. WONG, MD
MICHAEL D. SORONEN, MD
THOMAS K. JONES JR., MD
STEPHEN M. BADER, C.P.A.
Administrator

February 9, 1988

October 21, 1987
52 FR 36942

(1)

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

Attention: Docketing and Service Branch

We would like to respond to the proposed rule changes recorded in the Federal Register Vol. 52, No. 191.

Although we are in full agreement with the assumption that human errors are inevitable and independent redundant checks are the best way to reduce errors, we feel some of the proposed rules need to be clarified.

Letter sent 2/15/88

35.432 A)Source strength measurements.

A meaningful check of the source strength of brachytherapy sources places an excessive burden on the licensee. It requires the purchase of a dose calibration or setting up and taking down of a dosimeter system. The measurement will at best be marginal relative to the calibrations and equipment used by the supplier. The measurements mean additional handling of the sources and additional exposure of the handler.

The problem is more difficult for shorter lived isotopes such as IR-192, I-125, and Au-198 because of the number of times these sources are purchased in a year.

35.432 B)

The reason for doing a source strength check would be to discover major discrepancies. We would advise against the licensee substituting his own calibrations for those of the manufacturer. We believe it would lead to more errors in the long run.

35.454

It seems reasonable to me that a second person check the calculations for a brachytherapy implant. In the case of a computer generated dose calculation the check should be limited to checking that the sources placed in the patient corresponded to the sources used in the computer and that the calculations to achieve the prescription dose are correct.

35.633

An independent check of full calibration measurements within one month would be reasonable if it were limited to a basic output check. It would be unreasonable if it required a check of all the parameters included in the full calibration. A TLD check by mail from a Radiological Physics Center should meet this requirement.

Sincerely,

Howard H. Wong

Richard A. Horn

Howard H. Wong, M.D.
Richard A. Horn, PhD.

sph
cc. Diane Millman
of McDermott, Will and Emery

UCSF

University of California, San Francisco . . . AD Health Sciences Campus

Karen K. Fu, M.D.
Professor, Department of
Radiation Oncology
Long Hospital Room L 75
San Francisco, CA 94143
415/476-4815

February 9, 1988

Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 21555
ATTN: Docketing and Service Branch

Dear Secretary Chilk:

I am writing to you concerning the revision of 10 CFR 35. The Executive Board of the American Endocurietherapy Society would like to strongly endorse the enclosed recommendations sent to you from Dr. Ravinder Nath on behalf of the Interstitial Collaborative Working Group.

Thank you very much for your attention to this matter.

Yours sincerely,

Karen Fu

Karen K. Fu, M.D.
President
American Endocurietherapy Society

KKF:cs

Yale University

Department of Therapeutic Radiology
School of Medicine
Hunter Radiation Therapy
P.O. Box 3333
New Haven, Connecticut 06510-8040

Campus address:
Hunter Radiation Therapy
333 Cedar Street

Ravinder Nath, Ph.D.
Chairman of ICWG

November 16, 1987

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

Dear Secretary Chilk,

The Interstitial Collaborative Working Group (ICWG) has reviewed the proposed rule change to 10 CFR 35 which was published in the October 2, 1987 Federal Register, Vol 52, No. 191, pg. 36942. The ICWG is supported by the U.S. Public Health Service under contracts from the National Cancer Institute. The purpose of the ICWG is to formulate, recommend, and describe the techniques, clinical procedures and quality assurance practices necessary to provide a comprehensive program in interstitial brachytherapy.

The ICWG has been studying current practices in interstitial brachytherapy for the past three years in an effort to recommend a model program to the radiotherapy community. While we concur that basic quality assurance in brachytherapy is an essential part of medical care, we believe that it is inappropriate for the Nuclear Regulatory Commission (NRC) to impose regulatory requirements which may infringe upon the practice of medicine. The NRC can require users to implement the minimum acceptable elements of an effective quality assurance program, but we believe that the proposed rules do not recognize the flexibility needed in clinical practice.

If the NRC implements the rules as proposed, regardless of their impact on medical care, and enforces an aggressive schedule of penalties and sanctions for misadministrations as currently defined, many practitioners can be expected to abandon their practice, thereby greatly reducing the availability of health care to the public.

The NRC has recognized that physicians are responsible for making decisions in the best interest of their patients. The authorized physician has the responsibility to ensure that the personnel, equipment and practices involved in the delivery of medical care meet the standards expected for their patients. Ancillary medical personnel share a similar responsibility to provide health care in accordance with current health care standards. Since most of the incidents cited in the NRC Therapy Misadministration Case Study Report of December 1985 (AEOD/C505) can be attributed to simple human errors, we believe that the proposed rules will have little impact on the number and extent of therapy misadministrations.

The NRC position that voluntary programs alone may not provide adequate assurance of public health and safety is incorrect. The number of misadministrations reported is very small when compared to the total number of therapy procedures performed per year. This low rate can be attributed to the quality assurance programs which already exist in therapy programs. Although misadministrations still occur, we doubt that the proposed rules will reduce these errors significantly. Most of the existing quality assurance programs are based upon the recommendations of professional standards committees who have an in depth understanding of the problems inherent in the clinical practice of radiotherapy. The ICWG is an example of a voluntary effort within the therapy community to establish an exacting standard of care.

To encourage progress towards a better and more uniform implementation of these standards the NRC should endorse a model program, possibly in a regulatory guide and continue to publish periodical descriptions of reported misadministrations to the therapy community so they can examine their programs for vulnerability to similar errors. Detailed regulatory constraints on therapy practices may result in a degradation of the quality of care because of reduced flexibility.

The NRC should consider the fact that the practice of medicine regularly requires the use of potentially hazardous methodologies for patient care, other than radiation therapy, without similar regulatory constraints. What is it that makes the use of radioisotopes a special case? The NRC must be aware that in the United States most radiation therapy is performed using x-ray machines which are not subject to NRC regulations. Incidents involving medical accelerators and teletherapy units are reported to the Center for Devices and Radiological Health which then notifies users of the problem in the monthly Radiological Health Bulletin. As this system works well, it is unclear as to what will be accomplished by the enactment of additional regulations that apply to byproduct material devices, and are not applicable to natural radioactivity or x-ray machines.

The NRC should also consider the fact that under the current climate hospitals are searching for methods to control costs. The costs of implementing these regulations will not be trivial. To comply with these regulations most programs will have to employ new personnel to handle increased workloads, hire outside consultants to perform independent checks, and reduce the efficiency of physicians. When these costs are multiplied by the 5,000 Agreement state licensee's and the 2,200 NRC licensee's, the true costs of these regulations become tremendous. Can these costs be shown to justify the benefits of the possible prevention of isolated incidents? The NRC does not show evidence that any individual licensee has a chronic misadministration problem which would indicate the need for regulatory measures. In each case cited by the NRC the licensee has taken appropriate measures to prevent similar events in the future. We submit that the cost/benefit ratio of these regulations cannot be justified.

In addition to these general criticisms, we have many specific reservations regarding these proposed rules, most of which are unenforceable. How does a licensee demonstrate compliance with these regulations? Much of the documentation for these regulations is contained in medical records which are privileged information. Will inspectors be allowed to examine patient charts to determine compliance? Who is to judge what is legible and unambiguous? We

know of no standards of legibility.

Part 35.43 (a) thru (d), is essentially unenforceable and impacts on medical decisions. For example, brachytherapy implants in which I-125 seeds are left in place for complete decay, the total tumor dose can be determined only after the sources are implanted. The physician must exercise his judgement at the time of implantation to determine the distribution and number of seeds needed. When I-125 implants are implanted after surgical removal of some tumors, how is tumor dose to be determined?

Part 35.65 states that a licensee may not use byproduct materials if a discrepancy in records, observations, or physical measurements are noted. What constitutes a discrepancy? How would a licensee determine when one has occurred? We find it hard to believe that any medical service would deliberately continue a therapy if a significant error was noted. How would the NRC determine that this rule has been violated?

As required by part 35.432, why must a licensee measure source strengths annually? The decay constants of all medically used sources are well known. Remeasuring source strength is unnecessarily redundant and contrary to the principal of ALARA. Quarterly inventories and semiannual leak testing requirements are adequate to ensure that sources are properly identified and have not lost activity other than from natural decay.

It is not uncommon in brachytherapy procedures (Re: 35.454) for the physician to change his prescription during the period of the implant. In this case, how can we determine when 50% of the dose has been delivered? Sometimes the desired tumor dose cannot be delivered because of limiting doses to non-involved structures. Many times there is no tumor and treatment is delivered to prevent recurrence of tumor. Treatments are sometimes prematurely terminated because of patient intolerance. Does this constitute a misadministration? The situation is similar for teletherapy procedures mentioned in part 35.354.

What would the impact of these regulations be on many small clinics which may not have the personnel to conduct these checks independently. While we believe that independent dosimetry checks are a highly advisable quality control method, it may be impossible for some programs to comply because of the national shortage of trained individuals to perform these checks. This rule could be easily ignored by having the physician certify that every patient is suffering from an emergent condition. If this occurs, who in the NRC will determine that the medical condition was not emergent?

In part 35.633, what would constitute an independent check of the output. One measurement within a specific field size and distance? Could a small clinic have a dosimetrist or technologist perform the check instead of a teletherapy physicist? It may not always be possible for a clinic to have a second physicist available within a month after a full calibration. If they cannot comply within a month, must they cease operations? Surely, this would be a detriment to patients needing this treatment.

In conclusion, we feel that these proposed rules are poorly conceived and will have little impact on preventing the misadministrations identified. In contrast, the regulatory burden they pose and the ambiguity they present in demonstrating compliance is an intolerable intrusion on the practice of

medicine. We feel that the public welfare would be better served by an NRC proposal of a model program of quality assurance which would be flexible and could be modified to suit individual situations and circumstances. The NRC should also periodically publish reported misadministrations so licensees would be alerted to potential shortcomings in therapy programs. The medical community would like to foster a cooperative relationship with the NRC to provide the best health care possible. These proposed regulations would only serve to foster an adversarial relationship to the detriment of everyone involved.

On behalf of the ICWG, these recommendations are presented for the NRC's consideration. If you have any further questions, please contact us.

Sincerely yours,

Ravinder Nath

Ravinder Nath, Ph.D.
Chairman of ICWG

ICWG MEMBERSHIP

Yale	UCSF	Memorial-Sloan Kettering
R. Nath, Ph.D.	K. Weaver, Ph.D.	L. Anderson, Ph.D.
Y. Son, M.D.	T. Phillips, M.D.	D. Nori, M.D.
J. Meli, Ph.D.	V. Smith, M.S.	S. Chiu-Tsao, Ph.D.
A. Meigooni, Ph.D.	K. Fu, M.D.	B. Hilaris, M.D.
R. Peschel, M.D., Ph.D.		J. St. Germain, M.S.
M. Bohan, B.S.		

ACNP
1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036
SNM

American College of Nuclear Physicians

202-429-5120

The Society of Nuclear Medicine

December 30, 1987

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

RE: Correction to ACNP/SNM Comments
in Response to 52 FR 36942

Dear Mr. Chilk:

It has come to my attention that the formal ACNP/SNM comments in response to the NRC's Notice of Proposed Rulemaking on Basic Quality Assurance Criteria for Radiation Therapy (52 FR 36942) contain an error that should be corrected.

Because of an error in converting milligray to rem, we stated on page three in the "Background" section, paragraph three, in reference to the new diagnostic brain imaging agent I-123 iodoamphetamine, that "Several millicuries will be used and radiation absorbed doses will be average to high for a diagnostic procedure (target organ dose 5-20 rem)." This statement is incorrect, since according to the manufacturer of the new agent, radiation absorbed doses will be low to average for a diagnostic procedure, and target organ dose will be typically less than 0.5 rem, not 5-20 rem as we had stated.

We regret this error, and formally request that the NRC delete the sentence quoted. To leave the sentence intact would do a disservice to both the manufacturer and the numerous physicians who have been awaiting FDA approval of this new agent for clinical use. Incidentally, the FDA just granted approval of this agent this week. Please consider this letter as an attachment to our formal comments.

Thank you for your assistance. Please call me if you have any questions.

Sincerely

Melissa P. Brown

Melissa P. Brown
Director of Government Relations

cc: David H. Woodbury, M.D., President, ACNP
B. Leonard Holman, M.D., President, SNM

James A. Haley
Veterans Hospital

13000 Bruce B. Downs
Blvd.
Tampa FL 33612

Veterans Administration

In Reply Refer To:

December 30, 1987

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, DC 20055

Dear Mr. Secretary:

RE: Proposed NRC Regulations on Quality Assurance Misadministrations-Memorandum dated November 4, 1987.

Permanent members of the Radiation Safety Committee of this institution were consulted and met: The collective comments on the ACNP Document are noted. The members present were Drs. Al A. Heal, Ph.D. (Radiobiologist), L. E. Tenorio, M.D., I. B. Tyson, M.D. (Nuclear Medicine Physicians), and Mr. Kenneth K. Coleman, M.S. (Health Physicst). Written comments from the Quality Assurance Co-ordinator and verbal in-put from the Chairman of the Utilization Committee were considered.

A. QUALITY ASSURANCE - GENERAL.

1. Because the Nuclear Regulatory Commission (NRC) is actively requesting such comment, it is possible to assert that the NRC has found reason to believe the voluntary standards promulgated by the American College of Nuclear Physicians (ACNP) and included to an extent in the Standards of the Joint Commission on the Accreditation of Health Care Organizations (JCAH), have failed to curb errors of administration of radioactivity. Further, it is not at all clear that a uniform standard of practice is possible among the various regulatory agencies including the American Board of Nuclear Medicine (ABNM), the American College of Radiology (ACR), the ACNP and the JCAH. It is important that these bodies review each others practice standards.

2. Misadministration being an omnibus word requires definition and if error is to be found, defined and rectified, such errors need to be so defined and proper limits set. These errors of procedure etc. should not be permitted to encroach upon the limits of the more ominous omnibus term malpractice. Clearly misadministration may not necessarily relate to harm physical or psychological to a patient.

3. If radiopharmaceutical is being administered to patients without request from a primary care physician, this clearly is not only misadministration, it could be a malpractice issue. In any case, if a therapeutic dose is considered, a collective opinion is essential. That is to say, a second opinion should always be sought. Historically, i.e. prior to 20 years

12/31

1/2

Rivs

ago, second opinion was considered accepted practice in all manner of serious and potentially life threatening or damaging interventions. Further, it should be considered that assigning a dose of radiopharmaceutical is equivalent to the writing of a prescription. Thus it would appear that the Academic Council of the Society of Nuclear Medicine (ACSNM), the (ACNP), and the JCAH should advise the NRC. The NRC should enforce the advisories if it is the collective opinion of the ACSNM, ACNP, and JCAH that there is a mandate to the NRC to be an enforcement agency in behalf of its advisors. Otherwise, the NRC should not interfere with Nuclear Medicine practice. This practice must be regulated by the ACSNM, ACNP, and the JCAH through continuous monitors of institutional Quality Assurance (QA) and Utilization Review (UR) resources.

Specific comment would include those related to standards of care. It is clear that the time has come for the ACNP to enforce its practice audit requirements.

With regard to specific comments related to 10CFR 35.2 - Definitions Items regarding the diagnostic doses: This limit is far too wide and should be reduced to plus or minus 20%.

ADDITIONAL COMMENT

With currently available dose calibrators, this is of sufficiently wide margin for minimal adherence to the prescription standards. Finally, it should be emphasised that the word dose must be properly defined and used. Too many users do not distinguish between administered radioactivity as a radiopharmaceutical and radiation absorbed dose. Strictly, the dose is correct in both instances. However, the former is a radiopharmaceutical, the latter a radiobiological measure whereas the word "dosage" is not proper (Webster's Ninth New Collegiate Dictionary).

A copy of this material has been sent to our local NRC office for their comments. Thank you for the opportunity to make these comments. I hope they are of help.

Yours sincerely,

Ian B. Tyson, M.D.
Chairman, Radiation Safety Committee

CC: Helen Malaskiewicz
Program Analysist
Veterans Administration

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DIVISION OF RADIATION ONCOLOGY

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LARRY W. HENRY, M.D.
JOHN S. CRAWFORD, M.D.

15 December 1987

Norman L. McElroy
Nuclear Regulatory Commission
Medical and Academic Section
Washington, D.C. 20555

52 FR 36942

RE: NRC INVOLVEMENT IN QUALITY ASSURANCE

Dear Mr. McElroy:

I received information today regarding the intent of the NRC to become involved in quality assurance. I have read your proposed rules from the federal register: Volume 52, no.91, Friday, October 2, 1987. In this report you have identified 27 misadministrations from November 1980 through July, 1984. Your conclusion based on these "misadministrations" is that further regulation on the part of the NRC is necessary. I disagree with your conclusion and feel your own data support the opposite conclusion.

There are some 2,000 active Radiation Oncologists in the United States. If each of them treats (conservatively) 30 patients per day for 200 days per year equals a total of 12,600,000 treatments per year. Multiply this figure by 4 years and you come up with 27 "misadministrations" for 50,400,000 treatments. Thus, there are approximately .5 misadministrations per million radiation treatments. It seems very clear to me that this data proves your present program quality assurance through the state regulatory system combined with the quality assurance program of the College of Radiology, local quality assurance programs in each hospital, and the incentives provided by the malpractice climate have proved more than adequate for patient safety. Any involvement in the NRC would be a needless duplication of effort which would only increase the cost of medical care and provide no measureable improvement in safety. The NRC should immediately discontinue efforts that involve quality assurance.

Thank you for considering my opinion in this matter.

Sincerely,

LARRY W. HENRY, M.D.
LWH/jo

cc: Terry Frazee
N.R. Wieseneck
AFROC

Acknowledged by card. Yes

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Montefiore Hospital

Corporate Member and Teaching Hospital
University Health Center of Pittsburgh

3459 Fifth Avenue
Pittsburgh, Pennsylvania 15213
(412)648-6000

December 21, 1987

Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

RE: Comments on 10 CFR 35 Proposed Rule-Basic Quality Assurance in Radiation Therapy

Dear Sirs:

This letter is a compilation of the comments from physicians, physicists and technologists working in the Departments of Radiation Physics and Radiation Safety, Radiation Therapy and Nuclear Medicine at Montefiore Hospital. It also incorporates comments by the administrative personnel responsible for these areas and the Radiation Safety Committee following their review of the proposed regulations. Although <u>everyone</u> supports and actively participates in quality assurance programs for patient care, our overall response to the proposed regulations is not supportive for reasons which are detailed below:

1. <u>Need for Proposed Regulation:</u> The basis for these regulations is that "the NRC is obliged ... to establish and enforce regulations that protect the public from ... unacceptable risk of improper or careless use of by-product material in medicine". Twenty-seven different types of therapy misadministrations involving seventy-nine patients, over a period of almost four years, during which time an estimated 720,000 patients were treated, does not in our opinion constitute an unacceptable risk to the public (0.01%). Furthermore, it has not been demonstrated that a misadministration, as defined in the regulations, results in any real risk to patients, much less an unacceptable risk. Clearly, when misadministrations occur, less than optimal care has been delivered to the patient. While misadministrations may represent problem areas in patient care delivery which should be addressed, in the majority of misadministrations it would be extremely difficult to quantify the real risk to the patient from such an event. This is <u>not</u> to say that there are not risks which can result from misadministrations but most of the misadministrations reported have not caused identifiable harm to the patients.

2. <u>Intent of the Regulation:</u> The NRC states "the amendment is intended to reduce the chance and the severity of therapy misadministrations" which result from three basic causes: "inadequate training, inattention to detail and lack of redundancy".

a. Inadequate Training - The misadministration report did not detail the training of the personnel involved in the misadministrations. Were they registered technologists and/or certified physicians or physicists? What was their educational background, training and experience in Radiation Therapy? Perhaps there should be stricter requirements on training programs, recertification and experience for those personnel working in Radiation Therapy. Institutional inservice and education training, while important, cannot substitute for adequate pre-employment education and experience.

b. Inattention to Detail - How can this be regulated?!

c. Lack of Redundancy - Redundant procedures are good practice, however just as in applying the ALARA concept in radiation protection, "reasonable" must be the byword when specifying redundancy requirements. Individual departments and institutions can more accurately pinpoint specific areas where various levels of redundancy are indicated in their patient care operations. Additionally, in this era of hospital cost containment and shortage of adequately trained personnel in these fields, to impose detailed redundancy requirements may be unreasonable and unachievable.

In general, with the exception of the misadministrations due to the wedge factor measurements, all of the reported misadministrations are errors that can be expected to occur in any Radiation Oncology/Nuclear Medicine department, particularly a busy one. Again, with the exception of the wedge factor measurements, the variety of the errors and the infrequency of each type of error does not, in our opinion, justify regulation of this magnitude. It seems as though the NRC is attempting to regulate human error out of existence.

3. Comments on Specific Regulations:

a. 35.39 Ordering, Prescribing and Administering Certain Radiopharmaceuticals - The regulation states that a licensee may not order any radiopharmaceuticals of iodine for diagnosis or therapy, or any radiopharmaceutical for therapy, without the approval of the authorized user. What is the intent of this regulation and how is it to be interpreted? In departments which do not have full time nuclear medicine physicians present, disallowing the ordering of materials until the authorized user specifically approves it will only result in delays to patient treatment, increasing both the cost and length of inpatient care. The implication of this regulation is that only authorized users may order diagnostic iodine or therapeutic procedures, not referring physicians. If the intent is to insure that the Nuclear Medicine Physician

examines the patient and chart, and prescribes the administration of the radiopharmaceutical, that is adequately covered in subsection (b) of the regulation. Restricting the ordering of radiopharmaceuticals pursuant to an authorized users's direct approval is counterproductive and unreasonable.

b. 35.43 Prescription, Records and Checks of Medical Use for Therapy - This regulation requires that workers must request clarification from the prescribing physician if "any element of prescription or other record is unclear, ambiguous or apparently erroneous". Obviously, if a technologist or physicist cannot read something regarding a prescription they would ask for clarification. Does the NRC feel that this requires regulation? If the intent of this regulation is something more than an unclear prescription, what is the exact intent of the NRC regarding interpretation of this item? For example, should a therapy technologist refuse to treat a patient if there is no pathology report on the chart indicating a malignancy: does this come under the heading of "other records"? This regulation is unclear and ambiguous to us and places an unreasonable burden on paramedical personnel.

c. 35.65 Discrepancies in Records and Observations - This appears to be an all-encompassing regulation to allow citations by the NRC for any occurrence involving misadministrations. Again, there are no specifics as to what defines a discrepancy in a record or observation. Common sense dictates that an unreadable or incomplete prescription requires investigation. This regulation is too broad, infringes on the practice of medicine and it is not reasonable to expect licensees and paramedical personnel to interpret and implement it.

d. 35.432 Source Strength Measurements - This regulation requires the licensee to measure source strengths but allows them to use the manufacturer's measurements of strength for dose calculations. It does not define what is considered to be an unacceptable difference between the manufacturer's report and the licensee's source strength measurement, nor what actions are required when there are discrepancies in the two values. If the intent of this regulation is to verify that the manufacturer's report of source strengths are in fact accurate, then specific requirements regarding measurement techniques, accuracy of measurements, unacceptable ranges of measurements, and reported strengths are necessary, as is a requirement to measure each source, not just a representative from each lot. We are either verifying the reported activity of each source or we are not.

e. 35.452 and 35. 652 Physical Measurements of Patients - Specific regulations for these two sections have not yet been proposed, however, the NRC requested comment about the thought that two individuals independently make physical measurement of the patient for dosimetry purposes. There was one incorrect tumor depth measurement in the misadministration report. Does the NRC truly feel that this one incident justifies a regulation requiring redundancy of this magnitude? We do not!!!

f. 34.454 and 35.654 Checks of Dose Calculations and Measurements of Dose - This requires that a licensee shall check dose calculations for accuracy before 20% of the prescribed dose has been administered in teletherapy and 50% of the prescribed dose has been administered in brachytherapy. Again, we believe that dose calculation checks are an important part of quality assurance programs, however, to implement such strict regulations and redundancy for all situations is unreasonable and unjustified considering the few misadministrations which occurred as a result of calculation errors. For those physicians who do not prescribe doses for the full course of therapy but prescribe in a stepwise fashion pending evaluation (e.g. 2000 rads in two weeks, patient to be reevaluated) would require that the independent check occur after the first or second treatment. In fact, in our institution many of these checks are performed, however, not always in the time frame which the NRC requires.

g. 35.632 Full Calibration Measurements - We agree completely with the requirement to include the measurement of beam modifying devices in the annual calibration.

h. 35.633 Independent Check of Full Calibration Measurements - We feel that this is a completely unreasonable and unjustified requirement to have an independent check of the output performed within one month of the full calibration by a teletherapy physicist who did not perform the full calibration, using a dosimetry system other than the one used to measure the output in full calibration. We believe that full calibration measurements need to be carefully reviewed, but to implement such strict and specific regulations, not accounting for the various, well-accepted methods of quality assurance checks is unwarranted.

In summary, we believe in and fully support quality assurance programs in Radiation Therapy. We do not support these proposed regulations because we feel they address only those elements of quality assurance related to the reported misadministrations, in a very restrictive, nonfunctional way. It appears to us that the NRC has not fully evaluated quality assurance in radiation therapy for purposes of

protection of the public but rather is more interested in developing a basis for citations and imposing sanctions that may or may not be warranted. We do not believe that the reported misadministrations, resulting in these proposed regulations, define an unacceptable risk to the patients or the public. Additionally, we do not believe that enactment of these regulations will reduce or eliminate misadministrations but will impose serious burdens on facilities. We believe that there needs to be a thorough risk/cost/benefit analysis performed on these proposed regulations.

We agree with the need for regulatory actions in this area and would support the development of general quality assurance regulations requiring each institution to develop a quality assurance program that addressed issues such as redundancy, independent calculation and measurement verifications, patient and equipment measurements, record checking, etc. They could be similar to the JCAH quality assurance requirements or the NRC ALARA program requirements. Regulation of this type would allow institutions to individualize their quality assurance programs to the specific needs of their patients and radiation therapy departments while satisfying the regulatory goals.

These comments are being submitted after the December 1, 1987 deadline following a conversation Margaret Eddy, Radiation Safety Officer, and Norman McElroy at the RSNA and her attendance at the AAPM Radiation Therapy Committee meeting. Although our comments were ready for submission at that time, Mr. McElroy indicated that late comments would be accepted. We therefore chose to address some of the items raised at the Radiation Therapy Committee and to involve the Hospital's Radiation Safety Committee, which met on December 9, 1987. We trust that the Commission will fully consider these carefully prepared comments. Thank you.

Sincerely,

Irwin Goldberg
President

IG:kew

cc: Richard Kalla, M.D., Chairman
Radiation Safety Committee

Margaret Eddy
Radiation Safety Officer

William Youngblood
Associate Administrator

Medical Center

1201 Northwest 16th Street
Miami FL 33125

Veterans Administration

December 22, 1987

In Reply Refer To:

The Secretary
Nuclear Regulatory Commission
Room 1121,
1717 H. Street N.W.
Washington, D.C. 20558

Dear Sir:

Ref: Proposed NRC Regulations pertain to comprehensive quality assurance in use and standard of care (10CFR part 35) and also basic quality assurance in Radiation Therapy published in the Federal Register Volume 52 No. 191 Friday October 2, 1987.

Enclosed are the comments that I would like to offer before the proposed rules are published as regulations.

In general I agree that some of the proposed rules have merit. However, the regulations as such might be restrictive in the practice of Radiation Therapy, especially when a therapy facility is small as defined by you. Some modifications may be necessary to accomodate the small non profit institutions. An example would be that of a second Radiation Oncologist in the department not concerned with patient's therapy plan, providing the second check.

The concept of the expert Radiation Therapy Oncologist consulting with primary care physician is not appropriate (page 36952, column No. 1 under quality assurance item 3). This should be replaced, in both the sections. On occassion, the patient directly consults with the Radiation Oncologists. Since Radiation Oncologist is basicly a clinician with several years of experience solely of cancer therapy he should be free to administer such therapy as the patient's condition would benefit. A Radiation Therapy colleague working in the same department as the prescribing physician perhaps could provide the second check which is desirable in the management of patients.

I trust that these comments would help to modify the proposed rules.

Sincerely yours,

K.K.N. CHARYULU, M.D.,FRCR,FACR
Chief, Radiation Therapy Service

Enclosure

"America is #1—Thanks to our Veterans"

'87 DEC 28 P2:02

COMMENTS ON ADVANCED NOTICE OF PROPOSED RULEMAKING

10CFR Part 35

COMPREHENSIVE QUALITY ASSURANCE IN MEDICAL USE AND A STANDARD OF CARE.

Federal Register Vol.32 No.191, Friday, October 2,1987.

1.0 INTRODUCTION

1.1 The proposed actions by the NRC are well intentioned however, it is felt that the statistical analysis of the Therapy Misadministrations reported to the NRC for November 1980 to July 1984 and upon which the NRC is basing its actions, has been poorly presented. The reported cases of Therapy Misadministrations account for seventy nine (79) patient treatments, which compared to the over three (3) million patient treatments administered across the country during the same three and a half (3.5) years, is infinitesmal. It appears that the majority of "good" radiotherapy centres are being made to suffer because of a few "bad" apples in the barrel.

1.2 It might be more prudent to review all cases of therapy misadministrations with a view to obtaining better correlation with a more specific parameter or combination of parameters.

For example, perhaps the occurences of misadministrations are at specific centres or types of centre,

e.g.
- Corporate chains
- Franchises
- Facilities within a radiology department
- Facilities with no full time radiotherapist
- Facilities operating very old treatment machines

.....
etc.

or perhaps the occurences of misadministrations are following a particular individual or group of individuals.

1.3 With a better "fix" on the source of the problems giving rise to misadministrations, a better solution can be designed rather than the blanket approach being suggested by the NRC in an attempt to smother the whole service. With this view in mind and also without the specific statistical analysis of the misadministrations data to hand, but with the personal experience of many thousands of patient treatments, calculations, charts and planning, the following general comments are presented for consideration.

2.0 GENERAL COMMENTS

2.1 Redundancy Checks.

The concept of redundancy checking is a good one and if implemented, will go a long way in avoiding mistakes being made which could lead to possible misadministrations..

2.1.1 Teletherapy Treatments.

A mandatory requirement for the owner of this type of equipment who intends to use this equipment to treat humans, should be the full time employment of at least two (2) trained and qualified technicians per treatment machine, to administer the clinical treatments.

The administration of a teletherapy treatment automatically involves :

(i) Selecting the patient and the corresponding chart and/or treatment sheet
(ii) Setting the patient up under the treatment machine according to the instructions on the treatment sheet
(iii) Selecting a treatment time for the field being treated according to the instructions on the treatment sheet
(iv) Delivering the treatment
(v) Documenting on the treatment sheet, particulars of date, treated field, treatment time, accumulated tumour and/or given dose and the initials of the technician who actually delivered the treatment.

Qualified technicians working in pairs will check each other and contribute equally to the proper care of the patients undergoing treatment.

Over and above these clinical responsibilities, the treating technician is very often required to attend to various administrative tasks associated with each patient being treated such as:

(i) Making out appointment notices for further treatments, follow up visits, x-ray examinations, pathology work, etc.
(ii) Filling in pathology and x-ray request forms.
(iii) Recording treatment particulars for billing purposes on specialised billing forms.

(iv) Completing patient summaries for the patients completing treatments.
(v) Routing patients to examining rooms if either the physician wishes to see the patient after the treatment or if the patient wishes to see the physician.
(vi) Filling in various and sundry forms associated with the patient and their treatment such as transport requests, parking approvals, prescriptions for medication, special diets , etc.

It is impossible for one individual to cope with all of this and still be expected to be error free in the most important aspect of their job and that is the actual set up, treatment and completion of the treatment sheet.

2.1.1.1 Currently available electro-mechanical "record and verify" apparati absolutely do not substitute for a qualified person. In fact, due to their complexity and unreliability, the use of such electronic check systems along with all that is expected of the treating technicians, could very well demand the need for a third person just to handle the "record and verify" module.

Also, it is essential that such a system have an "overide" feature, which immediately destroys its credibility. The hazards of this type of configuration were tragically brought home by the recent A.E.C.L. Therac-25 incidents.

2.1.1.2 Similarly, the use of pseudo dosemeters for making actual measurements of some quantity of radiation delivered to each patient treatment field is definitely not recommended. This concept of dose verification during actual treatment has been entertained for many years but found to be clinically unproductive and impractical.

Diodes used as dosemeters are very unpredictable in their response and could lure inexperienced users into a false sense of security. The ionisation chamber is the de facto standard for measuring radiation dose as per all definitions of radiation dose. Diodes are not dosemeters, but being on the patient, could persuade some users to adjust treatment times (which are based upon absolute ion chamber output calibrations), incorrectly and for medico legal rather than clinical reasons.

Lithium Fluoride under very special conditions, can be calibrated to read radiation dose in the radiation therapy range, but needs scrupulous quality control to anneal, clean and generally prepare, catalogue and read the dosemeters.

In either case,the use of diodes or lithium fluoride would be counter active to the overall goal of cost containment.

2.1.2 Sealed Source Intracavitary Brachytherapy.

All sealed radioactive source intracavitary brachytherapy treatments should be planned as to distribution and strength and type of radioactive material, before the treatment is administered. Also, the overall plan of treatment should be duly noted in the patient's chart, also before the treatment is administered.

However, at the time of treatment, there are invariably some changes to the treatment plan due to new clinical findings which can only be ascertained with certainty during the process of implanting or placing the radioactive sources or source holders. In all cases, verification x-rays or measurements, should be taken at the time either the source(s) or source holder(s) is installed and final dose calculations performed before 50% of the dose has been delivered.

The dose calculations for these brachytherapy treatments should be done by a second person, independent of the person actually administering the dose or inserting the source holders. In some instances, the treatment will conform to a standard geometry with well documented dose distributions, however, this should not dispense with the redundancy check by the second individual who should be a radiation physicist or someone with extensive experience in radiation physics and the physical aspects of brachytherapy.

2.1.3 Radiopharmaceutical Therapy.

Specifically, the ordering, prescribing and administration of Iodine-131.

The chart entry for the patient being treated should be checked by an independent individual not involved directly with the administration of the radioactive material, before the dose is actually administered. This would ensure that the correct type and quantity of radioactive material was being prescribed for the patient and malady at hand. The prescription in the chart should be signed and dated by this individual.

The person actually administering the radioactive material should check the patient's chart prior to administering any radioactive material to verify that the whole prescription has been checked by an independent individual.

The person actually administering the radioactive material should make a notation in the patient's chart to include:- the time, the date and identification of the dose administered (type and quantity of the radioactive material and departmental identification for the preparation and calibration of the dose).

2.1.4 Output Calibrations.

2.1.4.1 The chart and treatment sheet for all patients undergoing teletherapy treatments, should be checked by an independent person at least once per week. All chart entries should be read and those pertaining to treatment changes, signed and dated by the independent. Similarly, any treatment changes not implemented or incorrectly implemented, should be queried by the independent for verification and/or modification by the physician responsible.

Also, all treatment sheet entries should be checked for the initial central axis calculations and thereafter for arithmetic errors and duly signed and dated by the independent.

2.1.4.2 A full calibration of the radiation output from a teletherapy treatment machine is required annually. This output calibration should also be checked by an independent person using independent dosimetry equipment.

2.2 Calibrations.

2.2.1 Because of the high degree of reliance on computers in the treatment planning aspect of radiation therapy treatments, it is imperative that measurements are made at regular intervals to ensure that the output from any computer used in the planning process, agrees with what is actually happening in the patient. Part of the full calibration of teletherapy units should include a measurement of outputs for a selection of treatment distances (SSD's) (say 60, 80 and 100cm) and a selection of Field Sizes (say 8x8, 10x10 and 15x15cm) and for at least two depths in a unit density phantom (say 5.0 and 10.0cm). These measurements should then be compared with any computer generated treatment times to verify the computer accuracy over this range of major clinical significance.

2.2.2 A serious aspect of this output calibration of a teletherapy treatment unit is the absence in the United States of a nationally accepted calibration Code of Practice to ensure that all absolute radiation outputs are measured uniformly. For such a Code of Practice to be effective, it should be:-

a. **SIMPLE.**
The more complicated the procedure, the higher the probability for making an error. Also, the overall confidence level decreases with the number of variables involved in the process, each step having its own unique error value (standard deviation). This requirement also applies to the instrumentation (dosemeter), which should have the absolute minimum of operator adjustable controls (preferably none at all or definitely no more than one to enable zeroing the instrument only).

b. **QUICK.**
It should be possible to accumulate many readings during a calibration and even repeat an entire calibration if necessary, without elaborate, time consuming set ups and without disrupting the normal departmental procedure.

c. **REPRODUCIBLE.**
No matter who performs the calibration or where in the State, Country or World for that matter, the calibration is performed, the results should be consistent from year to year and from center to center, which is of paramount importance to the patients undergoing treatments on these units, for the proper treatment of their diseases.

We are familiar with the American Association of Physicists in Medicine (AAPM) Task Group 21 protocol which requires the derivation and/or manipulation of some thirty four (34) variables, covering two (2) pages of worksheets, to arrive at an output calibration. It is primarily for this reason that TG-21 does not meet any of the requirements for a good calibration protocol listed above, but instead, has succeeded in introducing confusion into the ranks of physicists and physicians alike. The net result is that output calibrations have suffered, either because of incorrect assumptions or incorrect complex arithmetic in deriving the calibration factor or in the personal confidence in applying this very complex and time consuming protocol, with the result that calibrations are just not done.

There are true and tried Codes of Practice in existence throughout the world which do satisfy all of the criteria and any one of them, if implemented in the United States, would go a long way to establishing a uniform central axis calibration for all of the teletherapy machines in use in the country, those using byproduct material as well as those not using byproduct material.

2.5 Independent Person.

2.5.1 The independent person referred to in the foregoing comments on redundancy checking, should be a radiation physicist or someone with extensive experience in radiation physics such as an experienced radiotherapist. The NRC is suggesting that it be a radiation physicist who does the independent check of the full radiation output calibrations but this should be extended to all of the other independent redundant checks for the following reasons:-

(i) During the course of the weekly ongoing physics check of a patient's chart and treatment sheet, if prescription changes have been requested they are invariably subtle changes, involving a field size, treatment distance, use of a lead block, etc. and the individual performing the check should have the experience to know with certainty how the change will affect the original plan.

(ii) If any discrepancies between the prescription and the final treatment plan are discovered or even suspected due to a poorly worded prescription, at any phase of the treatment, a physicist is more likely to challenge the prescribing physician than perhaps a dosimetrist or technician. In the case of a major error or potential error, the treatments should be discontinued until satisfactory resolution of the discrepancy is obtained with the radiotherapist.

3.0 STAFF.

3.1 It is essential that a facility responsible for administering radiation therapy treatments to humans, be an autonomous department under the control of a qualified radiotherapist.

3.2.1 Similarly, a radiotherapy department operating teletherapy equipment should employ at least two trained and qualified technicians per treatment machine, to both be on the machine to treat patients as a pair. If the department is operational for brachytherapy and/or radiopharmaceutical therapy only, there should also be a minimum of two full time professional staff, one of whom should be a trained and qualified technician.

3.2.2 It has been the experience of this commentator that the error overall error rate in a department increases markedly with the hiring of new technical members of staff. This invariably occurs when a regular staff member resigns and a position has to be filled to cope with the workload and the new member is assigned responsibility too quickly without enough supervision. It is recommended that a new technical member of staff serve a three month probationary period in the department, under supervision to allow themselves to become fully acquainted with departmental procedure and routine. During this probationary period, any new member of staff should not substitute for the second person required on each teletherapy treatment unit, or sign any patient chart or treatment sheet.

3.3 There should also be a requirement that the services of at least one radiation physicist (or a suitably qualified person such as an experienced radiotherapist with extensive radiation physics experience), be employed in a radiation therapy treatment facility so that the principle of redundancy checking as outlined, is maintained.

4.0 SPECIFIC NRC QUESTIONS ON QUALITY ASSURANCE.

4.1 The Commission can most effectively implement requirements for comprehensive quality assurance and so ensure the minimum number of misadministrations as follows:-

4.1.1 Require that the treatment facility employ at least one full time radiotherapist and that this person physically be present in the department when treatments are being given.

4.1.2 Require that to administer any radiation therapy treatment, brachytherapy or radiopharmaceutical, the department employs at least two full time individuals, one of whom should be a trained and qualified technician. The second should have extensive physics experience to satisfy the requirements of redundant checking discussed earlier. For the administration of teletherapy treatments, the department should employ at least two full time trained and qualified technicians per treatment unit.

4.1.3 Require that the services of a radiation physicist or someone with extensive experience in radiation physics be employed for all of the redundancy checking, charts, treatment sheets, output calibrations etc.

4.1.4 Require that the department offering radiation therapy treatments be a separate autonomous radiotherapy department with a radiotherapist as head of the department.

4.2

4.2.1 The definition of misadministration as it stands is sufficiently clear as to its intent and it is recommended that it not be changed for fear that it become too rigorous and impossible to enforce.

4.3

4.3.1 The NRC should NOT require that the radiotherapist check with the primary care physician before prescribing radiation or deciding that radiation is not needed. This is an affront to the special qualifications of the specialist known as a radiotherapist who is the best person to know if radiation is the method of choice for a particular patient or not. It is the radiotherapist that the primary care physician consults for a professional opinion, not the other way around. cf 1.2, 3.1 and 4.1.4.

4.3.2 To improve the format and communication within a department, all chart entries - plans of treatment, changes to plans, on-treatment notes, follow-up notes etc - should be typed and not handwritten. All such typed entries should be initialled by the person who originated the chart entry, within 24 hours of dictating or drafting the entry.

4.4

4.4.1 Systems of redundancy checking with at least two trained and qualified technicians involved in administering all radiotherapy treatments as discussed, will provide assurance that all patients are treated in accordance with the information in the charts and treatment sheets.

4.4.2 Systems of redundancy checking with at least two people involved, one to be a radiation physicist or person with extensive radiation physics experience, will provide assurance that the machine output, treatment plans, patient charts and treatment sheets are all in accordance with the prescribing physician's orders.

4.5

4.5.1 Current methods of training, certification, licensing, preceptor statements etc. are more than adequate to ensure that qualified persons are being employed in the administration of radiation to humans for therapaeutic purposes. Part of the problem with many treatment facilities is totally inadequate staffing, brought on perhaps by the relatively high salaries technicians with all of the required qualifications can demand. All treatment facilities, be they part of hospitals, large institutions, small institutions, privately owned free standing clinics, etc. should be required to employ at least two full time trained and qualified technicians per teletherapy treatment unit that will be used to deliver radiation treatments to patients.

The technicians in general are well trained in their occupation and can do an excellent job when not spread too thin.

4.5.2 It is strongly recommended that NO action involving more forms or checks or registration/certifications be imposed on the speciality for fear of employers cutting back further on trained staff to reduce expense and maximise profits, which in turn will be counteractive to the intent of the action.

4.5.3 Similarly, it is strongly recommended that requirements for "record and verify" or patient "dose" measuring systems NOT be enforced. In terms of cost containment, it appears that the emphasis is being misplaced. There is no restriction being placed on the industry as to the cost of the treatment machines and all of these peripheral devices. Some of these "record and verify" systems for example cost almost as much as a small treatment unit and to be clinically effective they all need an "over ride" feature and all together too much reliance is placed on an expensive machine at the cost of an intelligent, thinking human being in the form of an extra technician. It is extremely dangerous and morally wrong to cultivate a false sense of security in treating patients with radiation, by machines only and decreasing the human input. The positioning of patients under teletherapy radiation beams is too exacting for any "record and verify" system to monitor accurately and definitely requires two very competent technicians working together in pairs to accomplish.

4.6

4.6.1 As to whether a patient is entitled to a copy of his or her chart should be left to the discretion of the radiotherapist.

4.7

4.7.1 Computers are being used for many different operations in radiation therapy and the burden should be on the user of this type of equipment to prove to their satisfaction that the computer and the treatment machines are in clinically significant agreement. Such verification tests should be done by a radiation physicist or person with extensive radiation physics experience and be performed routinely as part of the calibration redundancy check program.

4.8

4.8.1 Physical calibration measurements and redundancy calculations both should be done to assure that the dose given is the same as the dose prescribed. The redundancy calculations and calibrations should both be done by an independent person using different dosemeters and computing equipment to that which is used routinely.

4.9

4.9.1 Cost containment from the patient's point of view, is very important. However, the types of redundancy checking which have been discussed are usually incorporated in the operation of a well run radiotherapy department and provisions have been made for ongoing physics checks and central axis treatment plans on a per patient basis in the majority of billing schemes. Again, in the properly organised radiation therapy department, these charges are being made and the redundancy checks are being performed by a radiation physicist and no misadministrations occur. The more unscrupulous treatment centers are undoubtedly making these physics charges but not proferring the redundancy checks and any form of quality assurance requirement which will also contain the patient's costs, should be geared at making sure that the patient at least gets that for which he or she is being billed.

4.9.2 Forcing treatment centers to employ adequate numbers of staff and use radiation physicists for the redundancy checks of charts, treatment sheets and output calibrations will ensure that patients will receive better treatments without increasing costs and with as low as practicably achievable (ALARA) number of misadministrations. Only those centres with sufficient numbers of patients to treat and able to support the minimum staff requirements will be able to comply.

5.0 SUMMARY

DO'S

5.1 Do require autonomous departments with a qualified radiotherapist as head.

5.2 Do require a minimum of technical staffing.

5.3 Do require redundancy checking by an independent.

DON'TS

5.4 Do not require "record and verify" electro-mechanical equipment.

5.5 Do not require on patient "dose" monitoring.

5.6 Do not require any extra forms or record sheets.

5.7 Do not require any extra licenses or qualifications for either the staff or the treatment facility.

NAME.....

TITLE.....

AFFILIATION.....

.....

.....

.....

DATE..... SIGNATURE:.....

Worcester Memorial Hospital
119 Belmont Street · Worcester, Massachusetts 01605
(617) 793-6611

December 18,1987

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

Dear Sir:

These comments are in regard to the proposed rule making for 10 CFR 35 as published in 52 FR 36942.

Although the stated comment period has expired on 12/1/87,I would like these comments to be accepted since notice of the proposed rule making did not reach us until after expiration of the stated period. We received the notice, through our subscription service, in supplement 60 to the NRC Rules and Regulations which was issued Nov. 17,1987 and did not reach us until after 12/1/87. I am surprised that, contrary to your usual practice, you did not mail a copy of the proposed rulemaking directly to our hospital.

These comments, in particular, refer to 35.39 (b). The proposed rule requires a physician prescribing radioiodine for diagnostic or therapeutic uses to examine the patient and the patient's chart. This rule may be valid for therapy doses but is extraordinarly burdensome for diagnostic procedures. Patients who are referred for diagnostic thyroid radioiodine uptakes and scans are almost all outpatients. Their charts are not available in the hospital and to require the referring physician to copy their complete charts and mail them to us is an unwarranted burden which can only increase the cost of medical care and delay patient diagnosis. It is the referring physician's responsibility to determine what diagnostic procedures he needs for a particular patient after fully examined that patient. It is not the responsibility of the Nuclear Physician to second guess the primary physician's need for diagnostic information. If that were the case I would have to see every patient in consulation and repeat the workup which would obviously generate extra expense and delay.It is my responsibility to assure that the primary physician gets the requested information by performing the requested test without error.

The purpose of the proposed rule is to prevent a misadministration of potentially injurious doses of radioiodine. I would suggest that the rule not require patient examination or chart review when diagnostic doses of radioiodine are involved (perhaps defined by setting numerical limits such as less than 500 uCi of I-123 or 100 uCi of I-131). Furthermore, in the case of outpatients referred for radioiodine therapy the rule should permit use of a summary letter from the referring physician rather requiring a full chart review.

Sincerely,

Peter B. Schneider,M.D.
Professor of Nuclear Medicine
University of Massachusetts Medical School
Co-director of Nuclear Medicine
Worcester Memorial Hospital

ST. ELIZABETH HOSPITAL · A Member of the Wheaton Franciscan System
1506 SOUTH ONEIDA STREET · APPLETON, WISCONSIN 54915

December 16, 1987

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

Attn: Docketing and Service Branch

Gentlemen:

This correspondence is in response to proposed regulations 10 CFR Part 35, Basic Quality Assurance in Radiation Therapy and Comprehensive Quality Assurance in Medical Use and a Standard of Care. Our Radiation Safety Committee meets quarterly (March, June, Spetember, December) and we had to discuss the content of this proposed rule before making a response.

§ 35.43 Prescriptions, records, and checks of medical use for therapy:
(c)(d): Both of these sections address a subjective area and will not be consistent from one institution to another. We do not believe that the NRC should be involved in defining an acceptable prescription protocol. There are instances where a prescription will require additional information for clarity and the prescribing physician is not available. The question is answered (appropriately) by another physician (radiotherapist) in the department.

§ 35.432 Source strength measurements:
(a): The measurement of source strength prior to use is reasonable for some isotopes (Cs-137) but how does one handle sources that are ordered in a specific orientation (i.e. Ir-192 seeds in a ribbon with a specific spacing)? To obtain an appropriate measuring geometry for ribbons is not readibly available in most radiation therapy departments. In addition, if a Cs-137 source is to be measured at annual intervals how will this improve quality of care? Once a source is determined to be the appropriate isotope and leak tested, what help does an annual source strength measurement have? This section appears to contradict the ALARA philosophy. We believe that a well controlled manufacturer would be more effective at maintaining source integrity and strengths.

§ 35.633 Independent check of full calibration measurements:
(a)(b): We believe that this will increase health care costs with an insignificant improvement in health care delivery. We are also not certain whether there are adequate manpower availability (physicists) to cover the requirement especially for small facilities.

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§ 35.354 Checks of dose calculations and measurements of dose: (a)(b)(c)(d)(e): In our opinion this section is far too cumbersome and does not effectively address chart accuracy. The prior statements for therapy misadministrations is adequate without trying to increase paperwork but not quality of care. Single day treatments would have to have double checks prior to treatment and departments that have only one individual could not legally operate. Weekly chart checks are routine for most departments but due to vacations, illness, busy caseloads, sometimes this frequency is somewhat variable. It is our opinion that few departments would rigorously meet all requirements in this section. Our department uses a system of checking patient charts prior to completion of therapy (as well as an approximate weekly check). Errors do occur after the first twenty percent and many prescribed changes occur during the entire course of therapy. This definition may actually reduce the overall accuracy.

In general we feel this proposed section will not significantly reduce the chance of therapy misadministrations but will likely increase the cost of health care. Most institutions (if not all) have requirements by medical/hospital policies and other agencies (JCAH, State) which address the details of quality assurance. We would hope and expect that a cost analysis (risk/benefit study) would be performed prior to adopting these regulations. We feel that the number of misadministrations described may be at an acceptable level considering the total number of procedures performed and that human beings are involved. The level of redundancy proposed is inconsistent with other areas of medicine.

It seems to us that the emphasis of the NRC should be to identify the proper and safe use of radioisotopes and regulate at a specific level for safe handling and at a general level for clinical procedures. Suspected errors in medicine are presently over addressed by our legal system. It also seems ironic to us that the NRC which inspects us at approximate three year intervals desires increasing mostly unnecessary documentation instead of trying to identify problems or potential problems in person and assuming a preventative role instead of emphasizing a punitive after the fact stance. The existing regulations appear more than adequate, and when an institution has significant preventable misadministrations then these should be addressed individually.

10 CFR Part 35: Comprehensive Quality Assurance in Medical Use and a Standard of Care

The statement "It is NRC's position that voluntary programs alone may not provide adequate assurance of public health and safety", has no apparent proof since a definition of an expected and acceptable misadministration rate has not been defined or determined. In the brachytherapy misadministrations listed, a quality assurance program may have prevented only one of the listed events, is that cost effective or reasonable?

We feel that the NRC should not be addressing the area of quality assurance and standards of care at the level addressed. First of all, to perform an adequate evaluation the NRC would have to exceed or equal the experience and qualifications of those being inspected. Secondly, at an infrequent inspection rate, the NRC doesn't provide a preventative measure and only duplicates our legal system for punitive measures. Third, the NRC needs to define what determines inappropriate care, if inappropriate care is being currently given, what additional cost does the proposed program have, and is it justified. Fourth, since the NRC only regulates a small fraction of the total ionizing radiation delivered to patients, (the total will continue to decrease in the future as well) and if there really exists a problem, then these regulations will not help the majority. Finally, the NRC should be working with state regulatory agencies and others in order to prevent inconsistency and duplication before creating regulations that appear to be generally unnecessary and not cost effective.

Thank you for your consideration on these comments.

Sincerely,

Stanley A. Reed

Stanley A. Reed, M. S.
Medical Physicist
(Radiation Safety Committee)

SARmmm
cc: Radiation Safety Committee

DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
WASHINGTON, DC 20350-2000

IN REPLY REFER TO
6470
Ser 455/7U396535
15 Dec 1987

Secretary of the Commission
Attn: Docketing and Service Branch
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Sir:

Enclosed please find U.S. Navy comments on the proposed ammendment to 10CFR35, Basic Quality Assurance in Radiation Therapy, as published in the Federal Register, Vol. 52, No. 191, on Friday, October 2, 1987.

Sincerely,

R. H. RICE, JR.
CDR, LEC, U.S. NAVY
DIRECTOR, ENVIRONMENTAL
PROTECTION, SAFETY & OCCUPATIONAL
HEALTH DIVISION

Enclosure:
(1) U.S. Navy Comments on Proposed Ammendment to 10CFR35, Basic Quality Assurance in Radiation Therapy

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U.S. Navy Comments on Proposed Ammendment to 10 CFR 35,
Basic Quality Assurance in Radiation Therapy
Federal Register, Vol. 52, No. 191, Friday October 2, 1987

1. The Navy concurs in general with the overall intent of the proposed amendment, recognizing the need for greater control and consistency in Quality Assurance (QA) requirements for measurements, calculations and record keeping. Specific comments are provided below.

2. Section 35.432: Source Strength Measurement: Disagree. The purpose of the licensee's measurement is not clear. If performed as a check on the manufacturer, what is acceptable agreement, 5%, 10%? What should be done in the case of a discrepancy? Which measurement should be used for dose calculation? Many licensees may not have dosimetry systems capable of accurately measuring sealed sources.

3. Sections 35.452 and 35.652: Physical measurements of patients: Agree. We agree with the requirement for two individuals to independently make the physical measurements of the patient needed for dosimetry purposes. For documentation purposes, it is suggested that having both individuals initial a single dosimetry data form would be sufficient.

4. Sections 35.454: Check of dose calculations: Agree with Portions.

a. Requiring calculation checks before 20% and 50% dose administration for external and brachytherapy, respectively. Agree with requirement and believe that it is workable.

b. Requiring manual checks of data input (and possibly dose to a single point) for computer-generated calculations. Agree with the requirement for manual check of data input for both external and implant computer-generated plans, and also with check of dose to a single point for external treatment plans; but, due to the complexity of the calculation, do not believe that a check of dose to a single point is required for brachytherapy plans (provided the computer software has been verified by the licensee). The NRC arguments against checking dose to a single point for computer generated external beam plans (calculations with corrections for tissue inhomogeneities, field contours, etc. may not be fully understood by the user, too difficult to check, etc.) are, in our opinion, reasons why a manual check should be performed. If the user doesn't fully understand the steps involved in the computer-generated plan, the computer should not be used. Except in the case of brachytherapy, where multiple sources truly make verification of each plan too difficult, we believe plans should be checked by manual calculation of dose to a single point. Documentation could be provided by performing the manual check on the computer printout and comparing the treatment times. The manual and computer-generated results should agree to +/-5%.

c. Independent check of dose calculation: Checking the calculation and initialing should be satisifactory. By checking the calculations the individual has assumed partial responsibility for the accuracy and would be remiss (and foolish) if all calculation parameters were not independently derived.

d. Weekly check of cumulative dose arithmetic: Agree.

e. Physical measurement of dose rate if the teletherapy unit settings or beam modifying devices used for a patient fall outside the ranges examined during the last set of full calibration measurements: Agree.

5. Section 35.633: Independent check of full calibration measurements: Agree, but believe requirements need to be clarified:

a. The independent check must be performed by a "therapy physicist" yet he/she does not have to be listed on an NRC or agreement state license. If the individual does not have to be a qualified expert on a license, who would be considered qualified as a "therapy physicist"? The level of education, experience, professional board certification, etc., acceptable for a "therapy physicist" must be specified. For facilities with more than one therapy physicist on staff, would the NRC consider it acceptable for one physicist to independently, and with a different dosimetry system, check the calibration performed by another?

b. The dosimetry system may be one described in Section 35.360, or it may be another system that provides a similar level of accuracy and precision. There really are not any field instruements that provide a similar level of accuracy and precision equivalent to those described in Section 35.360. For example, mailed TLDs are discussed as an alternative but they typically have an accuracy of only +/-5%, whereas Section 35.632 requires the beam calibration to be within +/-3%. Therefore, the proposed section in reality requires one to use a system as described in Section 35.360. The Navy believes this requirement should be relaxed to allow use of TLDs for the calibration check.

saint francis hospital 355 ridge avenue evanston, illinois 60202 312/492-

December 1, 1987

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

This letter is in response to the proposed change listed in the Federal Register Vol. 52 No. 191 regarding 10CFR Part 35 (35.39). I would like to object to the inclusion of diagnostic doses of Iodine in these additions. If implemented it would require a patient having a thyroid uptake and scan to make an additional trip to the hospital. The study therefore, would take 3 days and have an adverse effect on patient compliance as well as lose of time from work and other inconviences. The dosage for uptake is in the microcurie range compared with millicurie therapy doses and therefore, the radiactive effect is minimal in relation to the therapy levels.

I therefore, would suggest dropping diagnostic from the proposed addition.

Sincerely,

Joseph D. Calandra, M.D.
Director, Nuclear Medicine

JDC/mb

ACNP 1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036 SNM

American College of Nuclear Physicians

202-429-5120

The Society of Nuclear Medicine

December 10, 1987

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

Dear Mr. Chilk:

On November 25, the American College of Nuclear Physicians and the Society of Nuclear Medicine requested a 30-day extension of the December 1, 1987 deadline for commenting on the proposed rule on Basic Quality Assurance in Radiation Therapy (52 FR 36942).

In subsequent correspondence from Mr. Bill Morris, Director of the Division of Regulatory Applications, Office of Nuclear Regulatory Research, we were informed that it would still be practical for the NRC to consider our comments provided that they are received on or before December 11, 1987.

Enclosed are the formal comments of the American College of Nuclear Physicians and the Society of Nuclear Medicine; we were able to finalize our comments by December 11.

We therefore withdraw our request for the 30-day extension. Thank you for allowing us an extra 10 days finalize our comments on behalf of the 12,000-plus members of the College and Society.

Sincerely,

Melissa P. Brown

Melissa P. Brown
Director of Government Relations

Enclosure

cc: Mr. Bill Morris
Dr. Anthony Tse
Mr. Norman McElroy

ACNP 1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036 SNM

American College of Nuclear Physicians

202-429-5120

The Society of Nuclear Medicine

December 11, 1987

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

ATTN: Docketing and Service Branch

RE: NRC Proposed Rule on Basic Quality Assurance in Radiation Therapy (Federal Register Vol. 52, No. 19, October 2, 1987)

Dear Sir:

On behalf of the American College of Nuclear Physicians and the Society of Nuclear Medicine, we submit the following comments in response to the NRC's October 2 Notice of Proposed Rulemaking (NPR) regarding basic quality assurance in radiation therapy. The two organizations together represent over 12,000 physicians, scientists, technologists, radiopharmacists, radiochemists and other professionals engaged in the medical and research uses of by-product material. As such, our membership will be affected significantly by actions taken by the NRC with respect to the establishment of quality assurance criteria.

The NPR sets forth proposed quality assurance criteria for teletherapy, brachytherapy and radiopharmaceutical therapy. Since our members are not involved in teletherapy and brachytherapy, our comments will be limited strictly to the proposed regulations as they relate to radiopharmaceutical therapy.

OVERVIEW

At the outset, we would like to reaffirm the deep commitment of the members of the College and Society to quality assurance in Nuclear Medicine. It is because of this commitment that the Nuclear Medicine community has an extraordinary record of protecting its patients from misadministrations. The annual rate of diagnostic misadministrations in the United States is 1 in 10,000 (derived from roughly 1,500 incidents out of the total 20 million in vivo diagnostic procedures performed each year). Moreover, from the period of November, 1980 to July, 1984, only 6 radiopharmaceutical therapy misadministrations were reported from an estimated 112,500 such procedures, giving a rate of 1 misadministration in 18,750.

The College and Society share the concern of the Commission over those rare misadministrations that do occur. We have carefully studied the finely documented cases that the Commission has made available to us, and basically agree with the Commission that inadequate training, inattention to detail, and lack of redundancy are frequently at fault. However, we disagree with portions of the proposed regulation, and two fundamental issues are involved.

The first issue is NRC's philosophical approach to the solution of a problem. The proposed NRC regulation is a "shotgun" solution, imposing substantial, time-consuming changes in the practice of Nuclear Medicine, with the intent that somehow therapeutic misadministrations would be even less frequent because of these extra "safeguards." These "safeguards", however, would create significant administrative burdens, and very likely would increase the costs of numerous procedures to patients.

Instead, the College and Society wish to approach the problem of rare therapeutic misadministrations (and diagnostic misadministrations causing doses in the therapy range) by pinpointing the major source of the problem and applying a highly specific solution. It appears that the NRC's primary concerns in the area of radiopharmaceutical therapy is with misadministrations involving I-131 sodium iodide. As we see it, the Nuclear Medicine physician must evaluate all requests for procedures involving I-131 sodium iodide prior to administration of the radiopharmaceutical, with the occasional exception of low activity doses (up to 30 microcuries) used for uptake measurements and scans. All radionuclides of iodine except I-131, and all radiopharmaceuticals containing I-131 except I-131 sodium iodide, should be omitted from this proposed new regulation. The interposition of the Nuclear Medicine physician in this manner would appear to us to be just as effective as the shotgun approach in preventing these types of misadministrations, but considerably more reasonable and practical.

The second fundamental issue concerns the attempt by NRC to dictate the practice of medicine. The NRC establishes the criteria for physician licensure to use by-product materials. The NRC may also establish criteria for removing physician licenses, such as repeated misadministrations or non-fulfillment of various license requirements. It is appropriate for the NRC to expect that the administration of I-131 sodium iodide is carried out for appropriate medical indications. It is inappropriate for the NRC to tell a Nuclear Medicine physician that he must personally examine the patient and the patient's chart, and consult with the referring physician if reasonably available. It is up to the Nuclear Medicine physician to determine what constitutes appropriate prior evaluation of a patient on a case-by-case basis. Therefore in our suggested changes to this regulation we retain the concept of appropriate

prior evaluation but omit precise details of how this is to be accomplished. In the end, this is under the jurisdiction of state tort law and malpractice courts.

We caution the NRC to avoid over-zealous obsession in the design of regulations to stop extraordinarily rare misadministrations. Perfection is not obtainable. Although ideally a regulation should be designed to prevent all misadministrations, we do not believe it is conceivable that any regulation could be designed to avoid every single human error leading to a misadministration. The challenge, therefore, is to improve where possible upon existing quality assurance criteria so as to augment, not hinder, the provision of quality medical care.

BACKGROUND: RADIOPHARMACEUTICALS CONTAINING RADIONUCLIDES OF IODINE

This section briefly describes radiopharmaceuticals labeled with radioiodine and includes approximate doses. The purpose of including this information is to convince NRC that only I-131 sodium iodide, of all the radioiodine-containing radiopharmaceuticals, should be considered in this proposed regulation. The remainder are used only for diagnosis and involve low radiation absorbed doses.

I-125, I-123, and I-131 are commonly used in the clinical practice of Nuclear Medicine. Human serum albumin labeled with I-125 is used intravenously to diagnose abnormalities of plasma volume and total blood volume, generally in doses under 20 microcuries.

I-123 as I-123 sodium iodide is used extensively for diagnostic thyroid uptakes and scans. It is administered orally in doses usually less than 500 microcuries. The absorbed dose to the target organ, thyroid, is about average for diagnostic Nuclear Medicine procedures (several rem). I-123 is also used to label orthoiodohippurate, which is employed for diagnostic renal imaging and for measurement of renal function. The dosage is up to a few millicuries, and target organ absorbed dose (bladder wall) is about a rem. Because the gamma ray of I-123 is a favorable energy for imaging and the half-life is short, it is gaining in popularity as a label for other radiopharmaceuticals. Soon we expect to have I-123-iodoamphetamine available for diagnostic brain imaging. Several millicuries will be used and radiation absorbed doses will be average to high for a diagnostic procedure (target organ 5-20 rem). I-123 is cyclotron produced. It is not by-product material, and therefore is not regulated by the NRC.

I-131 is available as orthoiodohippurate and is generally used for diagnostic renal studies in dosages of less than 500 microcuries. With normal renal function the bladder is the target organ,

with absorbed doses of about a rem. With tubular nephropathy or obstruction, the kidneys can receive an absorbed dose of several rem. A partially obstructed kidney can receive an absorbed dose that is high for a diagnostic procedure (about 20 rem).

I-131 sodium iodide is still used for thyroid uptakes and scans in many Nuclear Medicine departments, including those that cannot depend on regular air shipments of I-123 sodium iodide. A dose of 30 microcuries results in a thyroid absorbed dose of about 25-40 rem, depending on uptake and retention.

I-131 sodium iodide is used to treat hyperthyroidism (usually in doses less than 30 millicuries, but the actual activity employed is determined by the fact that we aim for thyroidal absorbed radiation doses of at least 5,000-7,000 rem.

I-131 sodium iodide has three uses in patients who have had surgery for thyroid cancer. First, it is used to ablate remaining normal thyroid tissue after surgery. Second, it is used to identify functioning thyroid carcinoma metastases in a whole body scan. Third, it is used to treat functioning metastases that are found using the scan. The dose for a whole body scan is usually in the range of 1-10 millicuries. To ablate a normal gland remnant, a dose of up to about 100 millicuries is administered. To destroy functioning metastases, dosages up to several hundred millicuries are administered. Absorbed doses to normal gland remnants and to functioning metastases are very variable, but it is attempted to achieve doses approaching 100,000 rem.

It should be clear that of all the radiopharmaceuticals labeled with radionuclides of iodine, only I-131 sodium iodide, when administered in dosages greater than 30 microcuries, is of particular concern here for either diagnostic or therapeutic misadministrations. Therefore, we believe that the NRC should limit the scope of the proposed regulation to this drug.

SECTION-BY-SECTION COMMENTS

35.2 - DEFINITIONS

The College and Society agree with the proposed definitions.

35.39(a) - ORDERING CERTAIN RADIOPHARMACEUTICALS

Delete entirely. This serves no useful purpose since the problems of misadministrations are not associated with ordering, and will interfere with the practice of Nuclear Medicine. Standing orders with additional materials as needed is the only practical

and economical way to purchase radiopharmaceuticals, at least for larger departments. I-131 sodium iodide is not ordered on a case-by-case basis. It is often ordered in a set quantity (e.g., 150 millicuries, every two weeks.)

Section 35.39(a) would do little to reduce the chance of misadministrations of I-131 sodium iodide because the proposed language with our suggested modifications in 35.39(b) places the responsibility upon the prescribing physician to ensure that the correct drug in the correct dosage is being given to the correct patient for the correct indication.

If the NRC's intent for 35.39(a) is merely to serve as a quality control "trigger" to alert the medical staff that use of a dose of I-131 sodium iodide is imminent (ostensibly to heighten awareness and attention to detail) then perhaps suggestions made by NRC staff during informal conversations that I-131 sodium iodide be stored in the radiopharmacy in a specifically designated area apart from the storage area of other radiopharmaceuticals may be less onerous than the proposed language in 35.39(a). We do believe, however, that if acceptable safeguards are incorporated into 35.39(b) (see discussion below), then 35.39(a) is unnecessary and therefore should be deleted.

35.39(b) - PRESCRIBING CERTAIN RADIOPHARMACEUTICALS

After careful review of the misadministration reports compiled by the NRC as a basis for this rulemaking, it appears that the intent of the language in 35.39(b) is to prevent misadministration of I-131 sodium iodide leading to radiation absorbed doses in the "therapy range." This section has generated the most concern among College and Society members, as it is viewed to be needlessly restrictive and does not appropriately distinguish between the diagnostic and therapeutic uses of radioiodinated radiopharmaceuticals.

The proposed rule and background information refer repeatedly to such ambiguous terms as "therapy dose" and "dose in the therapy range"; however, "therapy dose" is not defined. While the College and Society fully agree that patients should be protected from inadvertent misadministration of large dosages of I-131 sodium iodide, we are not convinced that the available data indicate that there is a problem with this type of misadministration when the intended radiopharmaceutical is a compound labeled with I-123, or is I-125 albumin, or I-131 orthoiodohippurate, none of which would deliver a "therapy dose", even if administered to the wrong patient or at doses substantially greater than their routine diagnostic dosage level.

The College and Society believe that the NRC's concerns about misadministrations of radioiodine in the therapy range could be satisfied by replacing the language of 35.39(b) with the suggested wording below:

> (b) A physician may not prescribe administration of a dosage in excess of 30 microcuries of iodine-131 sodium iodide for diagnosis or therapy or any radiopharmaceutical for therapy without first ascertaining the appropriateness of the intended diagnostic study or therapy.[1] Prescriptions for the administration of these by-product materials must be in writing, and must include the patient's name, the intended type of diagnostic study or therapy, the radiopharmaceutical, dosage, route of administration, and the name and signature of the prescribing physician.

This wording would ensure that dosages of I-131 sodium iodide, other than those used for thyroid uptake measurements or in those situations where I-131 sodium iodide is appropriate for conventional thyroid imaging, could not be given to a patient without the express written prescription of the authorized user or a physician under the supervision of the authorized user. Moreover, requiring these prescriptions to be in writing and to include the patient's name, the radiopharmaceutical, dosage, etc., simply validates what is current practice as required by state laws governing medicine and pharmacy (as well as by JCAHO standards when the practice is based in the hospital[2]) and therefore is not objectionable.

The College and Society also believe, however, that while our suggested language for 35.39(b) may not be particularly burdensome for the medium-size or large medical centers where an authorized user or physician under the supervision of an authorized user is usually present during administration of dosages of I-131 sodium iodide in excess of 30 microcuries, this proposed regulation may present special problems for small community hospitals where the authorized user or his/her physician delegate may not always be on site. We would therefore suggest an additional clause regarding the written prescription following 35.39(b) which reads:

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[1]This 30 microcurie level was recommended in "Evaluation of Diseases of the Thyroid Gland with the In Vivo Use of Radionuclides," by the Task Force on Short-Lived Radionuclides for Medical Applications. Journal of Nuclear Medicine 19:107-112, 1978.

[2]The Accreditation Manual for Hospitals of the Joint Commission on Accreditation of Healthcare Organizations (chapter on Nuclear Medicine services, see attachment).

> The authorized user or a physician under supervision of the authorized user, if not immediately available, may prescribe of a dosage in excess of 30 microcuries of I-131 sodium iodide for diagnosis, if such prescribing physician has first consulted with the referring physician. The individual receiving the telephone prescription shall record in writing all of the information designated above, as well as the date and time of the telephone prescription and the name of the prescribing physician. Such prescription shall subsequently be co-signed by the prescribing physician. A radiopharmaceutical for therapy may not be prescribed by telephone.

This suggested additional clause would prevent the inconvenience to the patient of having to return to the hospital at a later time when the authorized user is present, and would be very helpful in emergency situations.

The NRC's proposed requirement for a physician to personally examine the patient and the patient's medical record, as well as to consult with the referring physician, if reasonably available, is unnecessary once the physician is required to perform prior evaluation to establish the appropriateness of the diagnostic procedure.

The College and Society fully agree, however, that when a nuclear physician is requested to perform radiopharmaceutical therapy, it is incumbent upon him/her to review the patient's medical history to confirm that the condition for which the therapy is administered exists, and that the radiopharmaceutical dosage is appropriate. Such confirmation is often supplied by the specific information in the written request submitted by the referring physician. Such a review is appropriately mandated under the NRC proposed rules 35.43(a) and (b). A similar prospective review of requests for diagnostic and therapeutic Nuclear Medicine procedures is also mandated by current JCAHO guidelines.

35.39(c) - ADMINISTERING CERTAIN RADIOPHARMACEUTICALS

In order to more strongly emphasize the requirements for product identity and dose measurement prior to administration, the College and Society would suggest the following language for 35.39(c):

> A licensee may not administer a dosage in excess of 30 microcuries of I-131 sodium iodide for diagnosis or therapy or any radiopharmaceutical for therapy without first ensuring that its identity and activity conform with the physician's prescription.

35.43(a) through (d) - PRESCRIPTIONS, RECORDS, AND CHECKS OF MEDICAL USE FOR THERAPY

(a) The College and Society agree with the rule as proposed.

(b)(1) The College and Society agree with the proposed rule with the following modification:

> Before beginning a patient's treatment, the licensee shall verify that the authorized user or a physician working under supervision of the authorized user has personally made or reviewed, dated, and signed a written prescription in the patient's chart that identifies the body part to be treated. Any change in the prescription must also be made in writing in the patient's chart, and must be dated and signed.

(c) and (d) The College and Society agree with the rules as proposed.

35.65 - DISCREPANCIES IN RECORDS

The College and Society agree with the rule as proposed.

35.302 - ADMINISTRATION OF RADIOPHARMACEUTICAL DOSES

See our suggested rewrite of 35.39(c).

CONCLUSION

In summary, the College and Society firmly believe that the NRC's proposed rules discussed above are unnecessary. The misadministration rate is so extraordinarily small in Nuclear Medicine, we question the need for the rulemaking at all. However, if the NRC feels compelled to move forward with this regulation, we urge you to favorably consider our suggestions and comments. We offer our full assistance to the Commission in developing quality assurance criteria that balance patient protection needs with professional medical autonomy to deliver Nuclear Medicine services of the highest quality.

Sincerely,

David H. Woodbury, M.D.
President
American College of Nuclear Physicians

B. Leonard Holman, M.D.
President
Society of Nuclear Medicine

Nuclear Medicine Services (NM)

Standard		Circle One
NM.1	Diagnostic and/or therapeutic nuclear medicine services are regularly and conveniently available to meet the needs of patients, as determined by the medical staff.*†	1 2 3 4 5 NA

Required Characteristics

NM.1.1	All individuals who provide diagnostic and/or therapeutic nuclear medicine services independently, whether or not they are members of the department/service, have delineated clinical privileges for the services they provide.*	1 2 3 4 5 NA
	NM.1.1.1 All nuclear medicine diagnostic and/or therapeutic procedures are provided and performed in accordance with appropriate institutional licensure requirements and/or applicable law and regulation.	1 2 3 4 5 NA
NM.1.2	The director of diagnostic and/or therapeutic nuclear medicine services is a qualified physician member of the medical staff who is clinically competent and possesses the administrative skills necessary to assure effective leadership of the department/service.*	1 2 3 4 5 NA
	NM.1.2.1 The director of diagnostic and/or therapeutic nuclear medicine services is certified by the American Board of Nuclear Medicine or the American Board of Radiology or affirmatively establishes, through the privilege delineation process, individual qualifications comparable to those required for such board certification, or has special competence in nuclear medicine.	1 2 3 4 5 NA
NM.1.3	The responsibilities of the director of the diagnostic and/or therapeutic nuclear medicine department/service, which may be appropriately delegated, include, but need not be limited to, the following:*	
	NM 1.3.1 Establishing an effective working relationship with the medical staff, administration, and other departments/services.	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

†These services are not required for hospitals that provide only psychiatric/substance abuse services.

Circle One

NM.1.3.2 Developing or approving all department/service policies and procedures.* 1 2 3 4 5 NA

NM 1.3.3 Approving the process or processes for determining the qualifications and competence of department/service personnel who are not independent practitioners and who provide patient care services.* 1 2 3 4 5 NA

NM.1.3.4 Advising the medical staff and hospital management regarding equipment and space needs. 1 2 3 4 5 NA

NM.1 3.5 Providing consultation to physicians and other individuals with delineated clinical privileges and to other clinical departments/services, as required. 1 2 3 4 5 NA

NM.1.3.6 Maintaining a quality control program. 1 2 3 4 5 NA

NM 1.3.7 Developing comprehensive safety rules in cooperation with the hospital's safety committee and the hospital's radiation safety committee, if one exists.* 1 2 3 4 5 NA

NM.1.3 8 Recommending to the medical staff, for its approval, a source(s) for nuclear medicine services not provided by the hospital.* 1 2 3 4 5 NA

NM.1.3.8.1 There is a description of the means for providing diagnostic and/or therapeutic nuclear medicine services when they are not provided by the hospital. 1 2 3 4 5 NA

NM.1.3.8.2 When diagnostic and/or therapeutic nuclear medicine services are performed outside the hospital, the outside source(s) meets the standards contained in this chapter of this *Manual*. 1 2 3 4 5 NA

NM.1.3.9 Developing and implementing a planned and systematic process for monitoring and evaluating the quality and appropriateness of nuclear medicine services (refer to Standard NM.4). 1 2 3 4 5 NA

Standard

NM.2 There are policies and procedures to assure effective management, safety, proper performance of equipment, effective communication, and quality control in the nuclear medicine department/service.* 1 2 3 4 5 NA

Required Characteristics

NM.2.1 Policies and procedures are developed in cooperation with the medical staff, administration, nursing services, and, as necessary, other clinical departments/services, and are implemented.* 1 2 3 4 5 NA

NM.2.1.1 The policies and procedures are reviewed periodically by a medical radiation physicist. 1 2 3 4 5 NA

NM.2.1.2 The policies and procedures are revised when necessary. 1 2 3 4 5 NA

NM 2.1.2.1 Each revision is documented. 1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix

NM.2.2 The written policies and procedures include, but need not be limited to, the following:* **Circle One**

NM.2.2.1 Diagnostic and therapeutic nuclear medicine services performed at the request of individuals licensed to practice independently and authorized by the hospital to make such requests.* 1 2 3 4 5 NA

NM.2.2 2 Access to and availability of consultative diagnostic and/or therapeutic nuclear medicine services regarding appropriateness and sequencing of diagnostic and/or therapeutic procedures. 1 2 3 4 5 NA

NM.2.2.3 The prescribing of nuclear medicine (radionuclide) therapy and the supervision of the course of therapy by a qualified physician. 1 2 3 4 5 NA

NM.2.2.4 The scheduling of and instruction in procedures for the preparation of patients for diagnostic or therapeutic procedures. 1 2 3 4 5 NA

NM.2.2.5 The procedure(s) for patients who require emergency services or who are seriously ill. 1 2 3 4 5 NA

NM.2.2.6 Informed consent. 1 2 3 4 5 NA

NM.2.2.7 The preparation and administration of parenteral diagnostic agents. 1 2 3 4 5 NA

NM 2.2.8 A quality control program designed to minimize patient, personnel, and public risk and maximize the quality of diagnostic information.* 1 2 3 4 5 NA

NM.2.2.9 Implementation of Standard PL.9 through Required Characteristic PL.9.8 in the "Plant, Technology, and Safety Management" chapter of this *Manual* for all electrically and nonelectrically powered equipment used in the diagnosis, treatment, or monitoring of patients to assure that the equipment, wherever located in the hospital, performs properly.* 1 2 3 4 5 NA

NM.2.2.10 The maintenance of records on radionuclides and radiopharmaceuticals from the point they enter the hospital to the point of administration and final disposal.* 1 2 3 4 5 NA

NM.2.2.10.1 Information in the records includes, at the least,

NM.2.2.10.1.1 the date, method of receipt, identity of radionuclide, activity, and disposal; 1 2 3 4 5 NA

NM.2.2.10.1.2 supplier and lot number; and 1 2 3 4 5 NA

NM.2.2.10.1.3 identity of recipient, identity of radionuclide, activity of radionuclide administered, and date. 1 2 3 4 5 NA

NM.2.2.11 Safety policies, including

NM.2.2.11.1 the receipt, storage, transport, preparation, handling, use, and disposal of radionuclides;* and 1 2 3 4 5 NA

NM.2.2.11 2 implementation of Standard PL.6 through Required Characteristic PL.6.10 in the "Plant, Technology, and Safety Management" chapter of this *Manual* (for the management of hazardous materials).* 1 2 3 4 5 NA

NM 2.2.12 Compliance with applicable law and regulation 1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

	Circle One
NM 2 2.13 For purposes of standardizing equipment performance, radiation standards having energies equivalent to those radionuclides used in patient studies.	1 2 3 4 5 NA
NM.2 2.14 Provisions that a qualified physician, qualified medical radiation physicist, or other qualified individual*	
NM.2.2.14.1 monitors performance evaluations of diagnostic equipment on a quarterly basis;*	1 2 3 4 5 NA
NM.2.2 14.2 monitors doses administered to patients for acceptable agreement with prescribed doses;*	1 2 3 4 5 NA
NM.2.2 14.3 monitors, for validity, quantitative results obtained from procedures; and*	1 2 3 4 5 NA
NM.2.2.14.4 monitors absorbed doses of radiation in individual patients as requested by the director.*	1 2 3 4 5 NA
NM.2.2.15 Guidelines for protecting personnel and patients from radiation.*	1 2 3 4 5 NA
NM.2.2.16 The monitoring of staff and personnel for exposure to radiation.*	1 2 3 4 5 NA
NM.2.2.17 The monitoring of receipt, storage, preparation, and use areas for radionuclide contamination.*	1 2 3 4 5 NA
NM.2.2.18 Guidelines to be followed in the event of radionuclide contamination of the environment, patients, personnel, or equipment.	1 2 3 4 5 NA
NM.2.2.19 Guidelines developed in consultation with the infection control committee for the protection of staff, patients, and equipment.	1 2 3 4 5 NA
NM.2.2.20 Orientation and a safety education program for all personnel.*	1 2 3 4 5 NA

Standard

NM.3	Reports of consultations, interpretations of diagnostic studies, and radionuclide therapy procedures are included in the patient's medical record.*	1 2 3 4 5 NA

Required Characteristics

NM.3.1	Requests/referrals for diagnostic and/or monitoring and/or radionuclide therapy procedures include the study or studies requested and appropriate data to aid in the performance of the procedure requested.	1 2 3 4 5 NA
NM.3.2	Only individuals with delineated clinical privileges to perform and/or interpret diagnostic and/or monitoring procedures and supervise radionuclide therapy procedures authenticate reports.*	1 2 3 4 5 NA
	NM.3 2 1 Individuals authenticate only those reports of procedures for which they have been granted specific clinical privileges through the medical staff privilege delineation process.	1 2 3 4 5 NA
NM.3.3	Authenticated reports are entered in the patient's medical record and, as appropriate, are filed in the department/service.*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Standard		Circle One
NM.4	As part of the hospital's quality assurance program, the quality and appropriateness of diagnostic and/or therapeutic nuclear medicine services are monitored and evaluated, and identified problems are resolved.*	1 2 3 4 5 NA

Required Characteristics

NM.4.1	The diagnostic and/or therapeutic nuclear medicine department/service has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care services and for resolving identified problems.*	1 2 3 4 5 NA
	NM 4.1.1 The physician director of the diagnostic and/or therapeutic nuclear medicine department/service is responsible for assuring that the process is implemented.*	1 2 3 4 5 NA
NM.4.2	The quality and appropriateness of patient care services are monitored and evaluated in all major clinical functions of the diagnostic and/or therapeutic nuclear medicine department/service.*	1 2 3 4 5 NA
	NM.4.2.1 Such monitoring and evaluation are accomplished through the following means:	
	NM.4.2.1.1 Routine collection in the diagnostic and/or therapeutic nuclear medicine department/service, or through the hospital's quality assurance program, of information about important aspects of nuclear medicine services;* and	1 2 3 4 5 NA
	NM.4.2.1.2 Periodic assessment by the diagnostic and/or therapeutic nuclear medicine department/service of the collected information in order to identify important problems in patient care services and opportunities to improve care.*	1 2 3 4 5 NA
	NM.4.2.1 2.1 In NM.4.2.1.1 and NM.4.2.1.2, the diagnostic and/or therapeutic nuclear medicine department/service agrees on objective criteria that reflect current knowledge and clinical experience.*	1 2 3 4 5 NA
	NM.4.2.1.2.1.1 These criteria are used by the diagnostic and/or therapeutic nuclear medicine department/service or by the hospital's quality assurance program in the monitoring and evaluation of patient care services.*	1 2 3 4 5 NA
NM.4.3	When important problems in patient care services or opportunities to improve care are identified,	
	NM.4.3.1 actions are taken;* and	1 2 3 4 5 NA
	NM 4.3.2 the effectiveness of the actions taken is evaluated.*	1 2 3 4 5 NA
NM.4.4	The findings from and conclusions of monitoring, evaluation, and problem-solving activities are documented and, as appropriate, are reported.*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

NM.4.5 The actions taken to resolve problems and improve patient care services, and information about the impact of the actions taken, are documented and, as appropriate, are reported.*

Circle One
1 2 3 4 5 NA

NM.4.6 As part of the annual reappraisal of the hospital's quality assurance program, the effectiveness of the monitoring, evaluation, and problem-solving activities in the diagnostic and/or therapeutic nuclear medicine department/service is evaluated.*

1 2 3 4 5 NA

NM.4.7 When an outside source(s) provides diagnostic and/or therapeutic nuclear medicine services, or when there is no designated diagnostic and/or therapeutic nuclear medicine department/service, the quality and appropriateness of services provided are monitored and evaluated, and identified problems are resolved.*

1 2 3 4 5 NA

NM.4.7.1 The medical staff is responsible for assuring that a planned and systematic process for such monitoring, evaluation, and problem-solving activities is implemented.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Note: Refer also to the "Quality Assurance" chapter of this *Manual*.

The "Nuclear Medicine Services" chapter was approved by the JCAH Board of Commissioners in April 1986 and becomes effective for accreditation purposes on January 1, 1987.

Notes and Comments:

Bringing Care & Science to Life

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November 30, 1987

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

Attn: Docketing and Service Branch

RE: Proposed Rules 10 CFR Part 35

Dear Sir or Madam:

This correspondence is in regards to the proposed rules, 10 CFR Part 35: basic quality assurance in radiation therapy which appeared in the Federal Register, Vol. 52, 19, pg 36942-36953, October 2, 1987.

It should be noted at this time that the comments and recommendations within this correspondence are solely mine and do not necessarily represent the opinions of either my co-workers or employer.

There is no doubt that quality assurance is an integral part of both radiation therapy and nuclear medicine. Numerous organizations such as the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM), to name a few, have published guidelines, procedures and techniques for the clinical initiation of a Quality Assurance Program. Therefore, with the impetus of the above mentioned organizations, it would seem that each facility involved with the use of byproduct materials would contain a certain, but not necessarily equal, amount of quality assurance in their day-to-day patient care.

I would like to present some general comments regarding the proposed rules on 10 CFR Part 35.

1. Basis for the Proposed Regulations:

These proposed regulations has been based on the misadministration study conducted from November 1980 through July 1984. If one totals the number of reported misadministrations in that time interval as well the number of patients treated as stated in the supplementary information the results are 79 misadministrations for 658,000 patients treated with therapeutic intent. This amounts to one hundredth of one percent. This is not done to condone those misadministrations which have occurred, but to ask, have we reached a limit by which the spectrum of human errors will overshadow any number of regulations proposed or enacted.

2. Rationale for the Proposed Regulations:

The basic themes presented in the document for the cause of these misadministrations are "inadequate training, inattention to detail and lack of redundancy" (page 36943). The proposed regulations only attempt to solve the lack of redundancy problem by repetitive iterations of the same process. They do little to deal with either inadequate training or the inattention to detail. The importance to adequately train technologists, dosimetrists, physicists and physicians in quality assurance methodology cannot be overstated. Appropriate training, results in personnel who not only understand the procedure that is to occur, but also the principles and implications of the procedure. Lack of knowledge leads to inattention to detail and may accelerate the error process. By simply rechecking a calculation, it does not necessarily mean that the individual understands either the thought process or technical aspects of the calculation.

3. The Status of Quality Assurance in the Clinical Setting:

There is no attempt in the document to investigate or quantify the degree of ongoing quality assurance that exists in radiotherapy or nuclear medicine centers. It would have been of far greater value if percentages relating to the degree of quality assurance were presented. For example, a statement saying that 60% of radiotherapy institutions do not recheck basic calculations would have a far greater significance in projecting the need for these regulations than to say that one patient had their tumor depth incorrectly measured. I feel that before regulations of this scope can be enacted there must be further analysis into the state of quality assurance in clinical radiotherapy and nuclear medicine departments.

4. Responsibilities:

The diagnosis, course of treatment, prescription and clinical verification of the patient's care in radiation therapy or nuclear medicine still lies with the physician(s) involved with the patient. The proposed regulations subtract from the fact that the ultimate responsibility for patient care lies with the physician and should not be unduly placed upon the institution or technical support staff. Other individuals who are not involved in the patient decision process should not be held accountable for inadequate patient review or failure to communicate.

5. Staffing:

The proposed regulations do not adequately expound upon the need for additional personnel for the implementation of these proposed regulations. For example, a weekly arithmetic chart check and chart review is done at our own institution. Reviewing an average of 40 charts at an average time of 8 minutes per chart (including documentation) results in 5 and 1/2 hours of quality assurance review in one individuals 40 hour work week. This is not to imply that this time is not well spent because we feel that our staffing is adequate for our department needs, however, I would certainly feel more comfortable if a time analysis study was performed to determine the impact on institutions where staffing may be below acceptable limits (i.e. two technologists per treatment unit). I am particularly interested in how this would affect the so-called "free-standing clinics".

Summary:

Quality assurance should be an integral part of a radiation therapy or nuclear medicine facility. However, I firmly believe that institutions do address and solve problems as they occur in the clinical setting. Regardless of all of our good intentions, procedures and analysis, the probability of human error still exists and will be part of all of us at one time or another.

Recommendations:

In view of the preceding comments, I make the following recommendations with respect to the proposed rules on quality assurance in 10 CFR Part 35.

1. That the degree of quality assurance in clinical settings be evaluated to further define areas of need.

2. That adequate training of individuals involved with patient care be stressed.

3. That the use and need for record and verify systems in the clinical setting be evaluated.

4. That staffing be a serious consideration in the proposal of any regulations.

My final recommendations regarding these proposed rules is that they be made voluntary in nature for a minimum period of three years during which time they can be assessed via standard NRC inspections as to what degree quality assurance is being conducted in the clinical setting and that this be entered into a data base to assess the needs as they apply to both large and small institutions.

Thank you for allowing me to submit my comments on these proposed regulations.

Sincerely,

Robert Specht

Robert Specht, M.Sc.
Medical Physicist

cc: M. Eddy
W. Youngblood
C. Steiner
Files

DOCKET NUMBER
PROPOSED RULE PR-35 (19)
(52 FR 36949)

DOCKET NUMBER
PROPOSED RULE PR-35
(52 FR 36942) (59)

James G. Ledbetter, Ph.D./Commissioner

GEORGIA DEPARTMENT OF HUMAN RESOURCES

Radiological Health Section, Suite 600
Office of Regulatory Services

DOCKETED
USNRC

878 PEACHTREE STREET, N.E. / ATLANTA, GEORGIA 30309

December 3, 1987

'87 DEC -8 A9:31

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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

Dear Sir:

This letter is in response to the U.S. Nuclear Regulatory Commission's proposed rules pertaining to Basic Quality Assurance in Radiation Therapy. The following comments are being submitted in response to the questions outlined in the proposed rules under Quality Assurance - General Questions:

1). The Georgia Radiological Health Section believes the USNRC should work with Medical experts to identify the areas where misadministration problems are occuring and try and develop rulemaking that may include some National Standards to prevent such problems.

2). We agree with the definition for misadministration. We believe the definition is broad enough to encompass activities that need to be monitored or reviewed, however it is not so broad to include inappropriate activities.

3). We believe that a written request from the primary care or referring physician should be provided to the authorized user prior to initiating treatment involving the use of radioactive material.

4). We believe that if a patient is able to talk and is capable of understanding questions regarding his identity that a verbal confirmation should be obtained, as well as a check of the patient's chart, and the patient's I.D. bracelet if hospitalized. If being treated as an out patient, the patient should provide a copy of the referring physician request.

5). We believe that each licensee should establish a formal training program regarding procedures and safety precautions. The training should be required for all new employees and annually thereafter for all employees. Presently licensees regulated by our Section are required to outline their proposed training programs and confirm that initial training will be provided to all new employees, with annual refresher training for all employees. Records of the training which include subject matter, date of training and individual(s) providing the training must be maintained for our review. We believe that the U.S. Nuclear Regulatory Commission should establish minimum criteria regarding training so that uniform training requirements exist for all regulatory agencies. We also believe that a written exam to evaluate the employees knowledge prior to participating in radiation therapy could be a very useful tool to help prevent misadministrations.

Acknowledged by card
Acknowledged by card

'87 DEC -8 A9:31

6). Other regulatory, certifying, accrediting, or inspecting organizations that examine medical quality assurance in our State are JCAH - Joint Commission for Accreditation of Hospitals and HCFA who provides actual certification based on JCAH standards. The main purpose of these agencies is to establish a standard of care for patients in medical institutions.

7.) We believe that the U.S. NRC should require physicians to provide a patient with their radiation dose prescribed or given if requested. It is our belief that the prescribed dose for a given patient is no different than any other Rx prescribed by a physician. We believe information pertaining to the reason for the prescribed or given dose, and results of the procedure should also be released to the patient if requested.

8). We believe that improved and more modernized equipment as well as better trained individuals to operate such equipment, may improve the quality of performance and minimize human error.

Responses for Teletherapy and Brachytherapy:

1). The Georgia Radiological Health Section believes that physicians, physicist and technologist should be board certified in Therapeutic Radiology, Health Physics, or as a Radiology Technologist repectively, and have adequate training and experience with the materials and procedures related to teletherapy and brachytherapy.

2). In lieu of a minimum case load, the licensee/applicant should be able to demostrate ongoing training and QA reviews.

3). We believe all of the facilities have some type of Quality Assurance program; however the majority due not include such requirements as second independent checks by another individual, etc. and in general are not as comprehensive as the proposed rule regarding quality assurance.

4). We are unable to answer this question without a conference with our licensees.

5). We would benefit from a complete model quality assurance program, because we do not have such a model established.

6). Yes We believe the staff and equipment that would be needed to implement a quality assurance program are available.

7). The Radiological Health Section has no comment on this question, other than we do believe quality assurance should be included for computer software used for calculating dose distributions and to control the operation of equipment.

8). The Radiological health Section believes the following additional methods are also available for reducing the frequency or impact of human error:

a. Double checks of the computer program should be performed prior to initial use of the program for calculating an actual dose distribution for patient treatments.

b. Establish an independent second check of the sources prior to loading, preferably this check could be done by the physician prescribing the dose as well as having a second independent manual check of the computer calculated dose distribution.

We believe that if an individual is unclear as to an authorized users prescribed dose a system should be established to confirm the dose.

c. Adequate staff who are properly trained, as well as adequate training programs would help reduce the frequency or impact of human error.

We have no comments on the Section pertaining to the Standard of care. This area is regulated by another group in Georgia.

Comments Regarding Proposed Rule

The Section is interested in determining who the second independent check is to be performed by in accordance with the proposed rule.

The Georgia Radiological Health Section generally agrees with the items in this proposed rule, and we do not feel that it would create any significant problems to our licensees or our program to implement these rules.

If we can be of any further assistance in this matter, please do not hesitate to contact us.

Sincerely,

Thomas E. Hill

Thomas E. Hill, Acting Director
Radiological Health Section

TEH/SMR

S.V. HILTS, M.D., F.A.C.P.
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December 4, 1987

U.S. Nuclear Regulatory Commission
Docketing & Service Branch
No address
Washington, DC 20555

LTR
^kT 05 10
3 December 1987

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

ATTN: Docketing and Service Branch

RE: NRC Proposed Rule on Basic Quality Assurance in Radiation Therapy (Federal Register Vol. 52, No. 19, October 2, 1987)

Dear Sirs:

My apologies for the lateness of this comment. As a Past President of the American College of Physicians, I have reviewed a draft of its comments, made in concert with the Society of Nuclear Medicine. I am in agreement with their remarks about the extremely small incidence of misadministrations in Nuclear Medicine, and the increasing overregulation of the specialty compared with more hazardous branches of mdicine. My specific remarks come from the perspective of a large community hospital in a state where most Nuclear Medicine is practiced by radiologists, many of whom cover several hospitals and are not available at all times in any one of them.

Sections 35.39 and 35.43 are direct interference in the practice of medicine, an activity in which the NRC has repeatedly stated it would not engage. These regulations, if implemented, would be deleterious to patient care, would deprive some patients of the benefit of Nuclear Medicine diagnostic tests, and would directly increase the cost of the tests, in clear conflict with the stated goals of the present Administration.

Iodine has definite advantages over technetium-99m for certain

types of imaging. Iodine-123 cannot be stored because of short half-life; Iodine-131 is the only isotope which can be kept on hand for uptakes. Therefore, smaller hospitals without access to a nuclear pharmacy must stock diagnostic iodine-131 capsules if they are to offer uptake and scan. Inpatient requests are urgent, since iodine studies often must precede use of contrast agents which block uptake. Outpatients have often travelled long distances to the referring patient, and need to be started on the same day to avoid another trip. The licensee must therefore order doses without prior knowledge of patient name, much less approval of a user.

It is my opinion that the cutoff level of 30 microcuries of iodine-131 suggested by the College and Society is unreasonably low to allow for storage and delivery problems. 60 microcuries would be more practical.

The delays intrinsic in a 24-hour iodine uptake mandate that it be begun as quickly as possible. The patient radiation inherent in a diagnostic sodium iodine I-131 test simply does not justify waiting for the presence of a physician with time to go to the ward, examine the patient, review the chart (which is incomplete for several hours after admission) and certify the whole process. In most cases this cumbersome requirement would delay the beginning of the test by a day (more if the physician comes from another city, as is common in rural hospitals). Given all these roadblocks, the procedure probably will not be done -- and after the first attempt, not ordered again. The patient will be deprived of the test, and the physician of his diagnostic choices, by "regulation."

Misadministrations involving the wrong patient or wrong bottle are not correctible by any of the suggested regulations. Protection against inadvertent use of therapeutic (>1 millicurie) amounts for diagnosis, or incorrect amounts for therapy, could be addressed better by clear separation of physical form:

1. When diagnostic doses are in capsule form, there is no hazard of misidentification. Requiring such use by any institution which lacks a radiopharmacy would cover 90% of the problem.
2. If in-house preparation of liquid diagnostic doses is necessary, a dye could be added to identify them as such.

It is my strong belief that therapeutic doses, including millicurie amounts for scanning, should be personally administered by an authorized physician; this is a much more reasonable use of physician time than running out to the wards to check on diagnostic doses, and would eliminate problems due to inadequate training.

The suggestion in the ACNP/SNM comment that a second person (presumably qualified) check the label is again from the background of large institutions. A small hospital contains no other person who knows a microcurie from a millicurie, and even in a large institution doses are often administered after the hours when others are available. This is common practice in our hospital, so that patients need not lose a day's work just to get the scanning dose.

It is strongly urged that the Commission think of the effect of its regulations on other than University centers. The proposed regulations would indeed reduce the incidence of misadministrations, by making comnpliance so onerous that the procedures will not be ordered. Our charges for an iodine uptake do not include 20 to 30 minutes of physician time before giving the pill; we would have to double them, and this would price them out of the market.

The power to regulate, like the power to tax, contains the power to destroy. The use of radioiodine is a valuable facet of medical practice, and the Commission is entreated not to destroy it.

Sincerely,

S. V. Hilt MD

SVH

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Secretary:

In response to a request for comments on proposed rules as published in the Federal Register Vol. 52, No. 191 on October 2, 1987, we desire to express our views as follows.

Paragraph 35.39
(b) The thrust of this regulation appears to have significant impact on the therapeutic uses of radioiodine and probably is reasonable in restating that which is good and standard care in the medical community. The inclusion of the word "diagnosis" introduces an unwieldy, odious, and obstructionist regulation which would seriously inhibit the function of most nuclear medical laboratories doing thyroid uptake studies on outpatients. It is not medically necessary to examine a patient prior to an uptake study. Outpatients frequently do not have charts, and the referring physician has already determined that the study is necessary for his clinical management. The dose prescription can never be precise when using standard precalibrated capsules because patients rarely arrive at the precise calibration hour. It makes no difference if the capsule is worth a little more or a little less than its calibration value. The laboratory work sheet, which includes the patient's name, radiopharmaceutical dosage at the time of administration, and the route of administration, should be sufficient legal documentation of what was prescribed.

Paragraph 35.43
(a) This section is absurd, requiring authorizing users to be certain that patients referred for specific therapy by primary care physicians really require such therapy. The implication of the paragraph is that no such certainty would be needed if a patient walked in and self requested such therapy. In the common practice of nuclear medicine, decisions to use radiotherapy come from either the patient's primary physician or on the advice to private patients of the user when the user is a trained internist or endocrinologist. It would be inconceivable that a walk-in patient could request and receive radioiodine therapy with no physician intervention.

(d) This paragraph is unclear, but our interpretation suggests that a section be included in the departmental policy and procedure manual instructing departmental personnel to ask questions when the instructions are not clear. Such a directive is demeaning to mature professional workers. Indeed, departments which employ individuals too simple to know when to ask questions have problems so severe that no amount of heavy handed regulation can ameliorate or prevent.

We also believe that the lumping of radiopharmaceutical diagnosis and therapy into a common pool of regulations with brachytherapy and teletherapy must lead to confusion among the various users, and should be specifically separated by appropriate sections.

Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

David Rossman, M.D.

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(208) 232-6150 EXT 323

December 4, 1987

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

Secretary of the Commission;

I am a Technologist registered with the American Registry of Radiologic Technology (A.R.R.T.) since 1976. My specialty is therapy. In my chosen profession I have had the opportunity to work as a staff technologist, assistant chief, chief technologist and my present position of Department Manager.

I am writing in response to the Commissions proposed rules for Quality Assurance in Radiation Therapy. A copy of the Federal Register Vol 52 No 191 Friday, October 2, 1987 section 10 CFR part 35 was finally forwarded to me a few days before Thanksgiving. I realize I will not meet the December 1, 1987 dead line but I hope my comments will not go in vain.

The observations and recommendations by the NRC are at least very thought provoking. I cannot agree more with the Commissions belief in a solid uniform Quality Assurance Program. All the Radiation Oncology departments I have worked in over the years have had a genuine concern for the accurate administration of the prescribed treatment plan. There are informal if not formal systems established to minimize the possibility of error.

Cancer in itself can be emotionally stressful whether the possibility of cure is high or if the disease is in the terminal stages. Stressful to the patient and to those who provide the health care.

A 1986 A.R.R.T. Annual Report stated there are 4673 registered Radiation Therapy Technologists in good standing. This is not to mean that all the technologists are actively working nor is it to mean that all radiation therapy technologists have kept their registration current. But it implies that there is not a great abundance of qualified individuals to administer the radiation treatments.

'87 DEC -8 A9:32

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

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Many technologist face job burn out. Frequent comments are "I can't deal with the stress." "They're not paying me enough" or "The money isn't worth the pressure."

The commission posed some pertinent questions regarding: the impact on costs, minimum case loads, model quality assurance programs and staffing issues to name a few. All are very key concerns. The Quality Assurance Program itself, as proposed, is ideal however I believe serious study should be given to the availability of qualified personnel and present educational opportunities that exist nationally.

There is one reality that has not been appreciated in the NRC proposals. A high energy linear accelerator is priced any where from $600.000 to $1.3 million. The manufacturers are not concerned whether 20 patients or 40 patients a day are treated. The price remains the same regardless. To financial administrator or those who's income is effected directly on volume of patients treated, there is a great concern to treat as many patients per day, per machine as possible. This is unfortunately, an unspoken fact.

The commission mentions a minimum case load, however ignore the concept of a maximum case load per unit. With qualified personnel there are less mistakes made when 20 patients per day are treated than when 50 patients per day are treated. The technologist is allowed the luxury to read the chart,have time allotted to accurately administer the treatment and check for changes in the treatment plan.

Beverly Buck R.T.(R)(T)(ARRT) reported in Radiology Technology volume 59, No.2 November/December 1987 issue, the findings of a recent survey she conducted. The highest percentage of causes of Job Dissatisfaction and Greatest source of Stress were Lack of sufficient time to devote to each patient and Pressure to schedule additional patients. Although Beverly recognizes a low statistical data base for her conclusions I am convinced the Oregon experience is not unique to professionals throughout the field.

The Government, Insurance carriers and the public at large has voiced a strong concern for the "high cost of medicine." Hospitals, physicians and administrators are taking measures to contain costs which result on pressures to maximize revenues through volume and decrease expenses.

Before any proposed rules are implemented I recommend the N.R.C. consult with the American Society of Radiologic Technologists, the American Society of Therapeutic Radiologists and American Association of Physicists in Medicine to grasp a better understanding of the actualities and staffing patterns in the operation of a Radiation Oncology department.

The NRC's proposed rules in conjunction with the Joint Commission on Accredited Hospitals proposed rules on Quality Assurance can surely enhance the quality of patient care in Radiation Oncology.

With the present nationwide staffing crisis, I am not sure such activities can be accomplished without some incentives for individuals to enter and remain in the field.

If I can offer further assistance or clarify some of my observations and concerns please feel free to contact me.

Respectfully submitted,

Eric B. Bielinski R.T.(T)(ARRT)

Eric B. Bielinski R.T.(T)(ARRT)
Department Manager
Intermountain Cancer Center

EBB/jb

BIO-MED ASSOCIATES, INC.
4 MAIN STREET FLEMINGTON, NEW JERSEY 08822 (201) 788-9440

December 4, 1987

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

Attn: Docketing and Service Branch

Dear Sir or Madam:

I am writing to comment on the proposed regulations regarding "Basic Quality Assurance in Radiation Therapy" published in the Federal Register, Volume 52, No. 191, Friday, October 2, 1987.

I wish to comment on the proposed section 35.39 of 10CFR Part 35. References to "iodine" should specify the mass number (131). Certainly all of the procedures specified need not be followed for a diagnostic administration of Iodine-123 which is most frequently used for diagnosis, is not regulated by the N.R.C., and carries minimal risk. Examination, consultation, and written prescriptions are rarely performed for a diagnostic administration of Iodine-123.

Having the same procedure for diagnosis and therapy will increase the chance for confusing the two. If a technologist knows that written prescriptions are required for therapy only, it will be less likely to be administered to a patient intended for diagnosis only. Whereas in the reverse situation, little adverse effect would be observed if a therapy patient received a diagnostic study due to lack of a written prescription or other procedure described in 35.39.

Your consideration of my comments will be appreciated.

Sincerely,

BIO-MED ASSOCIATES, INC.

Jack J. Merkin

Jack J. Merkin, M.S.
Certified Radiological Physicist
President

JJM:ljd

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*

November 30, 1987

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

Dear Sirs:

This constitutes an NCRP Response to the Federal Register notice of Friday, October 2, 1987 on the Proposed Rulemaking for 10 CFR Part 35 which has been prepared following comments from a number of Council members. There are three issues that deserve comment with regard to the USNRC proposed rulemaking. The first issue involves the rules specifically proposed by the NRC for adoption. These rules are reasonable and can be implemented without undue hardship on most therapy facilities.

The second issue relates to those topics for which the NRC has requested comment. Many of these topics deserve extensive comment, and some of them propose actions that are unnecessary and exceptionally burdensome. For example, requiring two individuals to make independent treatment calculations from nothing more than the patient prescription is unnecessarily duplicative and wasteful of personal resources. These topics need extensive discussion, and the NRC is encouraged to establish formal linkages with scientific organizations such as the American Association of Physicists in Medicine and the American Society of Therapeutic Radiation Oncology for this purpose.

This latter suggestion should be made even more forcefully for issue 3, the establishment of a comprehensive quality assurance in medical use and a standard of care. The questions raised on pages 36952-36935 are so broad and sweeping that it is impossible to respond to them short of writing a minor thesis as a response to each. As it has in the past, the NRC should work with scientific organizations to achieve the mutual objectives of effective therapy at least risk to the patient. The approach that should be utilized is to meet and work with organizations to evolve satisfactory standards, not simply to submit responses in writing.

The goal of the NRC to improve the quality of radiation therapy is important, however, the approach of using the regulatory process is not necessarily the best. In many cases the regulations are vague and requirements are impossible to document. Various assumptions are applied inconsistently and inappropriately, and, in some cases, approach the regulatory process from the wrong perspective.

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Specific comments are as follows:

Page 36945, Sect. 35.452 and 35.652.

It seems unnecessary to require independent physical measurements of the patient by two individuals. There is little evidence that erroneous measurements are a significant source of error and they would add to workload and cost. Much more significant are errors that may arise from limiting the body part measurement to that along the central axis of the treatment beam, ignoring the fact that at other positions in the treatment field the measurements may be considerably different. Also, for the patient who loses a significant amount of weight during a course of radiotherapy, the measurements may change; this may be a more likely source of error than the initial mismeasurement.

Pages 36946 and 36949, section 35.632.

Since there is no physical reason for tray, wedge, compensator, etc. transmission factors to change with time, there is no reason for revalidation of the effect of these devices on an annual basis. It is important that they be properly calibrated and checked initially.

Page 36946.

In response to the question about dose calculation checks, the requirement to check before 20 percent of the dose has been administered in teletherapy and before 50 percent in brachytherapy is reasonable. The best method for documenting these and other checks would be to initial in the patient's record that the check has been completed. It is not necessary, however, to begin the check with the prescription and independently calculate all the dosimetry and treatment plan.

Page 36948

35.2 The definition of "computer generated dose calculation" is somewhat unclear. It obviously assumes that previous human interaction has taken place to enter the beam data required for the dose calculations into the computer program.

35.39(b) It is not clear what NRC would accept as documentation of a physician's examination of a patient and chart and the physician's consultation with a referring physician.

35.39(c) Documentation would be difficult. How would the fact that the required comparison had in fact been made be documented? 35.43(a) Documentation is a problem. Also this paragraph states that the authorized user must insure that the patient has been referred for a therapeutic procedure requiring use of the byproduct material. The radiation oncologist is a highly trained individual capable of making an independent judgement and should not be deterred by the judgement of the primary care physician.

35.43(b)[2]. The "total tumor dose" is not well defined. It should be specifically stated that this is the prescribed dose for the particular radioisotope application. From the point of view of safety, dose to critical structures (e. g., spinal cord, kidney, lung, etc.) is more important than actual tumor dose. Is "total tumor dose" minimum, maximum or average?

35.302 How is documentation of this comparison made in an acceptable way.

35.432 Should "rental" sources be given any explanation? If source strength has been measured why use this instead of manufacturer's reported strength? The sampling procedure won't detect the occasional source that loses its identifying color coding and gets "misplaced."

Page 36949

35.454. It should be specifically stated in (a) and (b) that the checks of these dose calculations should be made by a radiological physicist or dosimetrist, i.e., someone who has been trained in therapy physics and dose calculations. In general, computer dose calculations can be manually verified if corrections for heterogeneities are not made. It would seem prudent to require a prior quality control function to verify that the computer codes used to make these calculations are adequately verified against measured data.

35.633 This section seems to challenge the professional competence of the physicist. If there is a demonstrated need for a second check it can be performed by the same physicist, otherwise all of the documentation of training and certification is meaningless. Also, an independent check of output would not detect the earlier cited error in which the wedge factor was incorrect. The quality of dose calibrations should be controlled adequately by requiring that only qualified individuals perform the initial full calibration. There is a statement on page 36950 that NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients. This same professional philosophy needs to be extended to the physicist.

Another problem with this section is that the one month time limit may be difficult or impossible for some institutions. This may inflict substantial hardship on these institutions, particularly those located in relatively isolated locations.

35.654. The comments made above at 35.454 apply to parts (a) and (b) of this section as well. 35.654(d). Too vague. For example, all configurations of blocked fields cannot possibly be measured. Explain parameters or parameter values that fall outside the range of those measured in calibrating the teletherapy unit.

If there are questions about the comments we would be happy to discuss them. The NCRP would be willing to initiate further professional input on these questions if the NRC would find this helpful. Thank you for this opportunity to comment on such an important area.

Sincerely yours,

Warren K. Sinclair
President

JAS/trb

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Secretary:

In response to a request for comments on proposed rules as published in the Federal Register Vol. 52, No. 191 on October 2, 1987, we desire to express our views as follows.

Paragraph 35.39
(b) The thrust of this regulation appears to have significant impact on the therapeutic uses of radioiodine and probably is reasonable in restating that which is good and standard care in the medical community. The inclusion of the word "diagnosis" introduces an unwieldy, odious, and obstructionist regulation which would seriously inhibit the function of most nuclear medical laboratories doing thyroid uptake studies on outpatients. It is not medically necessary to examine a patient prior to an uptake study. Outpatients frequently do not have charts, and the referring physician has already determined that the study is necessary for his clinical management. The dose prescription can never be precise when using standard precalibrated capsules because patients rarely arrive at the precise calibration hour. It makes no difference if the capsule is worth a little more or a little less than its calibration value. The laboratory work sheet, which includes the patient's name, radiopharmaceutical dosage at the time of administration, and the route of administration, should be sufficient legal documentation of what was prescribed.

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We also believe that the lumping of radiopharmaceutical diagnosis and therapy into a common pool of regulations with brachytherapy and teletherapy must lead to confusion among the various users, and should be specifically separated by appropriate sections.

Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

Dennis L. Hemingway M.D
Nuc Med
Kaiser Foundation Hosp - SCPMG
4647 Zion Ave
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HOWARD V. KAVANAUGH, M.S.
PHYSICIST
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November 28, 1987

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

Federal Register/Vol.52, No 191
Friday, October 2, 1987/Proposed Rules

Nuclear Regulatory Commission
10 CRF Part 35

Basic Quality Assurance in Radiation Therapy

Comments under Section 35.454
Check of dose calculations

(b) Computer-generated dose calculations---- assure that the correct parameters and parameter values were used in the calculations.

I would like to recommend that the following be added.

For computer generated external beam programs, central axis percent depth dose and treatment times be manually calculated using the tumor depths measured on the computer plots along with other data from the tables. These values should be within ± 3% of the computer printout value.

The reason for this check is because if the disc becomes scratched or some electronic glich occurs in the program this would be a way to detect it promptly.

Thank you.

Sincerely,

Howard V. Kavanaugh

Howard V. Kavanaugh

c.c. R.D. Funderburg
Louisiana Nuclear Energy Division

Texas Department of Health

Robert Bernstein, M.D., F.A.C.P.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
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Radiation Control
(512) 835-7000

Robert A. MacLean, M.D.
Deputy Commissioner
Professional Services

Hermas L. Miller
Deputy Commissioner
Management and Administration

November 25, 1987

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

Attn: Docketing and Service Branch

Dear Sir:

Thank you for the opportunity to review and comment on proposed changes to 10 CFR Part 35 regarding quality assurance in radiation therapy and the accompanying Advance Notice of Proposed Rulemaking (ANPRM). Staff of the Bureau of Radiation Control have reviewed the rules and supporting material. We offer the following comments for consideration:

1) In the explanatory material on Section 35.633, the Nuclear Regulatory Commission (NRC) describes an alternative procedure for independent checks of teletherapy calibrations as a specialized dosimetry service available by mail. It is unclear as to the type of quality control, if any, that would be required on the thermoluminescent dosimeter check program.

2) Verification of documents required by Section 35.43 would necessitate NRC inspectors checking patient charts. This regulation may violate patients' rights to privacy.

3) Regarding question #3 in the ANPRM, we think that the NRC should require the authorized user to consult with the primary care physician before radiation is prescribed. This would be one way in which unnecessary or inappropriate levels of radiation could be prevented.

If you have any questions concerning these comments, please contact us.

Yours truly,

David K. Lacker

David K. Lacker, Chief
Bureau of Radiation Control

cc: Donald A. Nussbaumer
State Agreements Program

12/1

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R105, 2 TSE

ACMP

American College of Medical Physics

November 24, 1987

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

Dear Secretary Chilk:

The American College of Medical Physics is a professional organization concerned with the practice of medical physics. The following are comments to the U.S. Nuclear Regulatory Commission request as published in the Federal Register, Vol. 52, No. 191, Friday, October 2, 1987, under proposed rule. The questions of basic quality assurance in radiation therapy is extremely important and has been the subject of many publications. AAPM Report #13, Physical Aspects of Quality Assurance in Radiation Therapy, essentially sets the standard of practice for all aspects of radiation therapy. Report #2, Radiation Control and Quality Assurance in Radiation Oncology - A suggested Protocol, by the American College of Medical Physics supplements the information contained in AAPM Report #13. A complete overview of modern radiation oncology, including quality assurance, can be found in Treatment Planning, Syllabus: A Categorical Course in Radiation Therapy, presented at the 72nd Scientific Assembly and Annual Meeting of the Radiological Society of North America, November 30 - December 5, 1986.

Generally all efforts to improve quality assurance in radiation oncology are applauded. The possibility of making a serious error which would adversely affect even a single patient should be of great concern to all individuals associated with the delivery of this treatment modality. The final paragraph of ICRU Report #24, Determination of Absorbed Dose in a Patient Irradiated by Beams of X or Gama Rays in Radiotherapy Procedures, should be kept in mind by us all. This paragraph states that errors of 5% or more in a cumulative tumor dose may be expected to occur at a rate of 3 or 4 percent and it is very difficult to reduce the error rate appreciably below this level. It also states that the error rate in localization of the tumor may well prove to be the most significant of all. Changes in diagnostic procedures, such as CT and MRI, may improve tumor localization. However, since the delivery of radiation oncology is done by human beings, there will always be some error rate. Reported misadministrations are described in Table 1 of the NRC document. In an earlier paragraph, the number of procedures for teletherapy and brachytherapy are also presented. If one assumes that each teletherapy patient receives 30 treatments, then the reported error rate per treatment for teletherapy Cobalt 60 is approximately 2×10^{-4}. The reported error rate per procedure for brachytherapy treatments is approximately 2×10^{-5}. Clearly, these reported error rates are lower than those that actually exists. The dilemmas facing the USNRC, as well as all scientific and professional organizations active in the field of radiation oncology, is to establish reasonable standards of practice which

aide in lowering the rate of error in the delivery of the radiation dose. Considerable work has been done on this problem in the past. There are many useful standards currently available, but there are many unsolved problems. Additional useful contributions are always welcome.

As a general critique, it is felt that the proposed document presents a picture of radiation oncology as a static medical discipline in which the referring physician orders the service, in much the same way as they order a chest x-ray or a bone scan. In fact, radiation oncology is a dynamic medical specialty in which the radiation oncologist, who has been trained in the diagnosis and treatment of cancer, decides if this modality is appropriate for a particular patient and monitors the patient throughout the entire treatment course and in follow-up thereafter. Radiation is not prescribed in the same fashion as drugs are prescribed. In theory, a decision is made each day as to whether another treatment should be given to each patient. In practice, at many institutions review points are defined at which the decision to continue treatment is made. During the first part of treatment, the review points are generally widely spaced, but towards the end of treatment the decision as to whether or not another fraction is required is made on a daily basis. Since each patient responds differently to a course of radiation, the total dose may not be defined until the patient's reactions and general medical condition are evaluated.

Brachytherapy is generally not practiced in the method described in this document. Section 35.454 states that "dose

calculations are made for each teletherapy and brachytherapy patient before radiation is administered to determine how long the source must be used to deliver the prescribed radiation dose to the treatment volume." In the case of complex implants, one approach is to perform pre-implant planning to determine the approximate source length and source strengths, to perform post-catheter implantation studies including CT to help define the target volume actually implanted, to load some of all of the catheters with radioactive sources, and finally to calculate the dose rate and isodose surfaces for the purposes of determining the length of time the sources will be implanted. For simple implants, this procedure can be shortened. However, in many cases the actual implant differs substantially from the planned implant due to the complexity of the implant or the changes in the patient's medical condition. It should also be remembered that permanent implants are different from temporary implants, in that the sources are not removed and generally total dose surfaces are defined.

Most institutions have long ago established redundant systems in the calculation of radiation doses. It is true, however, that in many cases the person who is checking the initial calculation must assume that the information provided on the patient is correct. This person is able to make a judgement that the patient information is reasonable, but is not actually able to say that for this particular patient the depth chosen is the proper one. It is not clear that an NRC rule prescribing documentation "needed to demonstrate that an independent check

of data transfers and calculations had been made" would be very helpful. A simple requirement would be to define the need for an independent check and let each institution decide for themselves how they are going to provide this within their own operational context.

The observations made in section 35.65 in the second paragraph could be interpreted as insulting to the specialty as a whole and to the radiation oncologist in general. It is a medical responsibility to insure that the patient's treatment record reflects the patient's condition. It is the responsibility of the radiation oncologist to evaluate the patient, including reports of pathological samples, and to decide if radiation oncology has something to offer to this patient. The radiation oncologist does not need a clear statement from the surgeon or from the pathologist or from the referring physician to determine whether tissue should be treated. It is the responsibility of the radiation oncologist to evaluate the patient and to decide, based upon the evaluation, oncology training and the information available in the literature, if the patient is appropriate for radiation therapy.

Section 35.432 states that "the NRC believes that an independent measurement is needed to insure the information relates specifically to the source under consideration." It is impossible to do this for I-125 seeds which are encapsulated in absorbable suture material. These seeds are packaged in a sterilized condition and are generally used to suture the radioactive seeds in the open wound during surgery. In this

instance, the manufacturer's data must be taken. If not all of the seeds are used, or if some of the seeds are cut off individual sutures which are used, then is it possible to measure these seeds. However, it is not common to measure the activity of the seeds implanted. In all other circumstances, it would be possible to make this measurement. This is common practice in some institutions, but not universally accepted. It seems a reasonable practice, however, in that decisions are going to be made as to the dose delivered based upon the individual source strengths. The NRC should recognize that there is a problem for institutions in establishing calibration systems for brachytherapy sources, which are traceable back to the USNBS. The NBS is not interested in calibrating sources for individual users. In at least one incidence, it required over 18 months for the NBS to calibrate Cs-137 tube. The AAPM is in the process of establishing brachytherapy calibration facilities. However, these do not currently exist. There is at least one institution in the United States whose Ir-192 calibration is based on calibrated Ir-192 wire obtained from the French National Bureau of Standards. However, this is not normally done.

Sections 34.452 and 35.652 discuss physical measurements of patients. This is an important activity in that the dose delivered is a function of the depth to which it is prescribed. The measurement is straight forward in the use of lateral or anterior and posterior fields. It is somewhat complex when oblique fields are used. It also should be recognized that in some cases the patient's diameter changes during the course of

treatment. The precision and the accuracy of the devices used for making this measurement is generally on the order of ± 0.5 to 1.0 cm. Fortunately, the percentage depth dose tables or the isocentric tables are not a strong function of patient diameter, especially for the higher energy photon beams. For Cobalt 60, one could mismeasure a patient diameter by as much as 2 cm and still not be in violation of the NRC requirements for misadministration. In general, both the physician and the physicist examine this number to determine if it is reasonable. It can be argued that physical measurements on patients does not represent a major source of error leading to misadministration.

Section 35.454 describes mechanisms and action levels for redundant calculations for teletherapy and brachytherapy. The 20% level for teletherapy doses is extremely liberal and should not pose a problem under most circumstances. The 50% level for brachytherapy applications is more of a challenge. A complex brachytherapy application, such as a 500 seed implant for a sarcoma of a lower extremity, may require approximately 50% of the implant time to perform the initial calculations. The exact point where the dose is finally defined is based upon these calculations and thus may not be established until after half the time of the implant has elapsed. Generally, it is the more experienced personnel working on the complex implants. These are the same personnel who normally check the work of others in the more simple cases. In all cases a redundant check should be made, but it may be extremely difficult to perform this independent check within the 50% criteria. The NRC is correct in

observing that there are several methods of making this independent check and that the emphasis should be on the parameters which go into the calculation. The exact mechanism for making this independent check should not be specified. The institution should just be required to indicate that an independent check has been made. Most mistakes are probably made using incorrect factors for the calculation. Thus, a simple calculation based upon independently chosen parameters should be sufficient to determine if gross errors are present. The accuracy of the software in computer generated dose calculations is probably better than established data to check the software against. Problems are most likely to be found in the human error of inputting incorrect parameters.

It is the standard practice to review a patient's chart on a weekly basis to insure correct totaling of the dose and that directed changes have been incorporated. It is reasonable to require a physical measurement of the dose rate when a megavoltage treatment unit is used in a non-standard configuration. Certainly all the modifying devices should be checked during an annual full calibration.

AAPM's protocols have recommended an independent check of the full calibration measurement. A mail TLD service is a cheap and simple way to have this independent check. The price per beam from the service from M.D. Anderson Hospital and Tumor Institute is approximately $35. This is an inexpensive and reasonable solution and provides great reassurance to those institutions which have utilized this service for years.

Additional comments will be sent on this topic, as requested by the NRC under advance notice of proposed rule making. The deadline for this is December 31, 1987. However, the above comments are also appropriate for this. The American College of Medical Physics appreciates the opportunity to comment on these proposed rules. The American College of Medical Physics remains willing and anxious to cooperate with the USNRC in this area. As indicated earlier, quality control is a primary focus of ACMP members working in radiation oncology. Major portions of the professional lives of many ACMP members are devoted to consideration of this topic.

Sincerely,

Peter R. Almond, Ph.D.
Past Chairman

PRA:paw/121

cc: Lawrence Rothenberg, Ph.D.
Chairman, ACMP

Michael Gillin, Ph.D.

Peter R. Almond, Ph.D.
Brown Cancer Center
529 S. Jackson Street
Louisville, KY 40202

COMMENTS TO PROPOSED CHANGES TO
10 C.F.R. PART 35

II. NRC's Regulatory Program.

The regulations may be 'predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.', but the proposed rules do not apparently take the same attitude towards physicists, who have the responsibility for calibration of the equipment producing the radiation to be used on those same patients. Qualifications and experience for physicists are also detailed in the Commission's regulations. Would they not be expected to perform their duties in line with the best interests of the patients? If there is genuine concern for the patients, why are there no requirements spelled out for technologists, who operate the teletherapy units, and handle sealed and unsealed radioactive sources? It would be a simple matter to require training and certification acceptable to the Societies for Radiologic Technologists or Medical Dosimetrists.

The 'improper and careless use of byproduct material in medicine' is best controlled by organizations with personnel equipped to examine how the radiation is being used, for example, the Joint Review Commission and the American College of Radiology. N.R.C. inspections are carried out by individuals who examine the environment in which the radiation is being used, not how it is being used. Checking for compliance with regulations in no way ensures the proper use of radiation, and if the physics personnel meet the Commission's requirements, especially certification by the American Board of Radiology, such individuals are at least, if not more qualified than N.R.C. personnel to oversee the technical aspects of the medical use of radiation.

When a situation arises in which radiation has been carelessly applied to human beings, or has involved unacceptable exposure of the general public, surely the N.R.C. has the authority to ensure that the guilty persons and/or institutions will not have an opportunity to repeat the same infraction again, simply by limiting or withdrawing the person's/institution's license. The promulgation of yet more rules penalizes the vast majority of users for the indiscretions of a minority, a process that has been gaining momentum for all too long.

Quality assurance is an essential component of a radiation therapy program, but the design of such a program should be left to authorised users at each facility. The actual frequencies for checks of accumulated doses and implementation of prescription changes, along with examination of the complete therapy process by an 'outside expert', are choices that could be made by an individual, who is already charged with looking after patients interests.

The Joint Review Commission examines quality assurance programs in depth, and looks at the steps taken to correct problems that are found as a result of the program.

Section 35.43.

Requirements for the documentation of specific treatment related data does not seem to be unreasonable if this is done in such a manner that the authorised user determines how this should be achieved. From past experience, one ingredient that should be mandatory, is that each entry, prescription, calculation, treatment change, dose administered, and so on, be initialled and dated 'in ink'. This not only serves to identify the author of a treatment chart entry, in case of a subsequent need for clarification, but could also act as a stimulus for a person to seek clarification of instructions when there is any doubt as to what treatment is intended.

Section 35.432.

Independent measurement of 137-Cesium and similar sealed sources would be important because of the repeated use of such sources in a large number of patients over a number of years. Similar verification of the activity of 125-Iodine and 192-Iridium seeds would pose a problem for a facility with limited use of such sources because of the number of sources involved, the need for a reference linked to the N.B.S., instrumentation, and in the case of 192-Iridium, the encapsulation of the seeds in nylon strands.

It would be easier and cheaper for the manufacturer to initiate a method of independent checks than to expect individual users to set up their own systems.

The value of adding annual checking of sealed sources to section 35.432., would seem to be partially lost by allowing one source to be used as a representative of sources with similar strengths.

Sections 35.452 and 36.652.

The requirement 'that two individuals independently make the physical measurements of the patient' would probably reduce the chance of misadministrations from a purely statistical consideration of the situation. If a person is reliable and competent in a job, such redundancy would be unnecessary, and introduction of this type of checking could lead to laxity on the part of both persons, resulting in an increased incidence of errors.

Once again, if the authorised user has the best interests of the patient at heart, that person should be capable of judging the need for duplication of patient measurements. A good quality assurance program would indicate whether this was necessary or not.

Checking of calculations is best achieved when it is done completely independent of the original calculations. This poses problems in calculations using computers because of the time involved, availability of access to the computer, and the number of persons competent to use a computer. In the case of brachytherapy uses, the data is taken off X-ray films, and duplicate films may not provide adequate image quality if the original films are poor. If films are sent to another center for calculation, there is the problem of getting duplication of a calculation, along with the added expense.

A concern that I have in this regard, relates to the widespread use of after-loading techniques. X-ray films for calculation purposes are taken with dummy sources in position in order to verify source location, and to reduce personnel exposure. The taking of X-rays with the sources in position would seem to be warranted in view of the concern for a possible misadministration to a patient, but this would negate the safety advantage, and add to medical costs.

The imposition of time intervals for the completion of brachytherapy calculations is too restrictive. If a source application is completed in the late afternoon, it may not be possible to complete the calculations the same day, particularly if the data is transmitted to a distant center for computation. If the position of the sources appears satisfactory upon inspection of the X-ray films, delaying the calculation to the following morning would not pose any danger to the patient. This could amount to a 17 hour delay in a 50 hour application, corresponding to 34%. Once again the authorised user should be qualified to determine if such a delay is acceptable or not.

The overall idea of the time required for completing calculations being a matter for compliance or non-compliance, is abhorrent, and would obviously require records being kept. If this is in the best interests of patients, then it does not reconcile with another government department's requirement that patients be admitted the same day for gynecological brachytherapy procedures.

Section 35.633.

The regulations already require that the annual check of a teletherapy unit output be performed by a qualified individual. To require that a second individual check the first one using different instrumentation and methodology will not only increase costs, but create an atmosphere of mistrust. Instrumentation calibrations are quoted to no better than 2%, so when two individual determinations produce different results, which they undoubtedly will, especially when thermoluminescent dosimetry is used, which of the two outputs is to be selected as correct. The regulations already demand monthly checks of outputs, and these are usually reproducible to only 0.5% when performed by the same person using the same instrumentation.

The proposed change in 35.633.(b) that 'the teletherapy physicist does not have to be listed as a teletherapy physicist on an N.R.C. or Agreement State license' could also lead to disagreeable situations when the two calibrations differ by more than say 1%, the approximate correction applied for monthly decay.

This type of requirement may be reasonable within a large center with a duplication of physicists and instrumentation, but it will prove costly and difficult at facilities where outside contracts are written for physics services.

IV.Administrative Statements.

With the increase in records, and duplication of both services and instrumentation that the proposed rule making would involve, I am at a loss to understand how the Commission can certify that 'this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.' It would undoubtedly involve additional expenses, which would have to be passed on to small entities, namely patients.

Expanded N.R.C. regulations have placed increasing demands on byproduct users over the years. For example, the increased frequency of decay correction and output calibration of teletherapy units, and more recently the restriction of repairs to such units to 'qualified persons' only. There are numerous repairs that can be made quite safely by in-house personnel without interrupting patient treatment schedules while waiting for the arrival of service personnel, not to mention the expenses entailed. The lack of information on how to qualify an employee to perform repairs on teletherapy equipment is also frustrating, and an example of the issuance of another regulation without sufficient forethought.

The cost of increasing the number of inspectors to cope with the longer inspections that accompany expanded regulations, has to borne by the taxpayers.

35.65. Discrepancies in records and observations.

This would seem to infer that an authorised user would deliberately use byproduct material on a patient while knowing that a discrepancy existed. An infraction of this type would indicate that the licensee did not have the best interest of the patient in mind, and should result in strong action against the licensee.

Jack Wakley

Submitted by: Jack Wakley
Certified Radiological Physicist
Route 1, Box 39, Blue Ridge,
Virginia, 24064.

COLLEGE OF AMERICAN PATHOLOGISTS

WASHINGTON OFFICE
ALFRED S. ERCOLANO, *Director*
1101 VERMONT AVE., N.W. / SUITE 604
WASHINGTON, D.C. 20005
PHONE: 202-371-6617

December 1, 1987

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

Dear Mr. Chilk:

The College of American Pathologists (CAP) is pleased to submit comments on the proposed rule, "Basic Quality Assurance in Radiation Therapy," published Friday, October 2, 1987, 52 Federal Register 191: 36942-54. The College is a medical specialty society composed of more than 10,000 board-certified physicians who practice pathology in hospital and independent laboratories and in teaching centers.

The College supports the general aim and concepts espoused in the proposed rule for basic quality assurance in radiation therapy and commends the N.R.C. for its focus on this important area. We would like to comment specifically on two areas of the administrative requirements proposed in Subpart B of part 35 of the proposal rule.

Specifically:

1. 35.39 (a) - While the Regulatory Guide 10.8 defines a licensee as a physician, veterinarian, clinical laboratory, hospital, or medical institution (section 1.4), the sense of the usage in the proposed rules (35.39) (a), (c), and 35.43 (b) is that of an individual. This leads to considerable confusion when medical institutions are licensees, as is common. Since it is the authorized user who actually orders most radiopharmaceuticals, administers them, and makes, dates, and signs a written order on the patient's chart, not the administrative personnel of the medical institution which is the licensee, the resulting requirements are highly confusing. Accordingly, we suggest that the relevant subsections all be rewritten in a less ambiguous format.

2. We are also concerned about the application of the administrative requirements (35.39) to diagnostic radiopharmaceuticals of iodine. As written, this would require a complete quality assurance program for all radioiodine from 5 uCi of I-131 for uptake studies,

through 500 uCi of I-123 for thyroid scintigrams, to 1 -5 mCi of I-131 for diagnostic post-therapy studies of thyroid cancer. Clearly, while the use of I-131 in the latter context is a reasonable subject for quality assurance considerations, the two former items are not, and it is difficult to believe that their inclusion in an elaborate quality assurance program reflects the actual intent of knowledgeable people in the Nuclear Regulatory Commission. We suggest that some other more serviceable criterion be created to segregate radiopharmaceuticals and doses that are clearly hazardous to the patient if misadministered from those with trivial effects. Dose-based or radionuclide-based criteria might be two approaches.

In summary, the College of American Pathologists supports the proposed NRC rules dealing with basic quality assurance in radiation therapy. We have, however, reservations concerning the indiscriminate application of these rules to radiopharmaceuticals and doses that carry negligible potential for harm, and we are confused by the NRC's definitions regarding the respective roles of a licensee versus an authorized user.

We appreciate the opportunity to comment on this important issue.

Sincerely yours,

William B Zeiler, MD

William B. Zeiler, MD
President

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE

Office of the President
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November 30, 1987

Letter to the Secretary of the Commission
U.S. Nuclear Regulatory Commission
1717 H Street, NW
Washington, D. C. 20555

ATTENTION: Docketing Service Branch

Dear Sir:

Attached are comments of the AAPM on the proposed rule -- Basic Quality Assurance in Radiation Therapy -- of the Nuclear Regulatory Commission, 10 CFR Part 5, as published in the Federal Register, Volume 52, Number 191, Friday, October 2, 1987. These comments represent the carefully considered opinions of a large and highly experienced committee. We hope that they will receive your full consideration.

Sincerely,

Paul L. Carson

Paul L. Carson, Ph.D.

PLC/mhl

cc: Norman McElroy
Faiz Khan, Chairman, AAPM Radiation Therapy Committee
Gary T. Barnes, AAPM President Elect

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RADIATION THERAPY COMMITTEE
Comments to NRC on Proposed Amendments to 10CFR35
Approved by the AAPM Science Council
November 30, 1987

Page 36943, Column 3, Paragraph 4

Expense is not the reason in-vivo dosimetry is not performed routinely for brachytherapy treatments. In-vivo dosimetry for brachytherapy is not sufficiently accurate to validate tumor dose because of the steep dose gradients that occur in brachytherapy.

Page 36945, Section 35.43

The NRC recognizes that the radiotherapist may modify the prescription during the course of treatment based on the best medical care for the patient.

Page 36945, Section 35.432

The NRC should consider the recommendations of the AAPM Task Group #32 on brachytherapy source strength specification and allow this as an alternative to NCRP Report No. 41. These recommendations appear in Specification of Brachytherapy Source Strength, AAPM Report No. 21, published June 1987 by the AIP.

Page 36945, Section 35.452 & 35.652

Patient geometrical measurements used for calculation of beam-on time should be confirmed by an independent mean.

Page 36946, Section 35.454 No Comment

The recommendation for a 20 percent criterion for checking of external beam dose calculation and a 50 percent criterion for checking of brachytherapy dose calculation is reasonable.

Page 36948, Section 35.43

(a) This statement seems to imply the NRC is entering medical practice. If this requirement is adhered to a radiotherapist can not decide that a patient requires radiotherapy unless the patient has been referred specifically for radiotherapy by a primary care physician. This requirement removes the final decision for a therapy from the specialist and places it with a non-specialist. Can NRC cite any other medical speciality where this occurs? We are not clear of the intent of the NRC as to what is being recommended. The ACR should be consulted for response to this section.

(b) (3) It is not necessary to prescribe which unit the patient is to be treated, but rather, to prescribe the modality

(Co-60); the daily treatment record should reflect on which machine the patient has been treated. Therefore this should read "For teletherapy the prescription must also identify the modality to be used, the prescribed dose, and the treatment plan.

Page 36949, Section 35.632

While checking the transmission through wedges and trays on an annual basis is appropriate because a wedge may be dropped and remounted incorrectly or different thickness trays may be used, we see little is to be gained from measuring stock materials for compensators and bolus. We know of no instances when the attenuation coefficient of aluminum or wax has changed. Therefore, we recommend that 35.632 be modified to read "trays, wedges, and other permanent beam modifying device" and that selection of be dropped from "selection of beam modifying device". Elsewhere in the document, it should be stated that "Custom beam compensators should be verified by measurement of dose to at least one point beneath the compensator prior to use in patient treatment."

Page 35.633(a) add at end "for a new source".

Therapy Associates, Inc.

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November 25, 1987

Mr. Norman McElroy
Office of Nuclear Materials
Safety and Safeguards
U.S. Regulatory Commission
Washington, DC 20555

Dear Mr. McElroy:

I would like to comment on the proposed changes in 10 CFR part 35, Basic Quality Assurance in Radiation Therapy. My comments are based upon the Federal Register, volume 52, No. 191, Friday, October 2, 1987.

Item 1. I am opposed to your proposed changes to bring quality assurance into an item regulated by the U.S. Nuclear Regulatory Commission. I have been actively involved in radiation therapy quality assurance for the last twenty years, and it distresses me that the U.S. Nuclear Regulatory Commission should decide to move into QA and only provide a six week notification to the facilities that will be effected by this new change.

Item 2. I believe the time frame between publishing of this proposed change and the deadline of December 1, 1987 for making comments, is much too short and should be extended.

Item 3. Section 35.43 Prescription and records of medical use for therapy. I believe that your suggestion that a requirement of legible handwritten or typed prescriptions be entered onto the patient's chart will be unenforceable. I am curious as to how you would define what is legible and what is not legible handwriting. Also, an independent check of data transfers and calculations may be troublesome to very small facilities without staff who would be able to do a double check. In large facilities this has been a standard procedure for the last three decades.

Item 4. Section 35.432 Source strength measurements. Your proposal that sealed sources be double checked to verify the radioactive content, is contrary to the ALARA concept in radiation therapy. It will be impossible to measure the activity of 30 to 40 cesium sources without getting some radiation exposure. Furthermore, I don't have any instrumentation that would allow me to make these measurements with the accuracy that I assume you would want. I am not aware of any instrumentation that is available for this particular purpose. Finally, when we purchase our sources, they are purchased from manufacturers authorized by the NRC to provide

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this service, and I assume that the NRC have quality assurance controls built in to their manufacturing process, and that these controls would more than suffice. I am curious as to who would be a qualified expert in terms of being able to provide this service, and finally, if I don't have to use my own measured values, why do I have to go through the trouble of getting radiation exposure and continue using the manufacturer's stated values.

Item 5. Section 35.452 and 35.652 Physicial measurements of patients. Different physicians measure patients differently and have doses calculated differently. I believe that your proposed requirement that someone double check the thickness of the patient becomes an intrusion upon the priveleges of a physician practicing medicine.

Item 6. Section 35.454 Check of dose calculations and Section 35.654 Checks and measurements of dose. I have been continuously involved in double checking dose calculations and additions of patient doses for the last twenty years, so what you propose to make a mandatory requirement is neither new nor strange to the radiation therapy community. However, I believe it is best that the NRC stay out of this area and leave it to national professional organizations to set the standards acceptable to the nationwide radiation therapy community. One treatment technique that I have seen used many times, is profilactic treatment of the male breast when cancer of the prostate is treated with hormones. A very common treatment technique is three treatments of 500 rads each. Please advise how you intend to have a double check before completing twenty percent of this treatment course.

Item 7. Section 35.633 Independent check of full calibration measurements. I belive that your proposal that not one but two teletherapy physicists, be involved in the calibration of a cobalt machine, and that not one, but two, calibration instruments be used for this, is redundant and excessively expensive. I assume that as a teletherapy physicist, I have demonstrated that I can provide the calibration services required by the NRC licensing conditions, and that this should be adequate. Your suggestion of a double check is as offensive to me as it would be to a physician, if you specified that a second physician must make an independent verification of the adequacy of treatment being given to a cancer patient.

I feel very negative about these changes. Less than one year ago, chapter 35 was totally rewritten, and now the Nuclear Regulatory Commission seems to be moving with undue speed into a totally new area, where it needs to rely much more on input from individuals with strong clinical backgrounds.

Sincerely yours,

Arnold Sorensen
Medical Physicist

AS:sf

November 19, 1987

Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Docketing and Service Branch

Dear Sir:

The following are our comments on 10 CFR Part 35, Basic Quality Assurance in Radiation Therapy.

Section 35.432: Source strength measurements

1) Long half-life sources (Ra 226 and Cs 137):

There is at least one reported case of a "blank" cesium source issued by the manufacturer with a serial number and used clinically. Therefore, we feel each source should be measured before first use, not a sample from each lot. Secondly this check should be made again two years later to insure that the source has the appropriate decay for the stated isotope. We see no reason that these measurements subsequently be repeated.

2) Short half-life sources (Ir 192, I 235, Au 198):

Three samples from each batch should be checked before clinical use. It is impractical to check each seed of a , for example, 100 seed implant, and a blank seed would be clinically insignificant.

Section 35.454: Check of dose calculations

Checking brachytherapy dose calculations before 50% of the prescribed dose has been administered is desirable but not always achievable. It may not be achievable in cases in which afterloading is not used, the treatment course is short (less than three days), and the patient remains in the recovery room for an extended time.

The check of the printout of computer generated dose calculations should be made by the physician or personnel who loads the applicators.

Section 35.633: Independent check of full calibration methods

TLD will not provide the ± 3% level of accuracy and precision necessary for a check of output. We feel a second physicist should be required to check the output.

WCCF WEST COAST CANCER FOUNDATION A NON-PROFIT CORPORATION
DIVISION OF RADIOLOGICAL PHYSICS
50 FRANCISCO STREET, SUITE 200, SAN FRANCISCO, CA 94133 (415) 981-4590

Section 35.652: Check of dose calculations and measurements of dose

In the case of a second individual checking point dose calculations for a simple set up, e.g., the physician requests "8 cm x 12 cm field calculated to a depth of 5 cm for bony mets", only the physician can verify that the dosimetrist has entered the correct parameters into the computer prior to treatment or later by reviewing the port film and patient treatment record. In the case of an isodose distribution the physician verifies that the dosimetrist has created the dose distribution which matches his treatment intention. It is the operating technologist who must verify that the parameters (field size, SSD, wedge, table height, etc.) match the computer printout.

In conclusion, a completely redundant checking system requires double dosimetry personnel. There is a shortage of dosimetry personnel in the United States with the present manpower needs. Doubling the manpower needs in an attempt to decrease the already low annual misadministration rate of 8 cases per 180,000 procedures is unreasonable. We suggest that the rules demand better qualifications for dosimetry personnel and physicists (e.g., ABR certified physicists) in an effort to minimize the number of misadministrations. For example, one reported misadministration error (report AEOD/C505) was an incorrect tumor depth of 16.5 cm being used in calculations for patient treatment instead of the correct value of 11.5 cm. An error of this magnitude should have been found during the weekly chart checking.

Sincerely,

Mary Louise Meurk, FACR

Devorah H. Novack, MS

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Landow Bldg., Room 8C08
7910 Woodmont Ave
November 23, 1987

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

Attn: Docketing and Service Branch

Dear Secretary Chilk,

The Interstitial Collaborative Working Group (ICWG) is supported by the National Cancer Institute to formulate, recommend and describe techniques, clinical procedures and quality assurance practices necessary to provide a comprehensive program in interstitial brachytherapy in the U.S. The ICWG is made up of investigators from three institutions who meet at regularly scheduled intervals three times each year to carry out the work called for in their contracts. The three institutions in the ICWG---Yale University, Memorial Sloan Kettering and University of California at San Francisco---make up one of the foremost group of experts in brachytherapy in this country.

The ICWG has prepared a letter for your consideration regarding the Nuclear Regulatory Commission's (NRC) proposed regulatory requirements in the administration of brachytherapy. Their thoughtfulness in responding to the various issues shows in-depth first-hand knowledge of how the regulations would negatively impact brachytherapy administration in a radiotherapy department. I hope that you will take these comments into serious consideration in your evaluation of the proposed regulatory changes.

Sincerely,

Sandra Zink

Sandra Zink, Ph.D.
Project Officer
Radiotherapy Development Branch
Radiation Research Program
(301) 496-9360

cc: Ravinder Nath

'87 NOV 30 P3:56

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Ravinder Nath, Ph.D.
Chairman of ICWG

November 16, 1987

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

Dear Secretary Chilk,

The Interstitial Collaborative Working Group (ICWG) has reviewed the proposed rule change to 10 CFR 35 which was published in the October 2, 1987 Federal Register, Vol 52, No. 191, pg. 36942. The ICWG is supported by the U.S. Public Health Service under contracts from the National Cancer Institute. The purpose of the ICWG is to formulate, recommend, and describe the techniques, clinical procedures and quality assurance practices necessary to provide a comprehensive program in interstitial brachytherapy.

The ICWG has been studying current practices in interstitial brachytherapy for the past three years in an effort to recommend a model program to the radiotherapy community. While we concur that basic quality assurance in brachytherapy is an essential part of medical care, we believe that it is inappropriate for the Nuclear Regulatory Commission (NRC) to impose regulatory requirements which may infringe upon the practice of medicine. The NRC can require users to implement the minimum acceptable elements of an effective quality assurance program, but we believe that the proposed rules do not recognize the flexibility needed in clinical practice.

If the NRC implements the rules as proposed, regardless of their impact on medical care, and enforces an aggressive schedule of penalties and sanctions for misadministrations as currently defined, many practitioners can be expected to abandon their practice, thereby greatly reducing the availability of health care to the public.

The NRC has recognized that physicians are responsible for making decisions in the best interest of their patients. The authorized physician has the responsibility to ensure that the personnel, equipment and practices involved in the delivery of medical care meet the standards expected for their patients. Ancillary medical personnel share a similar responsibility to provide health care in accordance with current health care standards. Since most of the incidents cited in the NRC Therapy Misadministration Case Study Report of December 1985 (AEOD/C505) can be attributed to simple human errors, we believe that the proposed rules will have little impact on the number and extent of therapy misadministrations.

The NRC position that voluntary programs alone may not provide adequate assurance of public health and safety is incorrect. The number of misadministrations reported is very small when compared to the total number of therapy procedures performed per year. This low rate can be attributed to the quality assurance programs which already exist in therapy programs. Although misadministrations still occur, we doubt that the proposed rules will reduce these errors significantly. Most of the existing quality assurance programs are based upon the recommendations of professional standards committees who have an in depth understanding of the problems inherent in the clinical practice of radiotherapy. The ICWG is an example of a voluntary effort within the therapy community to establish an exacting standard of care.

To encourage progress towards a better and more uniform implementation of these standards the NRC should endorse a model program, possibly in a regulatory guide and continue to publish periodical descriptions of reported misadministrations to the therapy community so they can examine their programs for vulnerability to similar errors. Detailed regulatory constraints on therapy practices may result in a degradation of the quality of care because of reduced flexibility.

The NRC should consider the fact that the practice of medicine regularly requires the use of potentially hazardous methodologies for patient care, other than radiation therapy, without similar regulatory constraints. What is it that makes the use of radioisotopes a special case? The NRC must be aware that in the United States most radiation therapy is performed using x-ray machines which are not subject to NRC regulations. Incidents involving medical accelerators and teletherapy units are reported to the Center for Devices and Radiological Health which then notifies users of the problem in the monthly Radiological Health Bulletin. As this system works well, it is unclear as to what will be accomplished by the enactment of additional regulations that apply to byproduct material devices, and are not applicable to natural radioactivity or x-ray machines.

The NRC should also consider the fact that under the current climate hospitals are searching for methods to control costs. The costs of implementing these regulations will not be trivial. To comply with these regulations most programs will have to employ new personnel to handle increased workloads, hire outside consultants to perform independent checks, and reduce the efficiency of physicians. When these costs are multiplied by the 5,000 Agreement state licensee's and the 2,200 NRC licensee's, the true costs of these regulations become tremendous. Can these costs be shown to justify the benefits of the possible prevention of isolated incidents? The NRC does not show evidence that any individual licensee has a chronic misadministration problem which would indicate the need for regulatory measures. In each case cited by the NRC the licensee has taken appropriate measures to prevent similar events in the future. We submit that the cost/benefit ratio of these regulations cannot be justified.

In addition to these general criticisms, we have many specific reservations regarding these proposed rules, most of which are unenforceable. How does a licensee demonstrate compliance with these regulations? Much of the documentation for these regulations is contained in medical records which are privileged information. Will inspectors be allowed to examine patient charts to determine compliance? Who is to judge what is legible and unambiguous? We

know of no standards of legibility.

Part 35.43 (a) thru (d), is essentially unenforceable and impacts on medical decisions. For example, brachytherapy implants in which I-125 seeds are left in place for complete decay, the total tumor dose can be determined only after the sources are implanted. The physician must exercise his judgement at the time of implantation to determine the distribution and number of seeds needed. When I-125 implants are implanted after surgical removal of some tumors, how is tumor dose to be determined?

Part 35.65 states that a licensee may not use byproduct materials if a discrepancy in records, observations, or physical measurements are noted. What constitutes a discrepancy? How would a licensee determine when one has occurred? We find it hard to believe that any medical service would deliberately continue a therapy if a significant error was noted. How would the NRC determine that this rule has been violated?

As required by part 35.432, why must a licensee measure source strengths annually? The decay constants of all medically used sources are well known. Remeasuring source strength is unnecessarily redundant and contrary to the principal of ALARA. Quarterly inventories and semiannual leak testing requirements are adequate to ensure that sources are properly identified and have not lost activity other than from natural decay.

It is not uncommon in brachytherapy procedures (Re: 35.454) for the physician to change his prescription during the period of the implant. In this case, how can we determine when 50% of the dose has been delivered? Sometimes the desired tumor dose cannot be delivered because of limiting doses to non-involved structures. Many times there is no tumor and treatment is delivered to prevent recurrence of tumor. Treatments are sometimes prematurely terminated because of patient intolerance. Does this constitute a misadministration? The situation is similar for teletherapy procedures mentioned in part 35.354.

What would the impact of these regulations be on many small clinics which may not have the personnel to conduct these checks independently. While we believe that independent dosimetry checks are a highly advisable quality control method, it may be impossible for some programs to comply because of the national shortage of trained individuals to perform these checks. This rule could be easily ignored by having the physician certify that every patient is suffering from an emergent condition. If this occurs, who in the NRC will determine that the medical condition was not emergent?

In part 35.633, what would constitute an independent check of the output. One measurement within a specific field size and distance? Could a small clinic have a dosimetrist or technologist perform the check instead of a teletherapy physicist? It may not always be possible for a clinic to have a second physicist available within a month after a full calibration. If they cannot comply within a month, must they cease operations? Surely, this would be a detriment to patients needing this treatment.

In conclusion, we feel that these proposed rules are poorly conceived and will have little impact on preventing the misadministrations identified. In contrast, the regulatory burden they pose and the ambiguity they present in demonstrating compliance is an intolerable intrusion on the practice of

medicine. We feel that the public welfare would be better served by an NRC proposal of a model program of quality assurance which would be flexible and could be modified to suit individual situations and circumstances. The NRC should also periodically publish reported misadministrations so licensees would be alerted to potential shortcomings in therapy programs. The medical community would like to foster a cooperative relationship with the NRC to provide the best health care possible. These proposed regulations would only serve to foster an adversarial relationship to the detriment of everyone involved.

On behalf of the ICWG, these recommendations are presented for the NRC's consideration. If you have any further questions, please contact us.

Sincerely yours,

Ravinder Nath

Ravinder Nath, Ph.D.
Chairman of ICWG

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Yale New Haven Hospital
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November 24, 1987

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

Dear Secretary Chilk,

Yale-New Haven Hospital's Radiation Safety Committee has reviewed the proposed rule change to 10 CFR 35 which was published in the October 2, 1987 Federal Register, Vol 52, No. 191, pg. 36942. Yale-New Haven Hospital believes that basic quality assurance in radiation therapy and nuclear medicine is an essential part of medical care. We believe that it is inappropriate, however, for the NRC to introduce regulations which complicate but do not improve the level of medical care, increase the cost of medical care, and in many cases are unenforceable.

The NRC has recognized that physicians are responsible for making decisions in the best interest of their patients. It is the authorized physician's responsibility to ensure that the personnel, equipment and practices involved in the delivery of medical care meet the standards expected for their patients. The NRC has failed to recognize that ancillary personnel involved in medical care ethically share a similar responsibility to provide the best medical care possible. This burden is not shouldered lightly, especially when a persons' health and welfare is at stake.

The NRC position that voluntary programs alone cannot provide adequate assurance of public health and safety is unfounded. Although misadministrations occur, we believe it is doubtful that the proposed regulations will have any significant impact on the frequency and extent of occurrences. Every radiation therapy and nuclear medicine service already has a quality assurance program based upon recommendations of such groups as the AAPM, ANSI, JCAH, and other professional groups. To encourage progress towards a better and more uniform implementation of these standards, we suggest that the NRC should endorse a model program, possibly in a regulatory guide and continue to publish periodical descriptions of reported misadministrations to the therapy community. In this way, therapy programs can examine their programs for vulnerability to similar errors. Regulatory constraints on therapy practices may result in a degradation of the quality of care because of reduced flexibility.

A review of the data published in the December 1985 "Case Study Report on the Therapy Misadministrations Reported to the NRC Pursuant to 10 CFR 35.42", does not support the notion that regulations are the answer to the problems of therapy misadministrations. With consideration to the total number of radiation therapies performed during the reported monitoring period, the error rate is very low. When the number of cases with clinically adverse reactions are

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considered, the rate is extremely low. With a complex technology such as radiation therapy, occasional errors will inevitably occur. When they do occur, injured patients already have adequate recourse through medical malpractice litigation. This in itself is a strong catalyst for medical services to provide the highest standard of care.

The impact of the proposed rule may result in the withdrawal of certain procedures to reduce exposure to regulatory sanctions. Reduction in the availability of these services will result in poorer medical care for many by comparison with the few who will benefit from it.

The NRC should consider the fact that the practice of medicine regularly requires the use of potentially hazardous methodologies for patient care, other than radiation therapy, without similar regulatory constraints. What makes the use of radioisotopes a special case? The NRC must be aware that in the United States most radiation therapy is performed using x-ray machines which are not subject to NRC regulatory oversight. FDA regulations on accelerators concern only the construction and installation of such units. Incidents involving medical accelerators as well as teletherapy units are reported to the Center for Devices and Radiological Health (CDRH) which then notifies users of the problem in the monthly Radiological Health Bulletin and other documents. As this system works well for accelerators, it is unclear why we must enact special procedures because we are using byproduct materials instead of natural or electrical sources of radiation.

The NRC should also consider the fact that under the current climate hospitals are searching for methods to control costs. The costs of implementing these regulations will not be trivial. To comply with these regulations most programs will have to employ new personnel to handle increased workloads, hire outside consultants to perform independent checks, and reduce the efficiency of physicians. When these costs are multiplied by the 5,000 Agreement state licensee's and the 2,200 NRC licensee's, the true costs of these regulations become tremendous. Do these costs justify the benefits of the possible prevention of isolated incidents? The NRC does not show evidence that any individual licensee has a chronic misadministration problem which would indicate the need for regulatory measures. In each case cited by the NRC the licensee has taken appropriate measures to prevent similar events in the future. We submit that the cost/benefit ratio of these regulations cannot be justified.

In addition to these general criticisms, we have many specific reservations regarding these proposed rules, most of which are unenforceable. How does a licensee demonstrate compliance with these regulations? Much of the documentation for these regulations is contained in medical records which are privileged information. Will inspectors be allowed to examine patient charts to determine compliance? Who is to judge what is legible and unambiguous? We know of no standards of legibility.

In part 35.39 (a), (b), and (c), the regulation refers to any "radiopharmaceutical of iodine" for diagnosis or therapy as a separate category of radiopharmaceutical. This section is unclear as to whether it refers to radiopharmaceuticals containing sodium iodide or includes all radioiodinated compounds as well. Also, different isotopes of iodine are not mentioned. It is

unclear why radiopharmaceuticals of I-123, or iodinated compounds such as I-131 labeled hippuran constitute a greater hazard than any other radiopharmaceutical. If radioiodine is to be singled out, a special definition must be made to clearly restrict the regulation to radioiodine compounds which do represent a hazard if misadministered.

Section (b) of this part refers to a prescription for these radiopharmaceuticals. In many states, only a licensed pharmacist or radiopharmacist may fill a prescription. This would be cost prohibitive for most licensees. Section (c) is essentially unenforceable. How can it be demonstrated that the prescription and label were compared before administration?

Part 35.43 (a) thru (d), again is essentially unenforceable and impacts on medical decisions. For example, in permanent brachytherapy implants, where seeds are left in place for complete decay, the total tumor dose can be determined only after the sources are implanted. The physician must excercise his judgement at the time of implantation to determine the distribution and number of seeds needed. If the computed dose is subsequently found to be higher or lower than planned it is extremely unlikely that a patient would submit to a second operation for the addition or subtraction of seeds. When I-125 seeds are implanted after surgical removal of the tumor, how is tumor dose to be determined?

As required in part 35.432, why must a licensee measure source strengths annually? The decay constants of all medically used sources are well known. Remeasuring source strength is unnecessarily redundant and contrary to the principal of ALARA. Quarterly inventories and semiannual leak testing requirements are adequate to ensure that sources are properly identified and have not lost activity other than from natural decay.

It is not uncommon in brachytherapy procedures (Re: 35.454) for the physician to change or modify his prescription during the period of the implant. In this case, how can we determine when 50% of the dose has been delivered? Sometimes the desired tumor dose cannot be delivered because of limiting doses to non-involved structures. Many times tumors are surgically removed and radiation treatment is delivered to prevent recurrence of tumor; this is based on the premise that tumor cells could in fact be present but not apparent. Treatments are sometimes prematurely terminated because of patient intolerance. Do these examples constitute misadministrations? The situation is similar for teletherapy procedures mentioned in part 35.354. What would the impact of these regulations be on many small clinics which may not have the personnel to conduct these checks independently, and would have to hire consultants to do this work.

In part 35.633, it is unclear what would constitute an independent check of the output. One measurement within a specific field size and distance? Could a small clinic have a dosimetrist perform the check instead of a radiological physicist? It may not always be possible for a clinic to have a second physicist available within a month after a full calibration. If they cannot comply within a month, must they cease operations? Surely, this would be a detriment to patients needing treatment.

In conclusion, we feel that these proposed rules are poorly conceived and

will have little impact on preventing the misadministrations identified. In contrast, the regulatory burden they pose and the ambiguity they present in demonstrating compliance is an intolerable intrusion on the practice of medicine. We feel that the public welfare would be better served by an NRC proposal of a model program of quality assurance which would be flexible and could be modified to suit individual situations and circumstances. The NRC should also periodically publish reported misadministrations so licensees would be alerted to potential shortcomings in therapy programs. The medical community would like to foster a cooperative relationship with the NRC to provide the best health care possible. These proposed regulations would only serve to foster an adversarial relationship to the detriment of everyone involved.

On behalf of Yale-New Haven Hospital and the Radiation Safety Committee, these comments are presented for the NRC's consideration. If you have any further questions, please contact us at (203) 785-2950.

Sincerely Yours,

Eugene A. Cornelius

Eugene A. Cornelius, M.D., Ph.D.
Chairman, Radiation Safety Committee

Members of the Radiation Safety Committee

Michael J. Bohan, B.S. Rad. Safety Officer	Joseph Chambers, M.D. Dept. of OB/GYN	Richard Donabedian, M.D. Dir. Clinical Chemistry
Douglas Doyle, M.S. Safety & Risk Manager	George Holeman, M.A Dir., Yale Rad. Safety	Barry Kacinski, M.D. Therapeutic Radiology
Jack Lawson, M.D. Diagnostic Radiology	Eleanor O'Connor, R.N. 9-5 Head Nurse	Richard Peschel, M.D., Ph.D. Therapeutic Radiology
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Other Interested Parties

James Fischer, M.D. Chief, Ther. Rad.	Paul Hoffer, M.D. Chief, Nuc. Med.	Angela Holder, LL.M. Medicolegal Affairs

Mayo Clinic Rochester, Minnesota 55905 Telephone 507 284-2511

November 24, 1987

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

Attn: Docketing and Service Branch

Gentlemen:

We wish to comment on the proposed rule on Basic Quality Assurance in Radiation Therapy, published in the Federal Register, Vol. 52, No. 191, October 2, 1987, pages 36942-36949.

While we support the efforts of the U.S. Nuclear Regulatory Commission to reduce the probability of therapeutic misadministrations, we are concerned that the proposed rule as written will significantly increase patient care costs with little reduction in misadministrations. Also, some of the revised sections are open to interpretation and should be clarified. Comments on specific sections are given below.

Section 35.39 (a): This section requires some clarification. Does this section rule out standing orders which are required to assure the availability of radiopharmaceuticals when they are needed by the authorized user? Radiopharmaceuticals on special order or standing order are ordered at the request of an authorized user or his designee with the approval of Radiation Safety, not vice versa. It is a function of the radiopharmacy laboratory to order and have on hand radiopharmaceuticals that may be needed by the authorized user. A requirement for the authorized user to sign a requisition for radiopharmaceuticals to be ordered from a vendor will not prevent a misadministration when the radiopharmaceutical is administered.

35.39 (b): We have two comments on this section. First, the initial two words "A physician" should be changed to "An authorized user" since only authorized users may prescribe a radiopharmceutical. Second, the requirement for the prescribing physician (authorized user) to personally examine each diagnostic iodine patient and consult with the referring physician is burdensome and would significantly increase cost. We anticipate that in 1987 approximately 1600 Mayo patients (excluding patients who receive ^{131}I-sodium iodide for thyroid metastases) will receive iodine radiopharmaceuticals such as ^{131}I-iodocholesterol, ^{131}I-MIBG, ^{131}I-hippuran, ^{125}I-fibrinogen, ^{125}I-iothalamate, and ^{123}I-iodoamphetamine. Assuming one-half hour to examine the patient, review the chart, and talk to the physician, approximately 800 additional physician hours or 0.4 FTE would be required to fulfill the requirements of this section of the rule.

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We propose that the rule require an authorized user (or a physician under the supervision of an authorized user) to examine patients and charts only in cases where large dosages (e.g. 100 μCi) of ^{131}I-sodium iodide are prescribed. A requirement for examination of all diagnostic radioiodine patients, chart review, and/or consultation with the referring physician is clearly too restrictive and too expensive for the small potential gain in preventing misadministrations.

35.39 (c): As discussed above, for large dosages of radioiodine and for other therapeutic radiopharmaceuticals, we are generally supportive of this section of the rule. However, it should be noted that a prescription for a diagnostic radiopharmaceutical normally does not contain the dosage to be administered to the patient. The dosage is part of the standard operating procedure for the test. Therefore, for diagnostic levels of iodine, comparison of the prescription with the dosage on hand has no relevance. For therapeutic quantities of radioiodine it is vital to compare the prescribed quantity of radioiodine with the dosage on hand.

35.43 (a): Some of us interpret this section of the rule to require that the authorized user or physician under supervision of the authorized user make direct contact with the referring physician only in cases where it is not clear in the patient's chart that the patient has been referred for a therapeutic clinical procedure. For others this section suggests that the primary care physician determines the necessity and suitability of a therapeutic procedure that requires the medical use of byproduct material. In fact, such determination is the province of the medical specialist (physician) that is the authorized user.

35.43 (b): We have no problem with the requirement that the authorized user write, date, and sign radiation therapy prescriptions that identify body part to be treated and that prescription changes be made in writing, dated, and signed in the patient's chart. In fact, we believe this to be common practice. It is our interpretation that as a licensee we have the flexibility of establishing our own procedure for verifying that the authorized user has personally fulfilled these requirements. We suggest that an acceptable method for verification is to require that any technologist or physician make such a verification prior to initiation of treatment.

1. We believe that this section is acceptable.

2. For brachytherapy, in many cases the total tumor dose is not determined prior to treatment. In common practice a "pre-plan" is prepared by hand or computer calculations or based on clinical experience. Exact implementation of such pre-plan is rarely possible, however, due to the nature of various source applicators and individual patient anatomy the exact source geometry for most brachytherapy procedures is thus not defined until the sources are in place. Post-application dosimetric calculations of dose rates in target (tumor) tissues and normal tissues condition the radiation oncologist's ultimate "prescription" of application time and thus total doses.

3. Is prescribed dose daily or total? In many situations the final dose believed is determined by events during treatment such as reactions, complications, response. What is "Treatment Plan"? Some treatment plans are a note in the patient chart while others are descriptions of complex treatments including computer printouts.

35.65: This section is appropriate, and we support its implementation.

35.302: We interpret this section to mean that it is acceptable to compare the written prescription to the label on the syringe or syringe shield (container label). In many instances it would be impractical to compare the written prescription to the original stock container which would be located in the radiopharmceutical laboratory, not near the patient. This would be especially true for nuclear medicine departments that utilize unit doses obtained from a nuclear pharmacy.

35.432: We agree that this section is appropriate for most sources. However, we are concerned that some hospitals licensed to rent brachytherapy sources would not have the capability of verifying source strength. Would such hospitals be permitted to use the source strength reported by the supplier? Or would they be required to purchase dose calibrators which will increase treatment cost? This is impossible for ^{125}I seeds in sterile suture without compromising sterility and patient safety. It would essentially rule out the use of ^{125}I seeds in sterile suture.

35.454: The NRC should take into consideration the added personnel costs, particularly for complex, multisource implants.

35.632: This section appears appropriate, and we support its implementation.

35.633: This section refers to section 35.360. Such a section currently does not exist.

35.354: We have no comments on this section.

Thank you for the opportunity to comment on this proposed rule. We continually strive to reduce the potential for misadministrations and fully support the effort of the NRC in this endeavor. However, we must point out the importance of taking into consideration the continuing escalation of costs associated with some of these rules and emphasize that care must be taken to prevent the cost of implementation of these rules from exceeding the benefits from such rules.

Sincerely yours,

Richard J. Vetter

Richard J. Vetter, Ph.D.
Radiation Safety Officer

Glenn S. Forbes

Glenn S. Forbes, M.D.
Chairman, Radiation Control Committee

jlm

Lexington Radiation Therapy Center

Oscar A. Mendiondo, M.D.

November 25, 1987

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

ATTN: Docketing and Service Branch

Dear Sir:

These are comments submitted as requested in reference to proposed ruling on basic quality assurance in radiation therapy.

It is not clear from the ruling if this would apply only to Cobalt-60 teletherapy services. I believe quality assurance is necessary for every type of radiation used and I would therefore suggest that this ruling be applied not only to Cobalt-60 units but also to Linear accelerators, cyclotrons, superficial x-ray machines and, of course, all types of sealed radioactive sources for interstitial or intracavitary implants.

In section 35.43, prescriptions and records of medical use for therapy, it is indicated that if there is a primary care physician, the authorized user shall ensure that the patient has been referred for a therapeutic clinical procedure that requires the medical use of byproduct material. I believe it is unwise to make treatment dependent upon the decision of the primary physician who may not be acquainted at all with the need for using a byproduct material. The responsibility of such treatment should be only the responsibility of the authorized user. All the other points in section 35.43 make perfect sense. Documenting compliance is, however, a difficult subject, and possibly there is little else to do but to audit patient's charts. The legal implications of this may, however, be quite significant.

Sections 35.452 and 35.652, physical measurements of patients, suggests requiring that two individuals independently make the physical measurements of the patient that are needed for dosimetry purposes. The same result would possibly be obtained by a single individual repeating measurements and using the median value. Section 35.454 requires double checking of all calculations. It is requested that calculations be done before 50% of the prescribed dose has been administered. In our office, all calculations are checked before the second treatment is given, by an individual who did not participate in the initial calculation. This should not entangle the operation of any department but does provide for better quality. Documentation is provided in each patient's chart since all the initial calculation and the second calculation must be made by different individuals who must sign and date their entries.

Section 35.354, checks of dose calculations and measurements of dose, requires the licensee shall check dose calculations for accuracy before 20% of the prescribed dose has been administered. Again, that is a good parameter of quality assurance and there should be no problems complying

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with it. Weekly checks of daily arrhythmic calculations should be standard in every therapy department. It is suggested that if the patient's dose calculations include parameters or parameter values that fall outside the range of those measured in calibrating the teletherapy unit, the licensee shall make a physical measurement of the dose rate to be administered to the patient. In our practice, the physical measurement of the dose rate is made for every patient and for every treatment port. There is very simple instrumentation available for those measurements and, I believe, there is no better way to check that everything has been done correctly but to actually measure in the patient the calculated dose. I am happy to say that after 4 1/2 years of practice in my office, treating 600 new patients every year, there has not been a case of significant misadministration of therapy, mainly because the actual dose delivered to the patient is measured for every patient and every treatment port with the first treatment. That independent dose measurement is a check of physical calculations and dosimetry and as well of the interposition of beam modifying devices such as wedges and compensators in the treatment beam. I believe that is the mainstay of quality assurance.

Implementation of requirements for quality assurance is indeed a difficult problem. Certainly, accreditation of practices by audit would seem to be the only way to verify that quality assurance programs have been put into effect.

My main point of disagreement is that of the possibility of requiring that an authorized user actively consult with the primary care physician before prescribing radiation or deciding that radiation is not needed. I want to emphasize again that it is the responsibility of the authorized user, in my case the radiotherapist, to decide when radiation is necessary and how it should be administered. Primary care physicians are usually not acquainted with the care required by patient's with cancer and in no way should that decision be given to anybody else than the responsible radiotherapist. We are requested to see patients in consultation and to advise on treatment, and in no way should we become pharmacists of radiation by simply implementing what somewhat else requests.

Medical records are already open to patients, and, therefore, the NRC should not make a special case of physicians having to provide patients with a record of the radiation dose prescribed and/or given.

I don't believe that minimum case load parameters should be set. Up to this point, most radiotherapy is done by radiologists or radiation oncologists certified by the American College of Radiology, and, therefore, there are already certain standards that have to be met. Our speciality is different from surgery in that manual dexterity is only infrequently a necessary element and where procedures are very standard. Caseload,

therefore, seems to be less of a requisite than good judgement and thorough knowledge of medical, physical and biological aspects of neoplastic disease.

As far as the key elements of a quality assurance program is concerned, clarity of prescription, documentation of everything done and actual measurement of dose delivered to the patient seem simple and sufficient to prevent most of the problems that have motivated the NIC to deal with this subject.

Sincerely,

Oscar A. Mendiondo, M.D.

OAM/jb

cc:
Mark L. Mays
Supervisor, Radioactive Material
and Environmental Monitoring Section
Radiation Control Branch
Cabinet for Human Resources
Department for Health Services
Frankfort, KY 40621

DOCTORS MERLIN and HAYMAN
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November 27, 1987

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

Attention: Docketing & Service Branch

Dear Sirs:

I am in receipt of the proposed rules published in the Federal Register Friday, October, 2, 1987 regarding basic quality assurance in Radiation Therapy. I am in general agreement of virtually all of the proposed rules which you recommend. In fact, in our institution and in most institutions, virtually all of these suggestions are already implemented. For example, we have an independent individual check the math, written prescription plans are required, etc.

There are a couple of areas in the rules which I have difficulty with and believe that it will be difficult for institutions to comply with. In Section 35.454 and Section 35.654 there is the question of checking of dose. Certainly on external irradiation doses these should be checked by a second individual and I believe that the 20% requirement is adequate. I do not believe that an independent Physicist or Dosimetrist needs to make these checks. In our institution we have a number of trained Radiation Therapy Technologists and a Dosimetrist as well as consulting Physicists. It is our policy that calculations are made by one person and then checked by a second person prior to the third treatment being given.

The biggest problem will be in brachytherapy. As you all point out, most temporary implants are only left in two to three days. By the time the computer generated dosimetry plans are produced by our onsight Physicist/Dosimetrist, at least a full day has passed. The logistics of bringing in an independent Physicist to double check that the source strength is correct and that the computer program has been run properly seem insurmountable. In my area there are other Physicists available but their primary comittments are to their facilities and not to mine. To get a Physicist here in that short a period of time would be extremely difficult. Secondly, the Physicist may not be familiar with our computer and may require data be entered on his computer. We cannot assure that, even if a second Physicist could be obtained, that he will deliver to us within that prescribed time a reasonable check of these doses.

It should be pointed out that many localities only have one Physicist or Dosimetrist in their area. How can a small town facility which has no nearby physics support comply with this particular proposed rule.

You point out that licensees perform approximately 50,000 brachytherapy

treatments annually. Another problem which I forsee is in payment of an independent check. It is hard for me to believe that the NRC will be responsible for the payment to this second individual. The hospitals and freestanding centers cannot absorb this cost so they will undoubtedly be passed on to third party carriers. Approximately one-half the patients that we see are Medicare patients and I can see that this regulation will result in over $3 million dollars in additional billings to Medicare on an annual basis to satisfy this requirement. As you know, Medicare is in deep trouble and is already implementing numerous cost-saving measures. While I realize that the quality of care is difficult to measure in dollars, I bring this up simply to point out that the cost of this one single item and the logistics of this one single item lead me to the inevitable conclusion that there will be widespread non-compliance with this proposed rule. I strongly recommend that you all reconsider what other alternatives may be available other than an independent check of the brachytherapy calculations.

Section 35.663 which would require an independent check of full calibration measurements to a much lesser degree also brings up the same problems. Some places may have difficulty in getting a Physicist into their area, there will be added cost. For this particular measurement, however, I am in full agreement that this should be done. An incorrect measurement on a teletherapy machine could result in improper doses given to large number of patients and the proposed rule certainly would reduce that to a minimum. On the other hand, an improper calculation on a brachytherapy case would only deliver an improper dosage to one patient.

All in all, I believe that the efforts on the part of the NRC are to be applauded. I believe that there will be a significant amount of non-compliance with the brachytherapy rule in its present form.

Sincerely yours,

Carl S. Merlin, M.D./nmg

Carl S. Merlin, M.D.
Medical Director
Radiation Therapy
Mercy Hospital of New Orleans

CSM/nmg

cc: Robert D. Funderburg
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Baton Rouge, La. 70898

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November 27, 1987

Addendum to Letter to Nuclear Regulatory Commission

In addition to the discussion in the body of the letter, it occurs to me that many people have afterloading remote devices which carry high intensity radioisotopes. In these cases, the isotopes are left in anywhere from ten minutes to one hour time. It seems to me to be a very difficult problem to get an independent Physicist in for this short a period of implantation to double check the source strength and the computer dosimetry.

CSM

CSM/nmg

RADIATION ONCOLOGY 744-2071
LaFORTUNE CANCER CENTER

ST. JOHN MEDICAL CENTER • 1923 SOUTH UTICA AVENUE • TULSA, OKLAHOMA 74104 • 918 / 744-2345

November 27, 1987

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

ATTN: Docketing and Service Branch

I would like to comment on the proposed rules changes for 10CFR Part 35 entitled, "Basic Quality Assurance in Radiation Therapy:

Section 35.65. The regulations need to recongnize that persons of widely different skills and education participate in the treatment of radiation therapy patients. What is an obvious discrepancy for one person may not be obvious at all to another. Many types of errors should be obvious to everyone while others may be obvious only to a physicist.

Section 35.452 and 35.652. The depth at which a patient's dose is calculated is merely a way of weighting the dose so that patients of different size receive the same dose. For single fields the depth of dose calculation is part of the physician's prescription and it should also be part of the prescription for parallel opposed fields. The physician should be responsible for verifying that the depth of dose calculation is correct.

Section 35.454. This institution uses an old Nuclear Medicine dose calibrator to check the intracavitary sources selected for use in a particular patient prior to their being after-loaded into the patient. Initially, the dose calibrator was adjusted so that its reading would agree with the calibratated value of a particular source. Therefore, this is not a calibration check of the sources but merely a check that the total activity actually being loaded agrees with the sum of all source strengths being used. The actual after loading apparatus is checked after all the sources have been inserted rather than each individual source. While this does not verify that the indidivudal sources are in the correct relative position, it does verify that the total activity is correct. This procedure has not resulted in a significant increase in employee exposure.

Section 35.633. Requiring that the results of each annual calibration be verified by an independent physicist (or TLD service) seems excessive.

For a physicist, the most likely time of making an error that could significantly effect a large number of patients is the initial calibration of a new source. If this is done correctly than the monthly spot checks and annual calibration merely confirm the first calibration (assuming no problems with the teletherapy equipment or calibration equipment).

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A more reasonable requirement would be for independent confirmation at the time of the initial calibration of a new source and whenever a calibration is performed due to the measured output being more than 3% different from the calculated output.

The accuracy of tray and wedge transmission factors could be improved if the manufactures would give an appropriate value for each wedge or tray so that physicists would have something to compare their measured values with.

Keith M. Jones, PhD

Keith M. Jones, Ph.D.
Radiation Physicist

KMJ:cam

MALLINCKRODT INSTITUTE OF RADIOLOGY
AT WASHINGTON UNIVERSITY MEDICAL CENTER

RADIATION ONCOLOGY CENTER

November 20, 1987

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

RE: NRC Quality Assurance Proposal to 10 CFR Part 35

In general, regulations of this type do little to improve overall quality assurance at facilities that are practicing good radiation therapy. Most of the various misdaministrations that have occurred were the result of human error and quality assurance procedures were in place and if they had been correctly followed, would have prevented the mistake. On the other hand, regulations are necessary to require more onsite services and to ensure that duties are not delegated to poorly trained individuals. Concerning the proposed NRC regulations:

1. Section 35.39 - Ordering, prescribing and administering certain radiopharmaceuticals. The discussion portion of the proposed rules indicate that the NRC would require close participation of the nuclear medicine physician in those cases involving the use of radiopharmaceuticals that are clearly hazardous to the patient if misadministrated. I do not understand this, since a board certified radiation oncologist is an authorized user of radiopharmaceuticals for therapeutic purposes. I suggest to change the wording of para 35.65 as follows: The new rule would require that a physician cannot prescribe a radio-pharmaceutical for therapy without personally examining the patient and the patient's chart and consulting with the referring physician if reasonably available. These are very reasonable and reflect minimal standard of medical care.

2. Section 35.43 - Prescription and records of medical use for therapy. This rule will require that a written (and signed) prescription be made before therapy can begin and that any changes be in writing, dated and signed. In addition, the licensee will be required to instruct all workers involved in the radiation therapy process orally and in writing to request clarification from the prescribing physician if any element of a prescription or other record is unclear, ambiguous or apparently erroneous. The NRC believes that dosimetrists or technologists are disinclined to request clarification from the physician. This rule could leave the licensee open for a citation or fine because if a misadministration occurs it typically will be the result of human error or likely a miscommunication or a misunderstanding of the treatment prescription.

3. Section 35.65 - Discrepancies in records and observations. This rule would require that when a discrepancy is noted, it must be clarified before therapy can be continued. The NRC makes a point that if the licensee fails to take reasonable clarifying actions and the discrepancy results in misadministration then a citation will be issued under this section. I assume the rule is being proposed to "give the NRC more teeth" in their monitoring of misadministration efforts. When a misadministration happens we would be better off if that information is openly shared with the radiation oncology community without risk of unfavorable publicity and fines.

Please reply to: (Check one)

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4. Section 35.432 - Source strength measurements. This rule would just require that independent measurements of source strength be made on sealed sources. This particular requirement is very reasonable.

5. Sections 35.452 and 35.652 - Physical measurements of patients. The NRC is considering requiring two individuals independently make physical measurements of the patient. I think this is the kind of redundancy that adds very little to the overall QA process and increases costs. I believe it is reasonable to have these determinations checked by a second individual and see if they fit reasonable standards. This is in fact what we do now in our chart check review.

6. Section 35.454 - Check of dose calculations and Section 35.654 - Checks and measurements of dose. The NRC proposes that a check of dose calculations be made before 20% of the dose has been administered for external beam therapy and 50% of dose for a brachytherapy patient. These are very conservative numbers, e.g. for 5000 rad treatment, the check would have to be made before 1000 rad was delivered, which would be about 5 treatments. I think the concept of having dose calculation checked by a second person is good practice. We routinely do this.

7. Section 35.636 - Full calibration measurements. This rule would require measuring the effects of beam modifiers (wedges, bolus, comp. filters, etc.) on output on a yearly basis. This is just good practice.

8. Section 35.633 - Independent check of full calibration measurements. The rule will require an independent check of the full calibration within 30 days. Just more redundancy. Little gain versus overall costs.

Sincerely,

Carlos A. Perez

Carlos A. Perez, M.D.
Director
Radiation Oncology Center

CAP:mjh

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Secretary:

In response to a request for comments on proposed rules as published in the Federal Register Vol. 52, No. 191 on October 2, 1987, we desire to express our views as follows.

Paragraph 35.39
(b) The thrust of this regulation appears to have significant impact on the therapeutic uses of radioiodine and probably is reasonable in restating that which is good and standard care in the medical community. The inclusion of the word "diagnosis" introduces an unwieldy, odious, and obstructionist regulation which would seriously inhibit the function of most nuclear medical laboratories doing thyroid uptake studies on outpatients. It is not medically necessary to examine a patient prior to an uptake study. Outpatients frequently do not have charts, and the referring physician has already determined that the study is necessary for his clinical management. The dose prescription can never be precise when using standard precalibrated capsules because patients rarely arrive at the precise calibration hour. It makes no difference if the capsule is worth a little more or a little less than its calibration value. The laboratory work sheet, which includes the patient's name, radiopharmaceutical dosage at the time of administration, and the route of administration, should be sufficient legal documentation of what was prescribed.

Paragraph 35.43
(a) This section is absurd, requiring authorizing users to be certain that patients referred for specific therapy by primary care physicians really require such therapy. The implication of the paragraph is that no such certainty would be needed if a patient walked in and self requested such therapy. In the common practice of nuclear medicine, decisions to use radiotherapy come from either the patient's primary physician or on the advice to private patients of the user when the user is a trained internist or endocrinologist. It would be inconceivable that a walk-in patient could request and receive radioiodine therapy with no physician intervention.

(d) This paragraph is unclear, but our interpretation suggests that a section be included in the departmental policy and procedure manual instructing departmental personnel to ask questions when the instructions are not clear. Such a directive is demeaning to mature professional workers. Indeed, departments which employ individuals too simple to know when to ask questions have problems so severe that no amount of heavy handed regulation can ameliorate or prevent.

We also believe that the lumping of radiopharmaceutical diagnosis and therapy into a common pool of regulations with brachytherapy and teletherapy must lead to confusion among the various users, and should be specifically separated by appropriate sections.

Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

Michael S. Kipper, M.D.
2095 W. VISTA WAY
SUITE 109
VISTA, CA 92083

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

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Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

Samuel L. Kipper, M. D.
Medical Director
Department of Nuclear Medicine
Tri-City Medical Center
4002 Vista Way
Oceanside, CA 92056

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

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Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

Richard L. Cole Jr. M.D.

Richard L. Cole Jr. M.D.
11275 Pabellon Circle
San Diego, CA. 92124

November 27, 1987

Secretary of the Commission
U.S. Nuclear Regulatory Commission
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ATT: Docketing and Service Branch

David L. Laven, CRPh, FASCP
Director, Nuclear Pharmacy
Nuclear Medicine Service (115)
P.O. Box 636
VA Medical Center
Bay Pines, Florida 33504

RE: Basic Quality Assurance in Radiation Therapy
(Proposed Rule- FR36942-36949, October 2, 1987)

Gentlemen:

I am offer the following thoughts and comments concerning your Proposed Rule for Basic Quality Assurance in Radiation Therapy. Being that I am principally involved with only radiopharmaceutical therapy, I will limit my discussion to this area.

First, I agree with the Commission that a 'lack of redundancy' in record-keeping and dispensinf records (I presume) means that there exist no independent mechanism for detecting errors. Furthermore, I also concur with the Commissions observation that, all too often, the pattern exists for the ordering of patient studies from primary care physician directly to nuclear medicine technologist (with ultimate dosing of patient) with minimal interaction by the nuclear medicine physician.

The Joint Commission on the Accreditation of Hospitals strongly suggests within the Nuclear Medicine Standards that:

"In striving to assure the optimal degree of quality, appropriateness, and safety in the provision of nuclear medicine services, the director shall document the review and evaluation of the services provided."

Embedded within this statement is, what the NRC seeks to obtain within its proposed rule, namely, that a nuclear medicine physician shall review patient requests for studies in terms of appropriateness, etc.

Within the text of the proposed rule, I also agree with the Commission that an extra measure of safety is necessary to avoid duplication of situations whereby patients scheduled to receive Iodine I-131 in diagnostic doses (i.e. capsules) are not inadvertently given therapeutic amounts instead, and vice versa.

However, use of an 'independent check' can in many situations place an unecessary burden on the timing of staff personnel relative to other work assignments, etc. Most certainly this will be the case if the NRC upholds its opinion that the Proposed Rule be applied to all iodinated radiopharmaceuticals, regardless if the agent is to be used for diagnosis or therapy as implied in Section 35.39(a).

As a practicing Nuclear Pharmacist, I have established a recordkeeping system that adequately tracks for, and allows for the detection of errors in radiopharmaceutical ordering, preparation and dispensing. Many Nuclear Pharmacist whom I know or have worked with over the past 10 years, apply similar principles within their own recordkeeping systems.

Commercial Nuclear Pharmacies also employ rather extensive recordkeeping measures. However, there is a loophole in this scenario, and it is this which raises concern in my mind, and I presume the NRC as well.

What about the situations where radiopharmaceuticals are utilized in-house, but are not acquired from a commercial nuclear pharmacy, nor are they prepared by a hospital-based nuclear pharmacist? I have come to realize that within the scope of the training programs for nuclear medicine technologist, that emphasis on radiopharmaceuticals and good record-keeping systems is not what it should be. As a consequence, less than optimum systems may be developed and utilized that lack the 'degree of redundancy' that permits the detection of potential error situations.

Recognition of this problem is one thing, but again, in situations where this applies, staffing patterns may negate the use of 'independent checks' via second observer dose calculation, assay, recordkeeping, etc. Therefore, I would urge the NRC to reconsider its promulgation of this concept.

Second, restriction concerning the ordering of iodinated radiopharmaceuticals without the prior consent of the authorized user is too inflexible to allow for application in all situations. For almost two decades, nuclear medicine technologists and nuclear pharmacists have been placing orders for radiopharmaceuticals. Given the number of doses ordered and administered, relative to the documented instances of misadministration, the percentages are extremely small. With traditional pharmaceutical therapy, the same claim of excellence most certainly cannot be found.

Independent action with regards to the ordering of radiopharmaceuticals should remain as a professional activity of both nuclear pharmacists and nuclear medicine technologists. However, in therapy situations, it is not unreasonable to assume that a nuclear medicine physician has completed his consultation for the request of a given patient study, and thus, alerts either the technologist or pharmacist to acquire the necessary material. This type of process would be in keeping with what the JCAH implies in its Nuclear Medicine Standards. No extraordinary measures should be required concerning the ordering of diagnostic amounts of iodinated radiopharmaceuticals!

In summary, I can most certainly agree with some of the concerns NRC has expressed in its Proposed Rule concerning radiopharmaceutical therapy, and the relationship of various health professionals and the role they play relative to the patient. However, I disagree with the intent of applying suggested safeguards for therapeutic amounts of iodinated radiopharmaceuticals to all iodinated radiopharmaceuticals, particularly those of routine diagnostic dosages. Concern should be primarily limited to therapeutic radiopharmaceuticals. And of course, emphasis for the proper education and training of nuclear medicine technologists with regards to radiopharmaceuticals and good recordkeeping practices could be mentioned to the appropriate groups, such as CAHEA (the accrediting body for nuclear medicine technology programs).

Sincerely yours,

David L. Laven, CRPh, FASCP

ECOLOGY/ALERT
BOX 621
BLOOMSBURG 17815

Nov 25 -87

E Nemethy, Sec'y

Re: Proposed rule - Basic Quality Assurance in Radiation Therapy
Fed Reg Oct 2-87, p 36942

Sec'y - NRC

ATT: DOCKETING & SERVICE BRANCH

Gentlemen -

We offer the following suggestions in hopes one or two of them may help prevent errors in administering radiation treatment:

1 - Except in life-threatening cases, prohibit oral Rx.

2 - Require all Rx to be TYPEwritten - on standardized forms - by the prescribing physician.

(Would it be useful to have Rx forms in different colors - for example, white for diagnostic; pink for teletherapy; yellow for brachytherapy?)

3 - In lieu of symbols like / and x, have a line pre-printed on Rx forms: "(100) rad per (day) for (3 days)"

4 - To prevent administration to the wrong patient, have prescribing physician give patient a carbon copy of the Rx, which he'd show to the technician at each treatment.

If the patient is bed-ridden, he could be given a plastic wristlet, indicating his treatment.

5 - Enclosed, photocopy of two types of sliding scale. If something like these aren't already in use, could the wheel-type scale be used to show rads/unit of body weight, per millicurie of various pharmaceuticals?

And the slotted envelope type to show the dose effects of the various beam-modifying devices?

6 - In Sec 35.454 and 35.654, indicate that only in life-threatening cases would prescribed doses be administered, before an accuracy check is made.

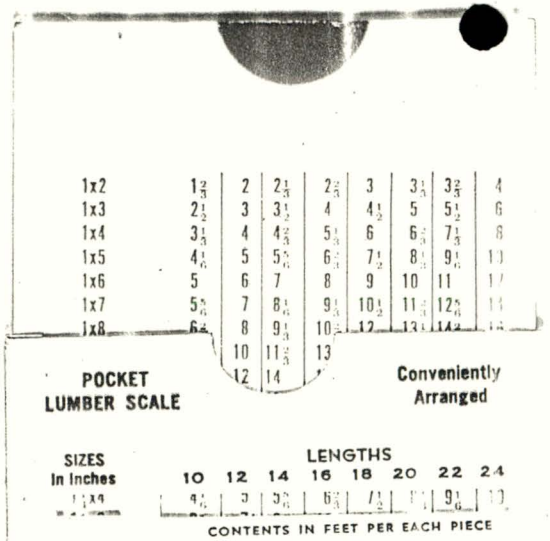
20% and 50% of

7 - Finally, for clarity in the various charts and graphs used in these therapies, we suggest using a type face like this one for numerals: 1234567890.

The numerals in the Federal Register are extremely poor. If there's the slightest blurring, 3,6,8,9 are easily confused.

As a case in point, see p 36949 of this notice, under 35.652. It says, "Sec 35.654 is added to read as follows:" Directly below, it reads, "35.354 Checks of dose...etc"

E. Nemethy



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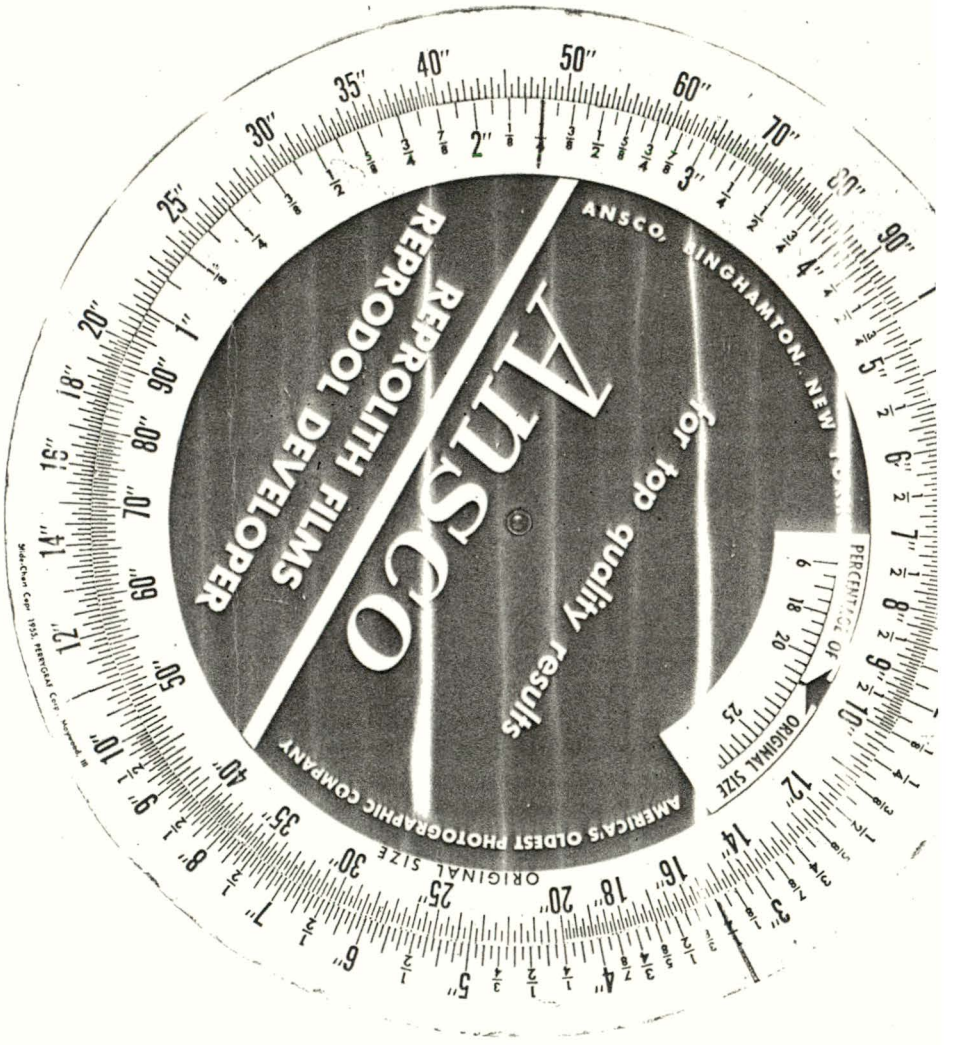

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 920
541 Clinical Drive
Indianapolis, Indiana 46223
(317) 264-4797
274

November 23, 1987

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

Attn: Docketing and Service Branch

Gentlemen:

The purpose of this correspondence is to comment on the "Proposed Rule" to 10 CFR 35 entitled "Basic Quality Assurance in Radiation Therapy" which was published in Vol. 52, No. 191 of the Federal Register. There is no question that an adequate quality assurance program is beneficial in minimizing the occurrence of misadministrations. I feel that there are some problems in attempting to establish a "standardized" quality assurance program which is what appears to be the intent of this proposed rule.

At a recent meeting which was set up by the Region III NRC office, broad-scope licensees met with NRC representatives to discuss various issues associated with the overall radiation safety aspects of broad-scope licensees. During that meeting, Norman McElroy discussed the impact of the revised 10 CFR 35 on broad-scope licensees. The revised 10 CFR 35 attempts to standardize medical radiation safety programs for the "typical" hospital; however, Mr. McElroy acknowledged that there is no such thing as a "typical" hospital. Unfortunately, the revised 10 CFR 35 required some fairly extensive modifications (primarily in paperwork) of our radiation safety program which in my opinion had little positive impact on our program in general.

It appears that this proposed rule will be another extension of standardization whereby all licensees will be required to establish and implement identical quality assurance programs, regardless of the size of their hospital or the scope of the radiation safety program. Because of the day-to-day procedures (e.g. how radiopharmaceuticals are ordered, paperwork flow, etc.) such standardization may require significant modifications in these procedures with no real benefit. This is especially true for those hospitals that are not "typical", which would include broad-scope medical licensees and small hospitals. It appears to me that it is more important to design the quality assurance program to fit the specific licensee rather than require all licensees to fit one quality assurance program.

Perhaps a better method of providing for an adequate quality assurance program would be to require in 10 CFR 35 that such a quality assurance program be in place; however, the specific quality assurance program would be reviewed and approved during the licensing process rather than prescribed within the rule. The information within the proposed rule could be incorporated into a Regulatory Guide which would then be utilized by licensees to establish their quality assurance programs. I realize that the revised 10 CFR 35 along with this proposed rule has been designed to streamline the licensing process; however, I would rather spend additional

'87 NOV 30 P3:52

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time and effort to custom fit a quality assurance program which can be easily and effectively implemented.

If the proposed rule is integrated into 10 CFR 35 as stated, there are some specific comments which apply, particularly regarding broad-scope licensees. Under 35.39 "Ordering, prescribing, and administering certain radiopharmaceuticals", it is stated that radioiodine cannot be ordered without the approval of the authorized user. This appears to be too prescriptive. Consider our situation - all orders for radiopharmaceuticals are placed by the Radiation Safety Office (RSO) upon request from the appropriate Nuclear Medicine Department (we have three). Typically, a nuclear medicine technologist (NMT) or the radiopharmacist requests that the RSO purchase the radiopharmaceutical. Interpreted literally, it appears that the "authorized user" (i.e. the nuclear medicine physician) would have to personally request the RSO to order the material; otherwise, there would be no direct way for the RSO (as the representative of the "licensee") to directly assure approval by the authorized user. Furthermore, we currently receive a standing order (i.e. prearranged automatic shipment) for radioiodine because of our frequent use. The aforementioned ordering requirement appears to disallow such a procedure.

Under 35.43 "Prescriptions, records, and checks of medical use for therapy", it is stated (in part) that the licensee shall verify that an authorized user has made, written, dated, and signed a written prescription that identifies the body part to be treated prior to beginning the treatment. As indicated above, the RSO is considered the working representative of the licensee. Given this interpretation, such a requirement necessitates that the RSO perform the aforementioned verification.

Perhaps the main problem illustrated by the examples listed in the previous two paragraphs is that the term "licensee" is inappropriate or needs to be defined. For example, is an NMT able to act on behalf of the licensee regarding ordering and/or verification prior to the administration of therapeutic radiopharmaceuticals? The individual who signs the license application (in our case, the vice-president of the university) is the ultimate representative of the "licensee". Obviously, it is not the NRC's intention to have the university v.p. approve and/or verify such activities. Perhaps using the terminology "the licensee or his designee" would allow enough flexibility to avoid such confusion. Although these examples may seem too specific, the whole point goes back to my original assertion. That is, quality assurance programs must be integrated into the existing operational framework. Attempts to establish prescriptive quality assurance programs will most likely confuse both NRC inspectors as well as licensees.

Thank you for your consideration of these comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer

Mayo Clinic

Rochester, Minnesota 55905 Telephone 507 284-2511

Manuel L. Brown, M.D.
Diagnostic Radiology

November 25, 1987

Secretary to the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Docketing and Service Branch

Gentlemen:

I wish to comment on the proposed rule on Basic Quality Assurance in Radiation Therapy published in the Federal Register Vol. 52, No. 191, pages 36942-36949, October 2, 1987.

I understand the importance for the US Nuclear Regulatory Commission to reduce the probability of a therapeutic misadminstration, and I am in support of that goal. I have a concern that the proposed rule as written will do little to reduce therapeutic misadministrations and could significantly increase patient costs and possibly even delayed delivery of medical services to patients requiring the administration of isotopes for both diagnostic and therapeutic applications.

The reason I believe that the proposed rule will not significantly reduce misadministrations is as follows: According to your estimates of 30,000 therapeutic procedures a years, there would have been approximately 110,000 procedures during the period November 1980 through July 1984. During this time period there were only 6 therapeutic misadministrations involving radiopharmaceuticals. Although these could have significant effects for the individual patients, the actual number and percentage of therapeutic misadministrations is very small. Although new rule making would specify procedures, they cannot and will not eliminate human error.

I am concerned about the potential delay in patient care which could result from Item 35.39(A). I believe it would be incorrect to restrict a licensee from ordering radiopharmaceuticals of iodine without the approval of the authorized user. Centralized radiopharmacies and large medical complexes should be allowed to have standing orders for radiopharmaceuticals. If deemed necessary, you could restrict the licensee from releasing the radiopharmaceutical until there was approval of an authorized user. This change would meet the spirit of the issue without delaying patient care.

The major concern I have is in the inclusion of radiopharmaceuticals of iodine for diagnosis with radiopharmaceuticals of iodine for therapy or other radiopharmaceuticals for therapy. We perform a large number of radionuclide procedures with various isotopes

'87 NOV 30 P3:48

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of iodine. These include 131I-iodocholestrol, 131I-metaiodinated benzylguanadine, 123I-iodoamphetamine, 125I-iodofibrinogen, 131I-iodohippuran, as well as very small amounts of 131I-sodium iodide for uptake measurements. We use larger doses of 131I-sodium iodide for treatment of thyroid metastases and hyperthyroidism and larger doses of 131I-sodium iodide for diagnostic studies in patients post-thyroidectomy to detect thyroid metastases.

I am supportive of more stringent rules regarding therapeutic administratration of radiopharmaceuticals including 131I-sodium iodide and for relatively large doses of 131I-sodium iodide for diagnosis (greater than 100 microcuries). I believe that if all diagnostic radiopharmaceuticals containing an isotope of iodine were included in the rule making this would cause an undue burden, expense, and impediment to patient care unto the Nuclear Medicine community and the patients that we serve.

This issue of diagnostic radiopharmaceuticals contained iodine should be clarified under 35.39A, 35.39B, 35.39C, and 35.302.

I would retain for purposes of rule making all radiopharmaceuticals for therapy and 131I sodium iodide for diagnostic purposes greater than 100 microcuries. This would balance the need for reduction in the potential for misadministrations with the issues of timely, efficient, and cost effective patient care.

Sincerely,

Manuel L. Brown, M.D.

MLB:rlf

The University of Texas Medical Branch at Galveston

Department of Radiation Therapy
UTMB Hospitals at Galveston
Galveston, Texas 77550
409/761-2531

November 24, 1987

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

Dear Sir:

I would like to comment on proposed rule 10 CFR Part 35: Basic Quality Assurance in Radiation Therapy. Not having sufficient time to respond to specific regulatory proposals let me make a simple suggestion which the NRC could implement without intruding into the practice of medicine.

I suggest the regulation state that no radiation therapy program be licensed that does not have a full time radiation safety officer who is a medical physicist who has been certified in Radiation Therapy Physics or Radiological Physics by the American Board of Radiology.

This simple requirement would result in implementing the vast majority of needed quality assurance steps without getting bogged down in a morass of proposals and counter proposals and above all avoiding the appearance of criticism of medical practices.

Since available manpower will be unable to meet the needs of full implementation immediately, the requirement for a full time board certified medical physicist could proceed in steps. As the objective is to get this level of knowledge and expertise into the radiation therapy process quickly, the starting point could be at a fairly low level - ie, a consulting physicist or his representative on site for as little as one day per week. Phasing in a full time individual working under the direction of a certified medical physicist should only take four to six years with the final step to an on site certified physicist taking six to ten years as the manpower situation is resolved.

I support the NRC in its quest to improve the safety of the patient undergoing radiation therapy procedures.

If the deadline for submission of comments is extended I will try to respond to specific items of this proposal.

Sincerely

Richard G. Lane

Richard G. Lane
Professor & Director
Division of Physics & Engineering

NORTHERN NEW MEXICO NUCLEAR SERVICES
1651 GALISTEO, SUITE 1
SANTA FE, NEW MEXICO 87501

November 25, 1987

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

ATTN: Docketing and Service Branch

I received a copy of the Federal Register notice of proposed rules which was discussed at our annual meeting on November 23, 1987. Our comments are as follows:

For avoiding misadminstration of miscellaneous radiopharmaceuticals, there is a need for routine checking of a particular isotope with dosage, date of adminstration, proper study and isotope needed, as well as, correlating the study ordered with the patient to receive the dose.

For avoiding misadminstration in I-131 therapy the above again needs to be observed but in addition there should be strict examinaton of the prescription for the study. It is the role of the referring doctor to concur in the dosage of isotope therapy, isotope to use, correct date, name of patient, body part evaluation and method of adminstration. This information should be written on the referral form or prescription for the study.

In order to eliminate potential error in handling a therapy dose, only a board certified or board eligible nuclear medicine technologist or board certified or board eligible nuclear medicine physician should administer the dose.

A mandatory annual meeting for nuclear technologists would be helpful to stay current on recent regulations. Also the license of the licensee should be held in jeopardy if flagrant violations of regulations are not corrected.

In conclusion, I agree with most of the proposed rules but implementation of some of the codes could significantly affect our clinical practice. Thank you for proposing rules regarding basic quality assurance for radiation therapy and for considering our comments.

Sincerely,

J. R. Damron, M.D.

'87 NOV 30 P4:04

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Medical Center

3350 La Jolla Village Drive
San Diego CA 92161

Veterans Administration

November 19, 1987

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Secretary:

In response to a request for comments on proposed rules as published in the Federal Register Vol. 52, No. 191 on October 2, 1987, we desire to express our views as follows.

Paragraph 35.39
(b) The thrust of this regulation appears to have significant impact on the therapeutic uses of radioiodine and probably is reasonable in restating that which is good and standard care in the medical community. The inclusion of the word "diagnosis" introduces an unwieldy, odious, and obstructionist regulation which would seriously inhibit the function of most nuclear medical laboratories doing thyroid uptake studies on outpatients. It is not medically necessary to examine a patient prior to an uptake study. Outpatients frequently do not have charts, and the referring physician has already determined that the study is necessary for his clinical management. The dose prescription can never be precise when using standard precalibrated capsules because patients rarely arrive at the precise calibration hour. It makes no difference if the capsule is worth a little more or a little less than its calibration value. The laboratory work sheet, which includes the patient's name, radiopharmaceutical dosage at the time of administration, and the route of administration, should be sufficient legal documentation of what was prescribed.

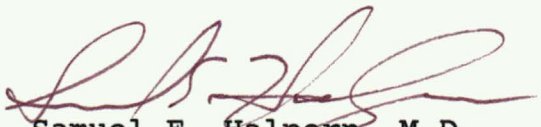
Paragraph 35.43
(a) This section is absurd, requiring authorizing users to be certain that patients referred for specific therapy by primary care physicians really require such therapy. The implication of the paragraph is that no such certainty would be needed if a patient walked in and self requested such therapy. In the common practice of nuclear medicine, decisions to use radiotherapy come from either the patient's primary physician or on the advice to private patients of the user when the user is a trained internist or endocrinologist. It would be inconceivable that a walk-in patient could request and receive radioiodine therapy with no physician intervention.

(d) This paragraph is unclear, but our interpretation suggests that a section be included in the departmental policy and procedure manual instructing departmental personnel to ask questions when the instructions are not clear. Such a directive is demeaning to mature professional workers. Indeed, departments which employ individuals too simple to know when to ask questions have problems so severe that no amount of heavy handed regulation can ameliorate or prevent.

We also believe that the lumping of radiopharmaceutical diagnosis and therapy into a common pool of regulations with brachytherapy and teletherapy must lead to confusion among the various users, and should be specifically separated by appropriate sections.

Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,



Samuel E. Halpern, M.D.
Acting Chief, Nuclear Medicine Service

Medical Center
3350 La Jolla Village Drive
San Diego CA 92161

Veterans Administration

November 19, 1987

In Reply Refer To:

Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Secretary:

In response to a request for comments on proposed rules as published in the Federal Register Vol. 52, No. 191 on October 2, 1987, we desire to express our views as follows.

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We also believe that the lumping of radiopharmaceutical diagnosis and therapy into a common pool of regulations with brachytherapy and teletherapy must lead to confusion among the various users, and should be specifically separated by appropriate sections.

Your consideration of these hopefully constructive criticisms is appreciated.

Respectfully submitted,

Gilbert Greenspan, M.D.

Gilbert Greenspan, M.D.
Staff Physician, Nuclear Medicine Service

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5001

November 25, 1987

REPLY TO
ATTENTION OF:

Health Physics Office

SUBJECT: Proposed Rules for Basic Quality Assurance in Radiation Therapy

Secretary of the Commission
US Nuclear Regulatory Commission
ATTENTION: Docketing and Service Branch
Washington, D.C. 20555

Dear Sir:

After careful review of the proposed amendments concerning the "Basic Quality Assurance in Radiation Therapy" in relation to the medical use of byproduct material, the following requests for clarification are made:

a. Reference paragraph 35.39(a) - Is it the intent of the Commission to require large major medical facilities, such as Walter Reed Army Medical Center which has a well established Radiation Control Committee and a License of Broad Scope, to obtain written approval from the principal user for ordering all radiopharmaceuticals of iodine for disgnostic study or therapy, or any radiopharmaceutical for therapy? Walter Reed's Nuclear Medicine Service has a considerable volume of on-the-spot requests for diagnostic and therapeutic uses of iodine (radioactive iodine uptakes, iodo-hypurate renal studies and hyperthyroidism therapies). May the authorized user delegate the approval of ordering bulk amounts of these compounds to a credentialled individual, such as a radiopharmacist?

b. Reference paragraph 35.39(b) - The Nuclear Medicine Clinic of Walter Reed Army Medical Center provides renal studies for an active renal transplant service, which includes indo-hypurate scans. The procedure entails an examination of the patient by the referring physician before initiating the request for the study and a review of each consult/request for appropriateness by an authorized and credentialled nuclear medicine physician. Must a nuclear medicine physician also examine again each of these patients?

This facility and its staff are as concerned about the occurrence of misadministrations as the Commission and have incorporated quality assurance mechanisms into all areas of diagnosis and therapy.

Sincerely,

Gerald M. Connock

Gerald M. Connock
Major, U.S. Army
Health Physics Officer

CF:
OTSG (DASG-PSP-E)
ATTN: COL Field
511 Leesburg Pike
Falls Church, VA 22041-3258

Methodist Hospital OF INDIANA, INC.

1701 North Senate Boulevard
P.O. Box 1367
Indianapolis, IN 46206
(317) 924-6411

November 12, 1987

United States
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sirs:

We would like to address the proposed rules published in the Federal Register. Specifically, we would like to address CFR Part 35.39(b) in the comments below.

CFR, Part 35.39(b):

> The way this currently reads, it would require seeing personally every patient who was administered a preparation labeled with radioiodine and does not distinguish between ^{123}I, ^{125}I, and ^{131}I. Therefore, this would include such studies as a total blood volume with ^{125}I RISA, a renogram with ^{123}I-hippuran, and a diagnostic uptake of iodide with 5-10 uCi of ^{131}I as sodium iodide.
>
> It would seem that the intent of the new regulations is to eliminate delivering an incorrect dose of radioiodine in the therapeutic range, i.e., No-I for radioiodine therapy in hyperthyroidism or thyroid cancer or in the future ^{131}I labeled to monoclonal antibodies for therapeutic purposes. Also, we are aware of 1-5 millicurie doses given for diagnostic purposes to a patient who has not had total thyroidectomy. These cases are part of misadministration records at the NRC. Therefore, some threshold level seems appropriate to specify, such as one millicurie of activity for ^{131}I or ^{125}I and perhaps 10 mCi or more of ^{123}I. This would allow adequate patient protection and not place undue burden on the busy physician whose attention may be required elsewhere.

Sincerely,

Larry L. Heck, M.D.

Jerry L. Kight, M.D.

Dale M. Apodaca, M.D.

E. D. Van Hove, M.D.

ACNP
American College of Nuclear Physicians

1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036

202-429-5120

SNM
The Society of Nuclear Medicine

November 25, 1987

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

RE: Extension of Comment Period Deadline for NRC Proposed Rule on Basic Quality Assurance in Radiation Therapy (Federal Register Vol. 52, No. 19, October 2, 1987)

Dear Mr. Chilk:

On behalf of the American College of Nuclear Physicians and the Society of Nuclear Medicine, whose 12,000-plus members will be significantly impacted by the above-referenced proposed rule, I respectfully request a 30-day extension of the December 1, 1987 deadline.

The proposed rule, if implemented, could have a profound impact on the practice of Nuclear Medicine and would result in significant NRC intrusion into the referral process, and the prescribing and administering of radiopharmaceuticals for medical purposes. Because many important, complex issues are addressed in the proposed rule, the College and Society arranged an ad hoc working group to develop a consensus document on behalf of the Nuclear Medicine community. The working group has made significant progress, but requires additional time to reach agreement on this issue of extreme importance to our members.

We hope that the Commission will grant our request for an extension so that it can benefit from a comprehensive consensus statement from the two medical specialty organizations representing Nuclear Medicine. Thank you for your prompt consideration of our request. Please call me at your earliest convenience at 429-5120.

Sincerely,

Melissa Brown

Melissa P. Brown
Director of Government Relations

November 25, 1987

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

ATTENTION: Docketing and Service Branch

Gentlemen:

On behalf of the 20,000 physician and physicist members of the American College of Radiology, I take this opportunity to comment on the proposed rule on basic quality assurance in radiation therapy. (Federal Register, October 2, 1987, Page 36942)

Our comments represent the review of the proposed rule by the ACR Commission on Radiation Oncology, the Commission on Physics and the Commission on Cancer. The ACR also endorses the comments previously submitted by Barry Siegel, M.D., vice-chairman of the ACR Commission on Nuclear Medicine.

The American College of Radiology is committed to quality assurance in radiation therapy and quality medical care provided by competent physicians. We agree with the NRC that protocols should be in place to reduce the number of radiation therapy misadministrations. However, we believe that further regulation will do little to improve the overall quality assurance of radioactive material administration.

Considerable concern has been expressed by ACR commission members that Table I on Page 36943 does not represent a data base from which to make significant changes in the regulations. The "degree of seriousness" has not been assessed for the 27 misadministrations included in Table I. It is possible that the changes in the proposed rule could result in only a negligible impact on the frequency of misadministrations. The changes could impact more upon the requirements for additional manpower and documentation than upon solving the problem of misadministrations.

Although 27 misadministrations is 27 more than desired, it is a relatively small number when compared to the total number of patients receiving multiple cancer therapy treatments during the period being reported. (November 1980 to July 1984) Human error played a major role in most of the 27 cases. We believe that quality assurance protocols to help minimize human error are already effectively in place.

AMERICAN COLLEGE OF RADIOLOGY
1891 Preston White Drive, Reston, Virginia 22091 (703) 648-8900

The ACR is always looking for paths to improve patient care and safety and is willing to work with the NRC to achieve this goal. We believe in this case, however, further regulation may not be the proper route. We would like no misadministrations to occur in radiation therapy but realize that because of the human error factor, this ideal may be difficult to achieve. We believe that individual radiation therapy departments' continued review of the patient on a regular basis throughout the course of radiation therapy in order to detect signs and symptoms suggesting a misadministration is the important ingredient in a quality assurance program.

Comments on particular sections of the proposed rule follow:

Section 35.43 PRESCRIPTIONS AND RECORDS OF MEDICAL USE FOR THERAPY

In Section 35.43 the NRC has asked for comment on what type of documentation is needed to demonstrate that an independent check of data transfers and calculations has been made. In response, ACR commission members think that although the requirement to specifically instruct workers to request clarification in cases where there may be ambiguity or error in therapy calculations is warranted, it does not seem appropriate for the NRC to prescribe the type of documentation necessary to demonstrate an independent check of data transfers and calculations. This documentation is appropriately left to the therapy department.

ACR commission members believe that check lists which provide simple documentation of the transfer of data from the prescription to the patient chart are very helpful in minimizing misadministrations. The design of the check list is important and should be kept simple as a highly detailed form may lead to additional errors.

Section 35.432 - SOURCE STRENGTH MEASUREMENTS

The requirement in this section that the source strength of sealed sources be measured, but that the licensees be permitted to use the values supplied by the manufacturer, seems to be an unnecessary addition of radiation dose to the physicist or dosimetrist who will be required to make the measurement. If the measurements of sealed source strength must be made, then it seems that the measurements should be required to be used.

Sections 35.452 and 35.652 - PHYSICAL MEASUREMENT OF PATIENTS

The requirements that two individuals independently make the physical measurements of the patient may place an unnecessary burden upon the medical community with little benefit. We suggest that this section be clarified because it is not clear whether a simple patient thickness measurement is being required, or whether the measurement of a patient contour in three dimensions or other complex patient parameters are the required measurements. Such duplicate measurements could involve significant time commitments by the dosimetrist, technologist, physicist, or physician in radiation therapy.

SECTION 35.454 - CHECK OF DOSE CALCULATIONS
SECTION 35.654 - CHECKS AND MEASUREMENTS OF DOSE
Regarding the concept of "independent check", ACR commission members believe that two completely independent treatment plans by separate individuals seems an impractical requirement. Such duplication of planning is not likely to reduce the cause of misadministrations, but significantly increase the requirement for physics and dosimetry staff. In addition, double checking of brachytherpy source identities is unnecessary because of the small number of misadministrations attributed to this source of error.

Referencing the selection of the dose calculation check criteron of 50 percent, ACR commission members suggest that the individual (and training) required for checking dose calculations for accuracy before 50 percent of the prescribed dose has been administered, should be specified. Although the physicist is qualified to check all dose calculations, the technologist or other staff may overlook important sources of error.

SECTION 35.633 - INDEPENDENT CHECK OF FULL CALIBRATION MEASUREMENTS
An independent check of the full calibration should not preclude the use of thermoluminescent dosimetry measurements, as these have been found to be reliable comparisons with ionization chamber measurements in the past. The requirements that the dosimetry system provide a "similar level of accuracy and precision" should be carefully reviewed. The independent check of the output may be satisfied without the precision required for full calibration.

The American College of Radiology appreciates the opportunity to submit comments on the proposed rule, basic quality assurance in radiation therapy. We urge your favorable consideration of the changes. If you have any questions, please feel free to call me.

Sincerely,

Otha W. Linton
Associate Executive Director

acr

11-24-87

Telephone comment to Norman L. McElroy re 52 FR 36942

Carl Merlin, MD, Member of Louisana Medical Advisory Board, (504) 454-1724

-We do most of the things you have in the draft regulation.

-re brachytherapy, you want an independent check before 50% of the treatment has beem administered. There aren't always two people available to do this. This would be expensive. We have an MD review the isodose curves and dose calculations.

-There are many small hospitals in my state that can't do this because the personnel needed simply are not available.

nlm

Beaumont
William Beaumont Hospital Nuclear Medicine

November 12, 1987

William C. Porter
Nuclear Medicine Department
William Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48072

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

Re: NRC NPRM ON BASIC QUALITY ASSURANCE IN RADIATION THERAPY
[FEDERAL REGISTER PAGE 36942]
AND NRC ANPRM ON COMPREHENSIVE QUALITY ASSURANCE IN MEDICAL USE
[FEDERAL REGISTER PAGE 36949]

In many instances a "microscopic analysis" of any given probelm will generate a mountain of data and subsequently a preoccupation with a detailed analysis of the data. Although this "leave-no-stone-unturned" approach is undoubtedly necessary in important matters such as therapeutic misadministrations, it is oftentimes quite rewarding to back up and simply take a look at the big picture. My comments are solely directed at the radiopharmaceutical misadministration issue.

For centuries there has been a well defined system of checks and balances in the delivery of pharmaceutical services. This system has evolved, and continues today, based upon a societal need and for the protection of the public health [a primary directive of the NRC.] The system involves the interaction of a trio of those concerned with the proper delivery of pharmaceutical services. Specifically, this is a physician-patient-pharmacist relationship.

The NRC is to be congratulated for recently recognizing the capabilities of individuals who have obtained board certification in nuclear pharmacy through the Board of Pharmaceutical Specialties. I believe that if you simply state that the overall problem you are trying to resolve is one of the assurance of proper DRUG delivery, you should readily identify the absence of the ACTIVE participation of [or input by] the pharmacist from the above mentioned triad.

In this specific issue of therapeutic radiopharmaceutical misadministrations and if one assumes that the majority could potentially occur in the hospitalized setting, it is certainly unfortunate that this circumstance prevails given the existence of fine and sophisticated mechanisms for drug delivery in

organized healthcare settings. The logic-flow which perpetuates this situation is one where the DISPENSING function is erroneously conceptualized by many nuclear medicine personnel as a much oversimplified and purely physical act. In reality, in any environment involving healthcare professionals whose primary function requires direct patient care (physicians, nurses,nuclear medicine technologists, etc.) and given the current status of organized healthcare cost-containment demands, it is difficult to argue that proper careful attention can be consistently given to the drug dispensing function.

Commercialized nuclear pharmacies have certainly contributed to improving a system which digressed so radically from the traditionally accepted concept of "the right drug to the right patient at the right time", (by a healthcare professional whose training and attitude are solely directed toward this goal).

I believe the NRC should recommend the following: 1. Where possible, hospital pharmacy departments SHOULD be involved in developing the system of safeguards to assure proper drug delivery within a nuclear medicine department within their institution (not only is this the loosely enforced LAW in virtually every state but is required by the Joint Commission on Accreditation). 2. encourage, where possible direct and continuing participation in the provision of pharmaceutical services to nuclear medicine departments by hospital pharmacies within the institution, and 3. encourage commercial nuclear pharmacies to develop standardized "prescription forms" for therapies requiring the nuclear physician's orders in writing and require that this function CANNOT be delegated to a secretary or technologist.

Diagnostic and therapeutic misadministrations can be virtually eliminated if proper control systems are developed and appropriate personnel are involved in the drug delivery system.

Sincerely,

William C Porter

William C Porter, Pharm.D., BCNP

3601 West Thirteen Mile Road Royal Oak, Michigan 48072 (313) 288-8020

COMMENTS ON PROPOSED RULES

10CFR Part 35

Basic Quality Assurance in Radiation Therapy.

Federal Register Vol.32 No.191, Friday, October 2, 1987.

35.39 Ordering, prescribing and administering certain radiopharmaceuticals.

IODINE-131

The chart entry for the patient being treated should be checked by an independent individual not involved directly with the administration of the radioactive material, before the dose is actually administered. This would ensure that the correct type and quantity of radioctive material was being prescribed for the patient and malady at hand. The prescription in the chart should be signed and dated by this individual.

The person actually administering the radioactive material should check the patient's chart prior to administering any radioactive material to verify that the whole prescription has been checked by an independent individual.

The person actually administering the radioactive material should make a notation in the patient's chart to include :- the time, the date and identification of the dose administered (type and quantity of the radioactive material and departmental ID for the preparation and calibration of the dose).

35.43 Prescriptions and Records of Medical Use for Radiotherapy.

It is recommended that no more forms or sheets of paper be required to be filled in and included in the patients' charts.

However, to eliminate one of the main sources of error, it is recommended that all "Plans of Treatment", "On Treatment" notes, "Follow Up" notes and any other information pertinent to the treatment, be typed and not hanwritten in the patients' charts.

The redundancy check concept is endorsed and all dose prescriptions and calculations leading eventually to the determination of the treatment time, should be reviewed by an individual who has not been involved in the initial process before 20% of the planned treatment has been delivered.

35.452 Physical Measurements of Patients.

35.652

If dosimetry insofar as patient treatment set up is concerned, is performed independently of the treatment operation, then it is recommended that at least two people with different responsibilities - dosimetry and treatment - be involved in working up the treatment of each and every patient.

If on the other hand, the planning is done on the treatment unit directly, then it is recommended that at least two technicians be employed on the treatment unit at all times, regardless of the number of physicians or physicists, full or part-time, so that treatment set ups can be checked and verified by the individuals actually delivering the treatments. On any patient, one of the treatment technicians should have taken the required patient measurements and calculated the treatment plan and the other treatment technician should use this plan to set up and treat the patient and so verify the physical set up and patient dimensions.

35.454 Check of Dose Calculations

35.654 Checks and Measurements of Dose.

For teletherapy units, part of the full calibration should include a measurement of outputs for a selection of treatment distances (SSD's) (say 60, 80 and 100cm) and a selection of Field Sizes (say 8x8, 10x10 and 15x15cm) and for at least two depths in a unit density phantom (say 5.0 and 10.0cm). These measurements should then be compared with any computer generated treatment times to verify the computer accuracy over this range of major clinical significance and the results preserved for posterity.

Again, the concept of redundancy checks is endorsed. All patient charts and treatment sheets should be reviewed by an independent person at least once per week. All chart entries should be read and those pertaining to treatment changes, signed and dated by the independent. Similarly, any treatment changes not implemented or incorrectly implemented, should be queried by the independent for verification and/or modification by the physician responsible. Also, all treatment sheet entries should be checked for arithmetic errors and duly signed and dated by the independent.

35.632 Full Calibration Measurements

35.633 Independent Check of Full Calibration Measurements.

The redundancy concept requiring an independent measurement of dose output is endorsed and should be extended to at least once per month. It is felt that one year is a long time and represents many patients possibly incorrectly treated, if a discrepancy in outputs is detected. (This is particularly important in light of the increasing average age of Cobalt-60 teletherapy units in use across the country.) Also, the concept of a mail service to satisfy this requirement is not endorsed. The reason for this is simply that the strength of a truly redundant test is the fact that other than the treatment unit itself, there is nothing else common to the two measurements. For example, setting up an incorrect isocenter or source to skin distance could be perpetuated by the same individual exposing "mail in" dosemeters. It is recommended that the concept of independant individuals be adherred to, with different measuring equipment as originally suggested.

A far more serious aspect of this calibration measurement and a contributory fact to the reason why mistakes leading to possible misadministrations occur, is the absence in the United States of a nationally accepted calibration protocol for teletherapy machines. The essence of a protocol for the absolute output calibration of all of these radiation teletherapy units is:-

a. **SIMPLE.**

The more complicated the procedure, the higher the probability for making an error. Also, the overall confidence level decreases with the number of variables involved in the process, each step having its own unique error value (standard deviation).

b. **QUICK.**

It should be possible to accumulate many readings during a calibration and even repeat an entire calibration if necessary, without elaborate, time consuming set ups and without disrupting the normal departmental procedure.

c. **REPRODUCIBLE.**

No matter who performs the calibration or where in the State, Country or World for that matter, the calibration is performed, the results should be consistent from year to year and center to center, which is of paramount importance to the patients undergoing treatments on these units, for the proper treatment of their diseases.

We are familiar with the American Association of Physicists in Medicine (AAPM) Task Group 21 protocol which requires the derivation and/or manipulation of some thirty four (34) variables, covering two (2) pages of worksheets, to arrive at an output calibration. It is primarily for this reason that TG-21 does not meet any of the requirements for a good calibration protocol listed above, but instead, has succeeded in introducing confusion in the ranks of physicists and physicians alike. The net result is that output calibrations have suffered, either because of incorrect assumptions or incorrect complex arithmetic in deriving the calibration factor or in personal insecurity in applying this very complex and time consuming protocol, with the result that calibrations are just not done.

There are true and tried protocols in existence throughout the world which do satisfy all of the criteria and any one of them, if implemented in the United States, would go a long way to establishing a uniform central axis calibration for all of the teletherapy machines in use in the country, those using prescribed material as well as those not using prescribed material.

GENERAL COMMENTS.

The overall concept of redundancy checking does work and has been practised by this commentator for many years with good success. It is also the view of this commentator that the independent individual referred to throughout this commentary should be a physicist or someone with extensive radiation physics experience. The NRC suggests that it be a physicist who does the independent check of full calibration measurements only, however, it is this commentator's opinion that this should be extended to all of the other independent checks as well for the following reasons:-

(i) During the course of the weekly ongoing physics check of a patient's chart and treatment sheet, if prescription changes have been requested they are invariably subtle changes, involving a field size, treatment distance, use of a lead block, etc. and the individual performing the check should have the experience to know with certainty how the change will affect the original plan.

(ii) If any discrepancies between the prescription and the final treatment plan are discovered or even suspected due to a poorly worded prescription, at any phase of the treatment, a physicist is more likely to challenge the prescribing physician than perhaps a dosimetrist or technician. In the case of a major error or potential error, the physicist would and should stop treatments until a satisfactory resolution of the discrepancy is obtained with the primary care physician.

18 November 1987

Darrell O. Poole
Radiation Physicist
Veterans Administration
Medical Center,
Miami, Florida.

Since Florida enjoys NRC Agreement Status:
Copies to:-
The Secretary,
Health and Rehabilitative Services,
Tallahassee, FL 32301.

Lyle E. Jerrett,
Director: Office of Radiation Control,
Department of Health and Rehabilitative Services,
Tallahassee, FL 32301.

South Carolina Department of Health and Environmental Control

2600 Bull Street
Columbia, S.C. 29201

Commissioner
Michael D. Jarrett

November 5, 1987

Mr. Donald A. Nussbaumer
Assistant Director for State
Agreements Programs
State, Local and Tribe Programs
Office of Governmental and Public Affairs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Nussbaumer:

This is in reference to your letter of October 14, 1987, requesting our comments on the proposed rulemaking Basic Quality Assurance in Radiation Therapy.

In general we support the rulemaking and agree with the necessity of such a program in nuclear medicine and radiation therapy.

However, we do have some concerns about Section 35.633, Independent Check of Full Calibration Measurements. Due to the nonavailability of qualified experts on staff at some of our medical facilities, it requires the services of a medical consultant to perform the full calibration measurements as required by Section 35.630. An independent check of full calibration measurements performed by another consultant may cause an unnecessary burden on the licensee. We agree that the independent check may be necessary in some instances, but it may be difficult for our licensees to comply with this regulatory requirement.

Thank you for the opportunity to provide our comments. Should you or the NRC staff have questions, please do not hesitate to contact us at (803) 734-4700.

Very truly yours,

Heyward G. Shealy, Chief
Bureau of Radiological Health

VRA:ms

ST. AGNES HOSPITAL

DEPARTMENT OF RADIATION ONCOLOGY
(414) 929-2360

Radiation Oncologist
Hong Chu Wang, M.D.

Radiation Physicist
John F. Wochos, M.S.

November 18, 1987

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

ATTN: Docketing and Service Branch

Dear Secretary:

RE: Proposed Rules on Basic Quality Assurance in Radiation Therapy

My single comment relates to section 35.633, the independent check of full calibration measurements. I think that, in reviewing the discussion section, it was indicated that a mailed TLD system would be adequate for this purpose. This should be made clear in the regulations. Also, in the proposed regulations it specifically indicates the independent check be made within one month after full calibration. I feel this would only be necessary on initial commissioning of the machine. Subsequently, during the clinical lifetime of the radioactive source, an annual measurement, which agrees with the decayed dose rate in clinical use should be adequate. This would allow institutions to use the mailed TLD programs sponsored by the Radiological Physics Center, which are not performed at the institutions time of convenience.

Sincerely,

John F. Wochos, M.S.
Medical Physicist

JFW:jw

William T. Moss, M.D., F.A.C.R.
Chairman, Commission on Radiation Therapy
Oregon Health Sciences University
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97201
(503) 225-8757

January 23, 1987

52 FR 36942 Basic Quality Assurance in Radiation Therapy

Mr. Vande L. Miller
Chief, Material Licensing Branch
Division of Field Cycle and Material Safety
Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Miller:

In my position as Chairman of the Commission for Radiation Oncology of the American College of Radiology, I received a copy of the amendment to 10 CFR Part 35 regarding misadministrations. In my opinion, most of the changes which are recommended are appropriate. However, I would like to call your attention to Item 2 on Page 17 which reads "for brachytherapy the prescription must also identify sources of radiation and the total dose". I am sure you must be aware of the fact that there is no uniform or standardized method of expressing total dose for brachytherapy irradiation, and while you might expect all radiation therapists to comply and express a dose, that figure will have very little meaning in the absence of a very complicated description of source locations, etc. I have enclosed a reprint of a recent article which emphasizes the problems which we have in this area.

I have no suggestion for any alternative, but a lack of an alternative is hardly a justification for suggesting that this type of expression of total dose, without a complicated description of how it is to be obtained, will help in assuring quality of care.

Sincerely yours,

William T. Moss

William T. Moss, M. D.
Chairman
Commission for Radiation Therapy

NB: Dr Moss had obtained a draft copy of the subject FRN, and this letter was received while the staff was still developing the proposed rule. N. L McElroy 11 18 87

Multi-institutional Survey of Techniques in Volume Iridium Implants

ARTHUR J. OLCH, PhD, A. R. KAGAN, MD, MYRON WOLLIN, MS, SANDRA CHAN, PhD, JOHN BELLOTTI, MS

Radiation Therapy Department, Kaiser Permanente Medical Center, Los Angeles, California

To study the consistency with which volume iridium-192 implants are treated, 40 major institutions in the United States and abroad were sent a questionnaire asking for source placement and dosimetric data for a given tumor volume. Only 12 centers responded. From these 12 responders, data related to implant technique and dose specification were extracted and intercompared. A threefold variation was found among the responses. The lack of participation (70% did not respond) and the large variation of responses among those who did participate highlight the current problem in dose specification and communication regarding endocurietherapy implants. More effort needs to be spent developing a widely accepted dose system and a language to communicate its results.

Key Words: Iridium Implant, Volume Implant, Dosimetry, Endocurietherapy

Endocurietherapy/Hyperthermia Oncology 1986;2:193-197

In an era of three-dimensional treatment planning, external beam quality control with 0.5% accuracy, and heightened interest in implant therapy, it seems incongruous that endocurietherapy techniques and dosimetry are so variable from center to center and so poorly communicated in the literature. At least in the United States, no implant guidelines and dose definitions have been generally accepted.

It is our experience that clinical research requiring data analysis of the implant literature is frustrating, to say the least. Interpreting reported doses is nearly impossible when there is no clear statement as to where the dose is located in the implant, what volume its isodose contour contains, and what the maximum dose and minimum dose are in the area of interest. We believed it would be enlightening to quantitate in some manner the scope of this communication problem. Therefore, a multi-institutional survey was constructed based on a given volume implant problem.

Address for Reprints: Arthur J. Olch, PhD, Radiation Therapy Department, Kaiser Permanente Medical Center, 4950 Sunset Boulevard, Los Angeles, CA 90027.
Submitted for Publication: July 3, 1986
Accepted for Publication: September 28, 1986

Methods

A letter was sent to 40 major radiation therapy institutions, which described the following problem:

> Assume you wish to implant a tumor whose dimensions are
> 3 cm l 4.5 cm l 5 cm (W l H l L)
>
> Based on your system of iridium-192 seed implantation, please answer the following:
>
> Diagram the location of the ribbons as you would implant them (see attached diagram).
>
> Please tell us what value you would use for the following:
>
> Prescribed dose rate: _____ rad/hr.
>
> (Is this the minimum dose rate in the target volume?)
> Yes _____ No _____
>
> Maximum dose rate: _____ rad/hr.
>
> Please enclose isodose curves showing the location of the above dose rate points or describe where these points are located in the volume.

Sketches of the tumor end view, side view, and perspective were included so that the respondent could draw the locations of the sources implanted. It was to be part of the survey for the partici-

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pants to determine how to implant this volume, ie, to include or not to include a margin around the tumor volume.

Results

Of the 40 institutions that were sent the survey, only 12 responded by providing answers to the questions asked. Thirteen parameters were chosen to study the responses (Tables 1 and 2).

The data in Table 1 describe the implant technique used by each institution. Note the variety of responses for the source separations, number of ribbons, and total activity. Overall, these parameters vary by a factor of about 3. The corresponding dosimetric data are shown in Table 2. PDR refers to prescribed dose rate while MDR refers to maximum dose rate. As could be expected, the reported doses also vary by about a factor of 3. To remove the effects of differing total activity on the variability of the reported PDR and MDR, we normalized all the reported doses to a total activity of 40 mg Ra eq. When viewing the fourth and fifth columns then, differences in dose rates are due to differences in technique. The last column, labeled "Ratio," is the ratio between MDR and PDR. The lower this ratio is, the more uniform the implant. The locations of the PDR and MDR as described by the respondents are displayed in Table 3. In more than half the cases, these locations were not specifically defined by the respondent. The majority of respondents subjectively chose their PDR and MDR values from isodose curves.

Those centers that used the most ribbons used smaller separations and used lower activity per centimeter. Three centers used ribbon separations of 1 cm or less. The ratio of MDR to PDR was 2.0 or greater in each of these cases. Institutions 2 and 8 used more ribbons than the others (25 and 30 ribbons, respectively) but used the lower linear activity (0.24 and 0.23 mg/cm, respectively). Institutions 2 and 8 were also two of the three centers

Table 1. Parameters Related to Technique*

Institution	Planes	Plane Sep	Rib Sep	AL	T/M	No. of Ribbons	TA (mg)	mg/cm
1	3	1.5	1.1	6	M	18	47	0.43
2	5	0.5,1	1.0	5	T	25	30	0.24
3	3	1.5	1.1	5	T	15	45	0.60
4	3	1.8	1.8	9	U	12	102	0.94
5	2	1.5	1.5	7	T	8	37	0.66
6	3	1.5	1.5	5	T	12	35	0.58
7	3	1.5	1.2	5	T	15	36	0.48
8	SYED	1.0	1.0	7	M	30	42	0.23
9	3	1.0	0.9	4	U	14	35	0.66
10	4	1.5	1.5	6	M	20	41	0.34
11	3	1.5	1.8	8	MT	13	61	0.58
12	3	1.5	1.5	5	T	12	36	0.60
Ranges	2-5	0.5-1.8	0.9-1.8	4-9	T,M	8-30	30-102	0.23-0.94

*Plane Sep indicates plane separation in centimeters; Rib Sep, ribbon separation in centimeters; AL, active length in centimeters (distance between end-seed centers); T/M, implant sources to tumor or to margin? MT indicates both (some ribbons implanted to tumor, some to a margin) and U indicates unclear; TA (mg), total activity in mg Ra eq; mg/cm, mg Ra eq/cm (linear activity); and SYED, SYED rectal template.

Table 2. Parameters Related to Dose*

Institution	PDR	MDR	PDR/40 mg	MDR/40/mg	Ratio
1	48	65	41	55	1.34
2	40	100	53	133	2.51
3	60	NS	53	NS	. . .
4	90	106	35	42	1.2
5	50	79	54	85	1.57
6	50	NS	57	NS	. . .
7	45	75	50	83	1.66
8	45	90	43	86	2.0
9	40	100	46	114	2.48
10	60	95	59	93	1.58
11	55	65	36	43	1.19
12	35	60	39	67	1.72
Ranges	35-90	60-106	35-59	42-133	1.19-2.51

*PDR indicates prescription dose rate; MDR, maximum dose rate; and NS, not stated.

that had a ratio value above 2.0. There was no trend, however, for the number of ribbons and total activity. Two of the centers reported that they use the Paris system (institutions 4 and 11). These centers used the larger total activities but had the smallest ratio value. Their reported technique and dose specifications were in good agreement with each other.

Discussion

We found the range of values reported for the 12 respondents to vary threefold. We did attempt to select subgroups of the respondents that appear to have similarities in their implant techniques. One can look at dose rate data for those eight centers using three planes for the implant. The range of the normalized PDR is 35 to 57. One can further select from that group four centers using three planes and ribbon and plane separations of 1.5 to 1.8 cm. Excluding center 6, the normalized PDRs of the remaining three centers are within about 6% of their mean. However, two of those three centers were using the Paris system.

Clearly, those two centers using 25 or 30 source lines used linear activity in the lower third of the range so as not to obtain inordinately high (more than 100 cGy/hr) prescription dose rates. The uniformity of these implants was relatively poor (2.0 or 2.5), perhaps owing to the 1-cm source line separations used.

To make sense out of the stated dose, its location within the target area must be known. The locations of our respondents' stated PDR and MDR are shown in Table 3. Seven of 12 chose their PDR by subjective methods. Eight of 12 either did not state the maximum dose rate or used subjective means based on their perception of clinical significance.

Before the advent of the computer for treatment planning, endocurietherapists relied on specific systems of source placement and dosimetry (Manchester, Quimby, Paris) to alleviate what otherwise would require time-consuming hand calculations. With the ability to compute dose distributions rapidly, therapists have been free to deviate from these established systems. The result can be seen in the responses to our survey. There is the tendency to individualize each implant with respect to source placement and to determine subjectively the PDR and MDR and its location. This approach may provide internally consistent results, but identical stated implant doses may vary among institutions by a factor of 3 in reality, or stated implant doses varying by a factor of three

Table 3. Locations of PDR and MDR*

Institution	PDR	MDR
1	"0.5 cm in from last seed in corner of implant and 0.55 cm from top ribbon in toward the next ribbon, midway between planes"	Not stated
2	Isodoses chosen subjectively from multiple planes	Highest dose around seed
3	Average dose rate 0.5 cm from tumor in central plane	Not defined
4	85% of basal dose rate in central plane	Basal dose rate between sources in central plane
5	Isodoses chosen subjectively from central plane	Computer reported maximum dose near seed in central plane
6	Isodoses chosen subjectively from central plane	Not stated
7	Isodoses chosen subjectively from central plane	Clinically significant maximum dose in central plane
8	Isodoses chosen subjectively from central plane	Clinically significant maximum dose in central plane.
9	Isodoses chosen subjectively from peripheral plane	Clinically significant maximum dose in central plane
10	Isodoses chosen subjectively from central plane	Clinically significant maximum dose in central plane
11	85% of basal dose in central plane	Basal dose between sources in central plane
12	0.5 cm outside peripheral plane at edge	2 × 2-cm area in central plane

*PDR indicates prescription dose rate; and MDR, maximum dose rate.

may, in fact, be identical.

It is apparent from the results of our survey that endocurietherapists should agree on a source placement system and dosimetric specifications that are well defined so that intercomparisons of results can be conducted in a common language.

Unfortunately, any isoeffect curve plotting implant dose against outcome cannot be accepted without detailed dosimetric distribution, whereas isoeffect curves of external beam dose versus outcome are relatively reliable.

Conclusion

In summary, only 12 of 40 institutions who were sent our survey problem responded. For these 12 centers, parameters related to implant technique and reported doses varied by about a factor of 3. For the majority, the doses reported were subjectively chosen from isodose curves rather than from predefined dose specifications.

As long as there is no standard communication system, comparisons of endocurietherapy dose between institutions will be misunderstood without an accompanying set of dosimetric displays and time-consuming analysis of each case.

Acknowledgments

We would like to thank the people at the 12 institutions who participated in this survey. Their interest and cooperation were essential and greatly appreciated.

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

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

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

Oct. 19, 1987

Attn: Docketing and Service Branch

Dear Sir:

This letter is in response to 10 CFR Part 35 issues raised in the Oct. 2, 1987 Federal Register, namely "Basic Quality Assurance in Radiation Therapy", and "Comprehensive Quality Assurance in Medical Use and a Standard of Care". I will address only radiopharmaceutical aspects of diagnosis and therapy.

I agree that certain safeguards are needed to decrease the probability of a misadministration of radiopharmaceuticals for diagnosis and therapy. However, the rules as proposed are not optimal in my opinion, and I would like to suggest some changes:

§ 35.39 Ordering, prescribing, and administering certain radiopharmaceuticals.

(a) Many nuclear medicine departments have more or less standing orders for I-123 for thyroid diagnosis and I-131 for thyroid therapy. They are not administered without a prescription, but I think that a license should be able to order them based on expected use.

(b) This is going a bit overboard, especially for diagnosis using I-123. In many institutions a primary care physician requests a diagnostic scan in writing and the nuclear medicine physician does not see the patient until after the I-123 has been administered. The nuclear medicine physician may review the primary physician's written request form in advance, but I don't think it is necessary for the nuclear medicine physician to personally examine the patient's chart, and consult with the primary physician in advance.

I do believe that the administration of I-131 for diagnosis or therapy should require prior authorization of the nuclear medicine physician, but again I do not think that prior personal examination, chart review, and consultation with the primary care physician is always necessary. In my practice, a primary care physician, usually a surgeon or endocrinologist, will request I-131 for therapy after thyroidectomy for the treatment of thyroid cancer. The request form will include the operative note, pathology report, and discharge summary, if the surgery was performed in this hospital. Why would

'87 OCT 26 P3:40

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I need to go to the patient's chart or confer with the primary care physician? All the necessary information is there. As far as personally examining the patient, all you find is a fresh neck scar. The most important thing is patient identification and explanation of the procedure; both can be done very well by a certified nuclear medicine technologist with the physician as back up.

(c) I would change the wording to read: "A licensee may not administer I-131 for diagnosis or therapy or any radiopharmaceutical for therapy without comparing the radiopharmaceutical label and dosage on hand with the physician's prescription."

§ 35.43 Prescriptions, records, and checks of medical use for therapy.

(a) Agree

(b) -1 Agree

(d) Agree

§ 35.65 Discrepancies in records and observations. Agree

§ 35.302 Administration of radiopharmaceutical dosages. Agree

Comprehensive Quality Assurance
in Medical Use and/a Standard of Care

The introductory comments and analysis of known misadministrations shows insight and excellent understanding of underlying problems.

Quality Assurance

General

1. Although the NRC could implement a quality assurance program that would provide absolute assurance that there would be no misadministrations, that program would be quite simply to refuse to license any physicians to administer radioactive material. That is, absolute assurance is an unattainable goal. What you really want is a very good system in which misadministration is highly unlikely. Let us aim for this.

2. The definition of misadministration is fine, and need not be changed. The situation in which the correct patient is given the correct radiopharmaceutical by the correct route of administration in the correct quantity as prescribed by the correct physician, but the patient doesn't have the correct disease in the first place, is called malpractice. It is not the province of the NRC, but the States take care of it just fine.

3. A radiopharmaceutical should not be administered without a written request by a primary care physician, with several exceptions. Occasionally, the nuclear medicine physician is the primary care physician (many nuclear medicine physicians run thyroid clinics, for example). Occasionally, a telephone conversation with the nuclear medicine physician leads to a verbal request by the primary care physician. The nuclear medicine physician should document that the request has been received from that physician.

Occasionally, a request for a nuclear medicine procedure is denied by the nuclear medicine physician, usually because of technical reasons. Communication appears to me to be appropriate here, and I do not think any new rules need to be made.

Occasionally, a request for one scan is denied but a more appropriate scan is substituted. As long as the primary care physician has communicated his diagnostic question(s) to the nuclear medicine physician, this presents no real problem. The primary care physician is usually promptly informed of the superior study. No new rules need to be made.

4. Matching the patient's name and identification number (on the request) to the bracelet ID is usually sufficient to insure that the correct patient is receiving the procedure. Very rarely, the primary care physician will pick up the wrong ID plate and stamp it on the request form without realizing it. Little can be done to avoid administering the radiopharmaceutical to the unintended patient except to hope that an astute technologist notices an apparent discrepancy in sex, age, or condition and questions the order.

5. The training of nuclear medicine physicians and radiologists is adequate. The training of radiotherapists in the use of radiopharmaceuticals for therapy is often not very extensive. I happen to be against the special limited licenses (e.g. for cardiologists, endocrinologists) because their knowledge of basic radiation sciences is often poor. I would certainly not decrease the current requirements. I do not think recertification examinations are worthwhile.

The training of technologists in nuclear medicine is variable. Those certified as nuclear medicine technologists (CNMT) are qualified, but certification is not always required (e.g. in California, although it may change shortly). I think that certification should be required. Again, I don't think recertification is necessary or particulary useful.

One sticky problem with technologists is civil service. Let us assume that a technologist, licensed or not, commits several misadministrations (because of carelessness, stupidity, alcoholism, or drug addiction). A radiation safety committee may remove the technologist from the hospital license, but you cannot fire him. You therefore have a technologist who is paid to not work, and you cannot hire another to take his place. I

would dearly love to see an NRC rule that would supercede all civil service boards and state that a radiation safety committee may fire a technologist who commits misadministrations. Or, some other rule that would result in the same action.

6. I run an RIA laboratory, and I am inspected by the State every year or two. However, they are more interested in biochemical quality control than in radiation safety. The JCAH inspects us every two years, but again, they are not rigorously into radiation safety. Inspections by our County and State Radiological Health Inspectors provide the in depth regulation that is needed. Occasional inspections of our Radioactive Drug Research Committee work by FDA is limited in scope and not rigorously focussed on radiation safety and quality control.

7. Not at all necessary. A patient has a right to insist on seeing a report of his study. Few demand it, but they may. The report contains administered dose information. NRC action is superfluous.

8. There are some companies that have a bad record of mislabeled radiopharmaceutical shipments and the habit of dumping radioactive shipments wherever they please, instead of in the nuclear medicine department. However, if that company was the low bidder and received the hospital contract, the radiation safety committee cannot force administration or procurement to cancel the contract and renegotiate with another company. I would like to see an NRC rule which gives a radiation safety committee the power to cancel a contract for radiation safety purposes, and promptly arrange for an alternate supplier.

Radiopharmaceutical Therapy

The quality control and assurance program is adequate. The problem is the people running them. An unlicensed technologist-even a licensed technologist-is not as good as a radiopharmacist. It is easy to mix up P-32-chromic phosphate with P-32-sodium phosphate if you're ignorant. It is important that the physician himself checks the vials if he doesn't have a radiopharmacist, and that it's clear in his mind that he is treating peritoneal metastases vs. polycythemia rubra vera. I think that the only appropriate thing for NRC to do is to insist on certified technologists. If a physician licensee makes an error, that is malpractice, and not really an NRC matter except that the State can, with good reason, suspend his license.

No special rules regarding patient identification need to be made. Those that exist are fine. It is always prudent to ask the patient some questions about his disease before you perform therapy; that is when you catch the rare error made by the primary care physician in requesting the treatment for the wrong patient. However, this is just common sense, and no regulatory agency has ever been able to pass laws to guarantee that!

Standards of Care

1. Standards of care are so variable and evanescent that I don't see any point in latching on to one.

2. If a "standard of care" were to be adopted by NRC, it would probably have little or no impact on radiation therapy care.

3. Penalties should be imposed on licensees in the form of fines, and there is always the possibility of suspension of license. Penalties to individual employees should be removal from the license and job loss.

The opinions expressed here are my own, and do not necessarily represent the views of the ACNP, the SNM, the University of California, or the County of Los Angeles.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Medicine Outpatient Clinic (213) 533-2845
and
Asst. Prof. of Radiology, UCLA
President, ACNP, California Chapter
Board of Trustees, SNM So. Calif. Chapter
Member, Govt. Relations Committee, SNM
Member, Govt. Affairs Committee, ACNP
Member, Radiopharmaceutical Committee, ACNP
Past Member, Radiopharmaceutical Advisory Committee, FDA
Vice Chair, Radiation Safety Committee
Chair, Radioactive Drug Research Committee

CSM:dt
cc: Leonard Holman, M.D.
Capt. Wm. Briner
David Woodbury, M.D.
James Conway, M.D.
Jose Martinez, M.D.
Melissa Brown
Henry Ernstthal
Jean Parker
Norman McElroy
Ismael Mena, M.D.
Alan Pasternak, Ph.D.

MALLINCKRODT INSTITUTE OF RADIOLOGY

AT WASHINGTON UNIVERSITY MEDICAL CENTER

BARRY A. SIEGEL, M.D.
Professor of Radiology and Medicine
Director, Division of Nuclear Medicine

13 November 1987

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

Re: 10 CFR Part 35; Basic Quality Assurance in Radiation Therapy; Proposed Rule (52 FR 36942; 2 October 1987)

Dear Sir:

As commentary on the above-named proposed rule, I wish to provide the Commission with background information and suggestions, which are detailed in full in letters dated 12 October 1987 and 30 October 1987 to Mr. Norman L. McElroy of the Office of Nuclear Material Safety and Safeguards. Copies of these letters are attached.

I appreciate the opportunity to comment on these matters, and hope the Commission will take my suggestions under consideration.

Sincerely yours,

Barry A Siegel MD

Barry A. Siegel, M.D.

BAS:ld

Enclosures

510 South Kingshighway Boulevard
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MALLINCKRODT INSTITUTE OF RADIOLOGY
AT WASHINGTON UNIVERSITY MEDICAL CENTER

BARRY A. SIEGEL, M.D.
Professor of Radiology and Medicine
Director, Division of Nuclear Medicine

12 October 1987

Norman L. McElroy
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Norm:

We haven't spoken for quite a while, but I see from my copy of the 2 October 1987 Federal Register that you have not been idle. I would appreciate it if you would send me a copy of the Regulatory Analysis and additional supplementary information you believe might be helpful relating to both the Notice of Proposed Rule-Making and the Advance Notice of Proposed Rule-Making in that issue.

For your information, I am enclosing a copy of the radioiodine prescription form in use in my Division. Although we have employed a written prescription for therapy procedures for a number of years, I expanded the form to include certain diagnostic procedures performed with I-131 sodium iodide after learning of the recent therapeutic misadministrations and diagnostic misadministrations involving I-131 at other institutions. I would be curious to know how well you believe our procedure complies with the intent of the proposed rule. I should point out that we use this form only for doses of I-131 sodium iodide, but only for purposes other than uptake measurements. Consequently, this includes those rare instances where I-131 (rather than I-123 or Tc-99m pertechnetate) is used for conventional thyroid imaging, and the more usual instances where I-131 is employed for detection of metastatic thyroid carcinoma or for treatment of hyperthyroidism. (I-131 therapy of thyroid carcinoma in my institution is performed by our Division of Radiation Oncology, rather than the Division of Nuclear Medicine.) I have not felt it necessary to include uptake doses in this prescriptive procedure because of the way these are prepared and dispensed in our laboratory; specifically, we use liquid solution to prepare a batch of diluted liquid I-131 doses for uptake measurements, initially callibrated at 6 uCi per vial and used down to a lower level of 2 uCi. Since the packaging for uptake doses is therefore different than the stock I-131 liquid used for imaging and therapy, I have not felt that the specific written prescription and redundant checks applied to the latter procedures were necessary for the uptake measurements. You will note that the form consists of three parts. The upper portion, which comprises the prescription itself, is completed by either a Nuclear Medicine resident, Radiology resident, or Staff Nuclear Medicine physician. The middle portion of the form is completed by the dispensing radiopharmacist or technologist (in addition to the usual radiopharmacy log entry). Our procedure requires that the third part of the form can be completed only by a Nuclear Medicine staff physician; that individual also cosigns the dispensing entry in the radiopharmacy log.

In the remainder of the letter, I would like to pose some questions informally for your consideration, in regard to the Notice of Proposed Rule Making. I hope, as in the

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past, you will be willing to react to my questions and suggestions, either in handwritten notes on a copy of this letter or by telephone discussion. Also as in the past, I would propose to reflect on your reactions prior to filing my own formal comments and before corresponding with the government relations people at SNM, ACNP, and ACR.

Am I correct in assuming that 35.39(a) means ordering a radiopharmaceutical of iodine from a vendor, rather than ordering for a patient? If so, what type of documentation constitutes "approval of the authorized user"? Would such ordering from a vendor require that a particular patient be in mind? I hope not, since this would preclude keeping iodine-labeled radiopharmaceuticals "in stock".

Is it really your intent that 35.39 apply to iodine radiopharmaceuticals other than I-131 sodium iodide? Is it really essential that a nuclear medicine physician personally examine the patient **and** personally examine the patient's chart **and** consult with the referring physician if reasonably available before prescribing a 2-5 uCi dose of I-125 human serum albumin for a blood volume measurement? I pose the same question regarding prescription of I-131 hippuran for renal imaging and small doses of I-131 sodium iodide for thyroid uptake measurements. The requirement for all three steps seems unnecessarily stringent even for prescription of larger doses of I-131 for metastatic carcinoma imaging or for therapy, but strikes me as clearly excessive for the other mentioned applications. An example from my own institution will illustrate the potential problem implicit in the present wording. We perform approximately 50 renal transplant imaging studies each month, and about 20% of these are performed by an on-call nuclear medicine technologist as emergency procedures, at a time when an authorized user is not immediately on the premises. Our standard procedure involves administration of 15 mCi Tc-99m glucoheptonate, 225-250 uCi I-131 hippuran, and 0.3 ml SSKI solution to block thyroidal uptake of any free I-131 iodide that may be present in the hippuran preparation. (We have included the latter as part of all of our procedures that involve iodine radiopharmaceuticals, other than sodium iodide, for over a decade, but I believe we are in a substantial minority regarding this simple practice to lower radiation exposure.) The requirements of 35.39(b) and (c) would at a minimum markedly inhibit our willingness to perform emergency renal transplant studies, and would delay the timely performance of such studies. Have there been a substantial number of misadministrations where I-131 sodium iodide was administered when I-125 human serum albumin or I-131 hippuran was intended? If not, I certainly urge that this rule apply only to I-131 sodium iodide for diagnosis or therapy and any radiopharmaceutical for therapy. Whether uptake doses of I-131 sodium iodide should be included is arguable, and I am willing to reserve my judgement until I see the regulatory analysis regarding those misadministrations of diagnostic radiopharmaceuticals resulting in doses in the therapeutic range.

I have not had a chance to look at the Advance Notice of Proposed Rule-Making in any detail, but will write to you soon regarding these.

I look forward to hearing from you.

Sincerely,

Barry A Siegel

Barry A. Siegel, M.D.

BAS:ld
Enclosure

MALLINCKRODT INSTITUTE OF RADIOLOGY

DIVISION OF NUCLEAR MEDICINE

RADIOIODINE PRESCRIPTION

To Be Completed By Physician

DATE _____

NAME: _____ BD _____

SEX: _____ REQ # _____

DOSE OF I-131 NaI PRESCRIBED: _____

FOR DIAGNOSTIC IMAGING _____ OR THERAPY _____

_____ M.D.
Prescribing Physician

To Be Completed by Dispensing Pharmacist or Technologist

LOT # _____ VOL _____

DOSE CALIBRATOR READING _____

_____
Dispensing Pharmacist or Technologist

To Be Completed by Staff Physician

NON-PREGNANT STATUS OF PATIENT CONFIRMED _____

VIAL IDENTITY & LOT # CONFIRMED _____

DOSE CALIBRATOR READING CONFIRMED _____

_____ M.D.
Staff Physician

MALLINCKRODT
INSTITUTE OF
RADIOLOGY
AT WASHINGTON UNIVERSITY MEDICAL CENTER

BARRY A. SIEGEL, M.D.
Professor of Radiology and Medicine
Director, Division of Nuclear Medicine

30 October 1987

Norman L. McElroy
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Norm:

In followup to my letter of 12 October 1987, and pursuant to our telephone discussion today, I have some additional thoughts regarding proposed 10 CFR 35.39. After reviewing the background information pertaining to diagnostic misadministrations resulting in doses in the therapeutic range, I believe it is eminently clear that the primary problem relates to selection and administration by a technologist of a relatively large dose of I-131 sodium iodide under circumstances where it would have been appropriate to use a smaller dose of I-131 sodium iodide, or either I-123 sodium iodide or Tc-99m pertechnetate, or an entirely different radiopharmaceutical (Tc-99m MDP). I strongly concur that it is appropriate to protect patients from such inadvertent misadministrations of large doses of I-131 sodium iodide. The available data do not, however, indicate that there is a problem with this type of misadministration when the intended radiopharmaceutical is I-125 Human Serum Albumin for plasma volume measurement or I-131 Hippuran for renal imaging. Thus, I believe that the proposed wording is unduly restrictive, and would interfere with the ability of many nuclear medicine laboratories to provide emergency renal imaging services in a timely fashion (as discussed in my 12 October letter). I am sure this is not NRC's intent.

I believe NRC's quite legitimate concerns in this matter would be satisfied if the wording of 35.39(b) and (c) were changed to read as follows:

> (b) A physician may not prescribe administration of a dosage in excess of 30 microcuries of iodine-131 sodium iodide for diagnosis or therapy or any radiopharmaceutical for therapy without first documenting the appropriateness of the prescription for the intended diagnostic study or therapy by: (1) examination of the patient; or (2) examination of the patient's medical record; or (3) consultation with the referring physician. Prescriptions for the administration of these byproduct materials must be in writing, and must include the patient's name, the intended type of diagnostic study or therapy, the radiopharmaceutical, dosage, and route of administration.
>
> (c) A licensee may not administer a dosage in excess of 30 microcuries of iodine-131 sodium iodide for diagnosis or therapy or any radiopharmaceutical for therapy without

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> comparing the radiopharmaceutical label and dosage on hand with the physician's prescription.

Essentially, this would mean that dosages of iodine-131 sodium iodide, other than those employed for thyroid uptake measurements or for the rare indications (and I mean rare) where I-131 sodium iodide is appropriate for conventional thyroid imaging, could not be administered to a patient without the explicit (written) intent of the authorized user or a physician under the supervision of the authorized user (since such individuals have the exclusive authority to prescribe byproduct material).

This requirement likely would not create substantial problems in medium-sized or large medical centers where an authorized user or a physician under the supervision of the authorized user is usually present during those times that a dosage of I-131 sodium iodide in excess of 30 microcuries needs to be prescribed and administered. The requirement also strikes me as entirely appropriate, since I believe it is incumbent upon the physician prescribing a dosage of I-131 that potentially can ablate thyroid tissue to be very certain it is the correct dosage for that particular patient.

However, I can imagine circumstances under which this requirement might create a problem for small community hospitals where the authorized user or his or her physician-delegate might not always be physically present. Hence, I wonder whether an "escape clause" could be included in 35.39(b) regarding the written prescription, as follows:

> The authorized user or a physician under supervision of the authorized user, if not immediately available, may prescribe a dosage in excess of 30 microcuries of I-131 sodium iodide **for diagnosis**, if such prescribing physician has first consulted with the referring physician. The individual receiving the telephone prescription shall record in writing all of the information designated above, as well as the date and time of the telephone prescription and the name of the prescribing physician. Such prescription shall subsequently be co-signed by the prescribing physician. A radiopharmaceutical for therapy may **not** be prescribed by telephone.

I believe that this emergency "escape clause" might occasionally be important in preventing great inconvenience to a patient. Imagine that a patient has arrived at Hospital A to receive a 5 mCi dosage of I-131 sodium iodide for whole body imaging to search for metastatic thyroid carcinoma, but the only physician authorized to prescribe I-131 sodium iodide is tied up at Hospital B. Shall we make the patient wait or come back another day, or will direct communication by the authorized user with the referring physician and a telephone prescription by the authorized user suffice? Note, however, that I specifically exclude therapy in the proposed "escape clause", because I believe it is incumbent upon the nuclear physician or radiologist performing therapy to have seen the patient.

I am still somewhat troubled by 35.39(a), because I am not exactly certain how to make it work in those nuclear medicine laboratories where iodine-131 sodium iodide is kept in stock in anticipation of diagnostic or therapeutic

uses. My own situation provides a good example. We keep approximately 30 mCi of I-131 sodium iodide on hand at all times, and use this material to prepare dilute I-131 for thyroid uptake doses as well as to dispense doses for whole-body I-131 imaging or therapy. When our stock is low, our radiopharmacist or one of our technologists contact the vendor to order more, or have our purchasing secretary do so. These purchases are authorized by blanket purchase orders, which are renewed annually, but in essence I authorize purchase of an entire year's supply of iodine-131 sodium iodide by approving those blanket orders. Although it would be possible for me or one of our other staff (as authorized users) to enter the loop and co-sign every order for I-131 sodium iodide, this would slow things down a bit, and would require that we generate additional paper records (since the orders are now placed by telephone, with the packing slip constituting our paper record of that order). I would argue, however, that 35.39(a) is unnecessary as an additional safeguard to prevent misadministrations of I-131 sodium iodide or radiopharmaceuticals for therapy, because 35.39(b) places the responsibility squarely upon the prescribing physician to make sure that the correct drug in the correct dosage is being given to the correct patient for the correct indication. As indicated in my earlier letter, we take this safeguard one step further since we require that a staff physician (an authorized user) validate the identity of the radiopharmaceutical and the dose calibrator reading before the dosage of I-131 sodium iodide is administered to the patient.

As an alternative safeguard to 35.39(a), your concept that iodine-131 sodium iodide be stored in the radiopharmacy in a specifically designated area that is distinct from the storage location of other radiopharmaceuticals would be much less onerous. I hope, however, that this would not require a **separate** refrigerator, or cabinet or fume hood, but rather that a shelf, or cubical or area could be designated as the I-131 sodium iodide storage area.

Please let me know if my suggestions strike you as viable alternatives to 35.39. As we discussed, I am sending copies of this letter to Melissa Brown, Otha Linton, and other interested individuals.

Sincerely yours,

Barry

Barry A. Siegel, M.D.

cc: Melissa P. Brown
Otha Linton
Capt. William H. Griner
C. Douglas Maynard

BAS/lb

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

13 November 1987

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

Attn: Docketing and Service Branch

Dear Sir:

We all strive to make as few errors as possible and should continue to take steps to reach a "no error" goal. My comments on the proposed regulation follow.

Sec. 35.43 - Federal regulations will not change the mind set of a technologist, dosimetrist who is "disinclined to request clarification". This type of individual has no place in medicine. Regulations will not change him/her.

Sec. 35.432 - How can a licensee measure the strength of an I-125 seed to the same degree of accuracy as the manufacturer?

Sec. 35.452 and 35.652 - If two individuals are to review "images such as radiographs, CT and ultrasound, etc." and to make independent physical measurements, one must assume certified "individuals" should do this - implying physicians. There are many facilities where two physicians are not readily available and if available there is the matter of reimbursement by patient and/or insurance and Medicare. Recent HCFA regulations (transmittal 1200) and past Medicare practices would not pay for two physicians rendering the same service to a patient.

Sec. 35.454 - This section again requires time from physicians or physicists and fails to address availability of these individuals or how this will be financed.

This section also implies a "second opinion" in essence regarding prescription dosimetry and treatment plan. It calls for a second radiotherapist to see the patient.

In these days of cost containment particularly in Medicare, these proposed regulations are doubling the cost of a course of radiation therapy without proof that misadministration would be decreased.

Using NRC numbers - 30,000 I-131 patients, 100,000 teletherapy patients and 50,000 brachytherapy patients - total 180,000 and only 27 reported therapy misadministrations we have an incident rate of .00426%. If only surgeons, internists, etc. did as well!!

Sec. 35.633 - Independent checks of therapy units should of course be done but the calibration equipment should be double checked prior to its use.

Regulatory Flexibility Certification - If implemented as proposed, there would be a tremendous economic impact on all small entities. A solo practitioner could not comply.

The goal of reducing errors is commendable. Much of what is proposed is already done by trained radiation therapists. But regulations will not reduce errors which are committed - as you say - those "disinclined" to prevent them.

Sincerely,

George H. Zenger

George H. Zenger, M.D.

GHZ/kb

STATE OF IOWA

TERRY E. BRANSTAD, GOVERNOR

DEPARTMENT OF PUBLIC HEALTH
MARY L. ELLIS, DIRECTOR

November 13, 1987

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

Attention: Docketing and Service Branch

Reference is made to the Proposed Rules found in FR Vol. 52, No. 191, dated Friday, October 2, 1987, regarding Basic Quality Assurance in Radiation Therapy. We have reviewed the proposed rule and support its intent. We feel that the Commission will have to provide guidance documents, as it has in the past, on the process to follow to implement such a rule. We would encourage the Commission to immediately start work with the appropriate group within the Conference of Radiation Control Program Directors, Inc., to establish the rule(s) within the Suggested State Regulations for the Control of Radiation to address the proposed rules. This is of extreme importance if it appears that the change will become an "item of compatibility."

Thank you for the opportunity to comment. If you have any questions, please do not hesitate to contact me or Donald A. Flater at 515/281-3478.

Sincerely,

John A. Eure

John A. Eure, Chief
Bureau of Environmental Health
515/281-4928

JAE/bf

cc: Donald A. Nussbaumer

'87 MAY 12 P5:09

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REPLY TO
ATTENTION OF

Radiation Therapy

November 5, 1987

Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Docketing and Service Branch

Dear Mr. Secretary,

I would like to comment on the proposed rules in the Federal Register, Vol. 52, No. 191, dated October 2, 1987. As a medical physicist in Radiation Therapy, and also the administrative officer for Department of Radiology, discussions with our professional staff in both Nuclear Medicine and Radiation Therapy have raised several important issues. I would like to add that the proposed rules are good quality assurance procedures, but are not all necessarily practical for all sizes of Nuclear Medicine and Radiation Therapy clinics. Comments are described below corresponding with their proposed 10 CFR section.

1. **35.39(b) - Ordering, prescribing, and administering certain radiopharmaceuticals:** Our physicians agree that for therapeutic iodine administrations, these procedures are prudent. However, for diagnostic use, a total review of the patient's chart and physical exam of the patient prior to administration of the dose is not practical or necessary, when merely a review of the written request from the primary physician with the patient's history provides an adequate level of quality assurance. One solution would be to exempt diagnostic use of Iodine-123, since the thyroid dose from this isotope is minimal compared to that of Iodine-131.

2. **35.432 - Source strength measurements:** My first concern with this section deals with its vagueness, since there is no designated range for deviation from the manufacturer's calibrated value, leading to an arbitrary and variable level of accuracy from clinic to clinic. I am not aware of any formal protocol for local measurement of sealed sources as requested nor is there a counting system for brachytherapy sources currently commercially available. Without such a standard system, counting geometries can vary widely depending on the type of system a physicist may use (dose calibrator, well counter with G-M tube or scintillation system). This is complicated by the fact that no manufacturer currently sells a commercial check source available with a similar geometry that would allow this procedure, which causes one to arbitrarily choose one of the brachytherapy sources, and use this as the "standard" against all other activities with that geometric shape should correspond. This provides a reproducible system, but does still not necessarily equate to accuracy. Additionally, the high specific activity associated with these sources due to the need to physically move them to another site within the hospital will dramatically increase the dose to the physicist, since our clinic does not have any system available other than the required survey and detection instruments required by 35.420. One way adequate quality assurance could be addressed would

be to specify certain measurement geometries or source jigs that would meet NRC approval.

3. **35.454 - Check of dose calculations:** Many smaller facilities do not have a backup physicist or dosimetrist available to double-check all data associated with a brachytherapy application, especially when one of them is on vacation or sick. However, the therapy physician, by nature of familiarity with similar procedures, has a professional ability to ascertain if the implant times are commensurate with those expected by either their prior experience or by clinical texts. If this section were to be satisfied by review of the calculations by the therapist, my concerns would be satisfied. If physician review would not be adequate, then I would strongly recommend that this rule be applied to the agreement states, which would insure cooperation with physicists and dosimetrists from other competing radiotherapy facilities.

4. **35.633 - Independent check of full calibration measurements:**

(a) Paragraph (b) of this section has a typo which should read 35.630.

(b) The description of the check system in paragraph (b) does not mention use of a TLD service, as mentioned in the description on page 36947 of the Federal register. If this type of output check is adequate, then I have no problem with this section if it were applied to the agreement states, since it would encourage cooperation between physicists of local competing radiotherapy facilities.

5. **35.654 - Checks of dose calculations and measurements of dose:**

(a) There is a typo in the heading of this section. It should read 35.654, not 35.354.

(b) Paragraphs (a) and (b) could be combined to simply require that all calculations, whether manual or computer, be checked by an individual other than the one who originally calculated the treatment time.

(c) I believe that adequate quality assurance can be provided by allowing the same individual to recalculate the treatment time, but must be by an alternative method, and checked at a time other than during the original dose calculation. An example would be if he first used the computer, and then followed this by a totally manual hand calculation. If these calculations were within two percent, then it would be adequate and meet these quality assurance requirements.

Joseph P. Hellman

Joseph P. Hellman
Captain, U.S. Army
Medical Physicist

Yale University
Department of Diagnostic Radiology

SCHOOL OF MEDICINE
333 CEDAR STREET
P.O. BOX 3333
NEW HAVEN, CONNECTICUT 06510

November 9, 1987

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

Attention: Docketing and Service Branch

Re: Proposed rule NCR 10CFR, part 35, Basic Quality Assurance in Radiation Therapy, Federal Register, Vol. 52, No. 191, October 2, 1987; specifically paragraphs 35.39, 35.43, 35.65 and 35.302

Dear Sir/Madam:

As a user of radiopharmaceuticals for both diagnosis and treatment and a Director of a nuclear medicine and nuclear radiology training program, I object to many aspects of the proposed new rules.

First, I object to the selection of "radiopharmaceutical of iodine" as a separate category of radiopharmaceutical. First, the definition is unclear. It is unclear whether the rule pertains to radiopharmaceuticals which consist of radioisotopes of iodine alone or also includes radioiodinated compounds as well. Second, it is unclear why certain isotopes of radioiodine such as I-123 constitute any greater hazard than any other radiopharmaceutical. Third, it is unclear why certain compounds of I-131 such as I-131 labeled hippuran constitute any greater hazard than any other radiopharmaceutical. With regard to the radiopharmaceutical sodium 131-iodine (iodide), it is true that doses above the 100 uCi range may constitute a special hazard. I believe that for doses in excess of 100 uCi of this particular specific radiopharmaceutical it is not unreasonable to expect to have an authorized user or a physician under supervision of the authorized user to be responsible for the actual administration of the radiopharmaceutical as well as providing documentation of such administration. This can be accomplished with a minimum of paper work and will offer a guarantee that the authorized user or physician under supervision of the authorized user will have actually seen the patient and presumably verified by history and physical examination that the medical indication for use of this byproduct material is appropriate.

I believe that certain provisions in the proposed regulations are essentially unenforceable. For example, Section 35.39C requires that a licensee may not administer a radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without comparing the

radiopharmaceutical label and dosage on hand with the physician's prescription. The only way that anybody could be found guilty of having violated this regulation is by self-incrimination, since no further documentation is required. Furthermore, the whole matter of prescriptions brought up in paragraph 35.39b may raise the question, in certain states, of whether or not a radiopharmacist or other licensed pharmacist must be employed to fill the prescription.

Under paragraph 35.43 there is a requirement that the licensee verify "the authorized user has personally made, dated, and signed a written prescription in the patient's chart". Many of the patients we treat with I-131 for Graves disease are treated as outpatients and do not, in fact, have a formal "chart" but rather a series of records that are incorporated in the radiologic report.

Section 3c of paragraph 35.43 requires prescriptions and other records made regarding medical use of byproduct must be legible and unambiguous. I do not know what constitutes a criterion for legibility.

In summary, I believe that all of the beneficial aspects in the proposed rule making could be accomplished by the simple expedient requiring all doses of the radiopharmacetucial sodium 131-iodide of greater than 100 uCi to be administered directly by an authorized user or a physician under the supervision of the authorized user and that documentation of such administration be maintained by the authorized user. I believe that the remainder of the regulations are unnecessary, confusing, require an excess of paper work or are unenforceable except by self-incrimination.

Respectfully submitted,

P B Hoffer

Paul B. Hoffer, M.D.
Professor of Diagnostic Radiology
Director, Section of Nuclear Medicine
Yale University School of Medicine

PBH/hc
cc: Alexander Gottschalk, M.D.
Radioisotope Committee

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Writer's Phone:
516-741- 7614

November 9, 1987

Secretary of the Commission
U.S. NUCLEAR REGULATORY COMMISSION
Washington, DC 20555

Attn: Docketing and Service Branch

Re: 10CFR Part 35
Basic Quality Assurance in
Radiation Therapy

We are in agreement with proposed rule, specifically Part 35.354(d).

We would also like to call to the attention of the Nuclear Regulatory Commission that instruments are currently available to perform these measurements.

Sincerely,

H. Glasser

H. Glasser

HG:dl
Enc. 228L, 371A

'87 NOV 13 A11:45

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DOCKETING & SERVICE
BRANCH

NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
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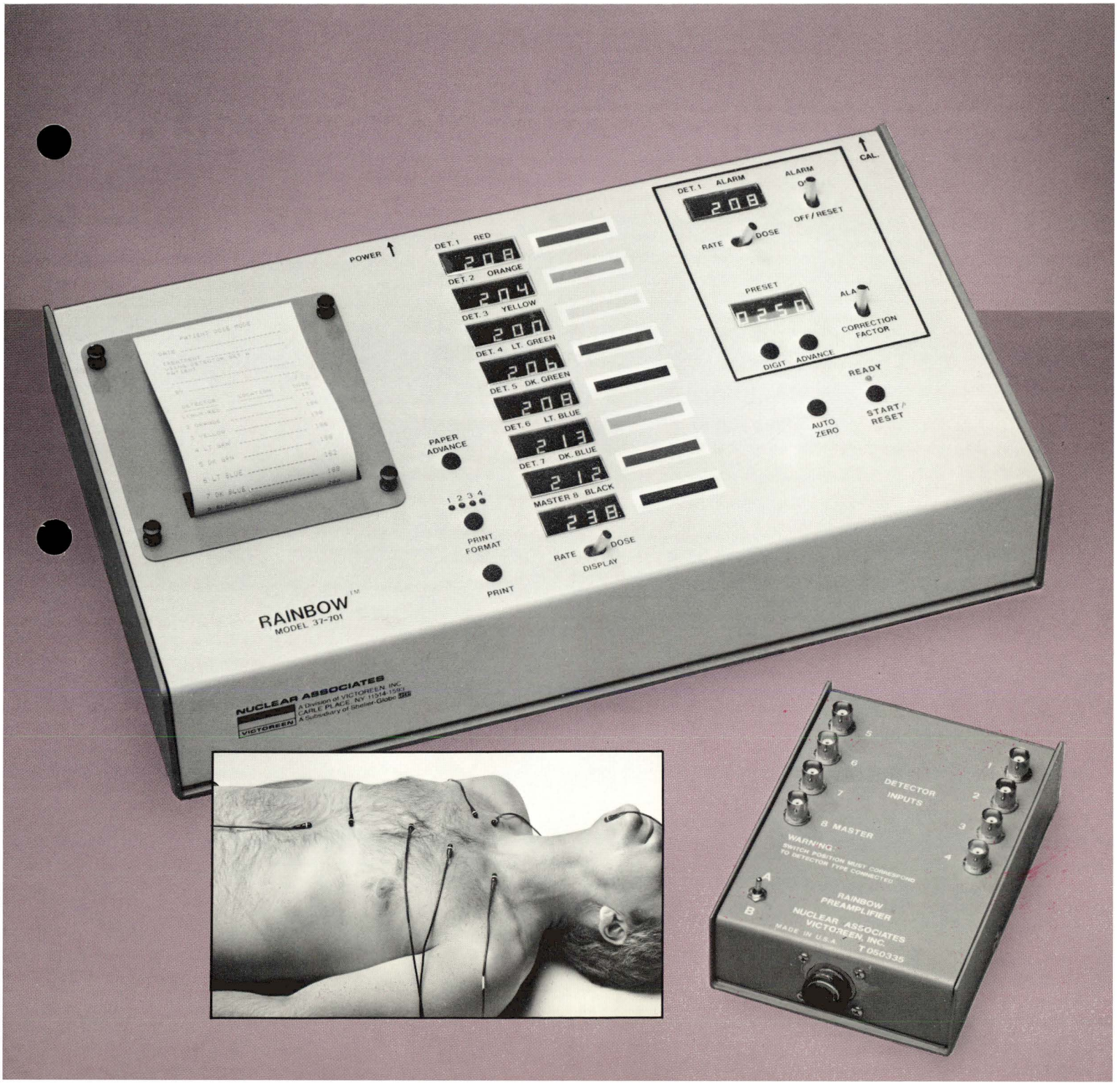
RAINBOW™

PATIENT DOSE VERIFICATION AND QA BEAM ANALYZER



RAINBOW

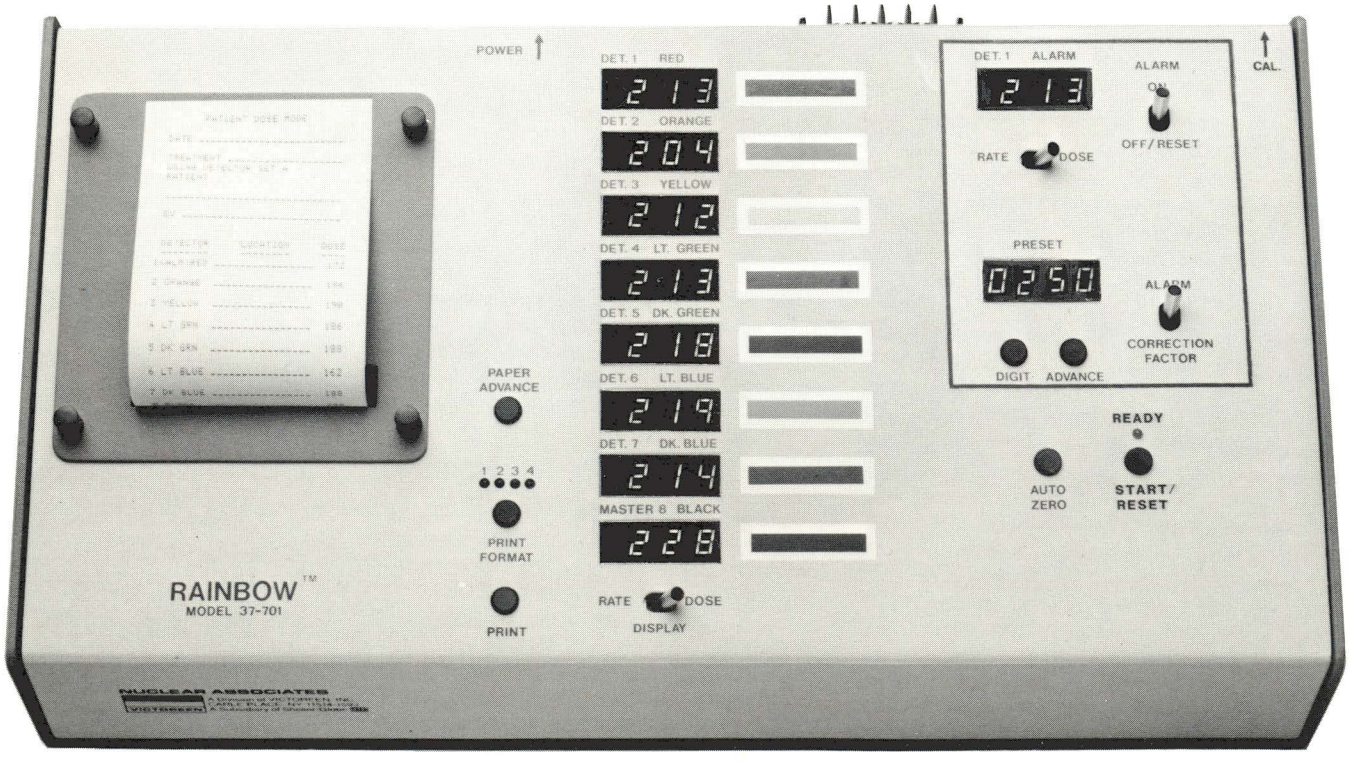
features

IMMEDIATE DISPLAY OF 8 CHANNELS
PRINTED RECORD OF ALL VALUES

- **Eight individual displays.**
- **Accepts eight diodes.**
- **All diodes monitored simultaneously.**
- **Dose and rate modes.**
- **Paper-tape printout.**

The RAINBOW DOSIMETRY SYSTEM combines an 8-channel digital electrometer with up to eight diode detectors for direct patient dose measurements during treatment. It also serves as a radiation beam analyzer. Each detector channel has its own LED display. A 50-foot cable connects the electrometer to a preamplifier that has eight BNC input jacks. The detector cables are 5 feet long.

RAINBOW utilizes detectors in three energy ranges: ^{60}Co to 4 MeV, 6 to 8 MeV, and 10 MeV. The detectors differ only in their integral build-up. RAINBOW offers the option of using two sets of different energy detectors by merely setting a selector switch on the preamplifier.

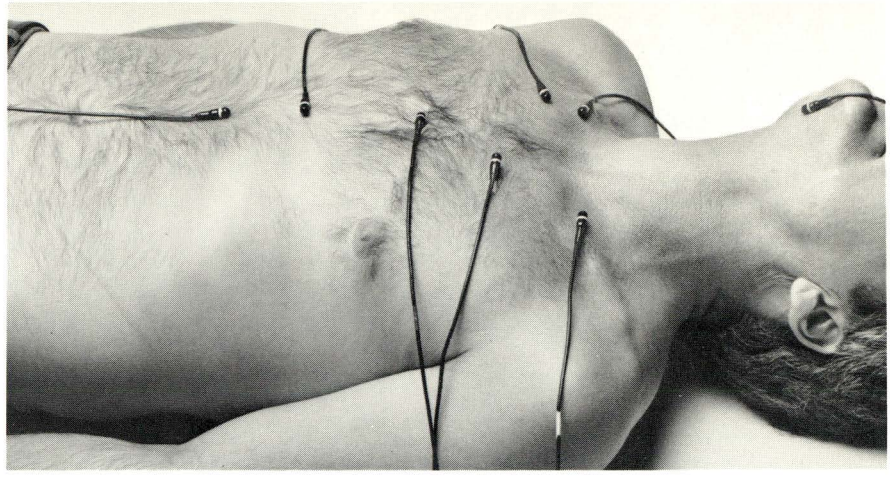


PATIENT DOSE MODE

- **Verifies techniques quickly.**
- **Ideal for whole body and irregular fields.**
- **Real-time dose display.**
- **Alarm value pre-set by operator.**

The patient dose is printed for each channel, providing a record for verification. Space is included for manual entry of date, treatment, location of diodes, patient and operator names.

Detector #1 can be placed in a specific area and set to actuate the alarm at a pre-set dose or dose-rate. A correction factor is indicated. By applying this factor, the user can employ the detector in other energy ranges.



PATIENT DOSE MODE

DATE _____

TREATMENT _____
USING DETECTOR SET A
PATIENT

_____

BY _____

DETECTOR	LOCATION	DOSE
1(ALM)RED	_____	172
2 ORANGE	_____	186
3 YELLOW	_____	190
4 LT GRN	_____	186
5 DK GRN	_____	188
6 LT BLUE	_____	162
7 DK BLUE	_____	188
8 BLACK	_____	200

DETECTOR 8 EXP. RATE IS
0197 UNITS/MIN

CORRECTION FACTOR IS 1.000
ALARM SETTING IS 300 DOSE
ALARM IS DISABLED

MACHINE TEST MODE

- **Quickly check central axis dose rate.**
- **Use detectors in a wide range of energies.**
- **Easily applied correction factor.**

In the machine test or rate mode, the master detector (channel #8) is used to measure the central axis dose rate. The remaining seven detectors are read out as a percentage of the master channel. A correction factor is indicated. By applying this factor, the user can employ the detector in other energy ranges.

MACHINE TEST MODE

DATE _____

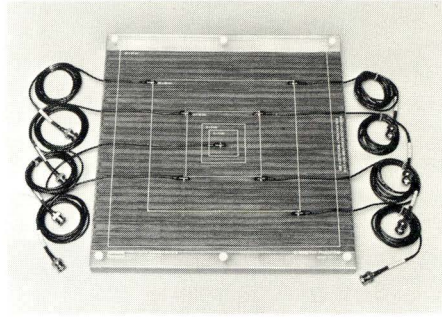
TEST _____
USING DETECTOR SET A
MACHINE

_____

BY _____

DETECTOR	DOSE	DOSE%
1 RED	170	85.4
2 ORANGE	185	92.4
3 YELLOW	188	94.3
4 LT GRN	186	93.1
5 DK GRN	187	93.7
6 LT BLU	162	81.5
7 DK BLU	187	93.8
8 BLACK-MASTER	200	100.0

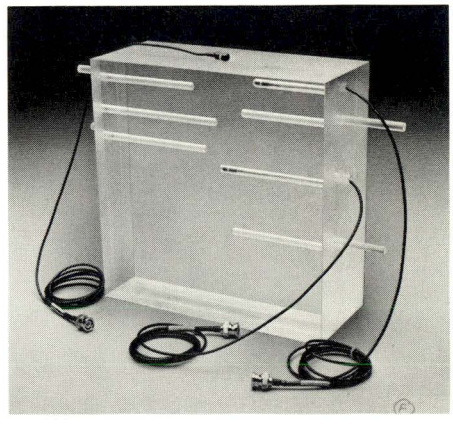
CORRECTION FACTOR IS 1.000



BEAM SYMMETRY PHANTOM

- **Helps to determine beam flatness.**
- **Helps to determine beam symmetry.**
- **Large 34 x 35 cm surface.**

Up to eight diodes can be positioned. Field-size markers aid in diode and phantom positioning.



DEPTH DOSE PHANTOM

- **Checks depth dose.**
- **25 x 25 cm size fits existing SCRAD blocks.**
- **Provides fixed measurement depths of 1, 2, 4, 5, 8, 10 and 16 cm.**

SYSTEM ACCESSORIES

DIODE CALIBRATION FIXTURE

- **Fixes diode-to-diode geometry.**
- **Easy diode positioning.**

A fixture is provided to facilitate diode calibration. Up to eight diodes can be placed in the fixture, controlling diode-to-diode geometry. The fixture and diodes may then be placed in a known radiation field for calibration.

DIODE DETECTORS

Diode detectors are available in three energy ranges: ^{60}Co to 4 MeV, 6 to 8 MeV, and 10 MeV. Diodes differ only in the integral build-up in each diode series.

SPECIFICATIONS:

Operational Mode:	Shorted junction
Build-Up:	Integral
Cable Length:	5 feet, terminating in BNC plug
Energy Response:	
Model 30-490-8	^{60}Co–4 MeV
30-493-8	6–8 MeV
30-494-8	10 MeV

ORDERING INFORMATION

37-701-1	RAINBOW Electrometer, Pre-amp and Calibration Fixture (does not include diode detectors)	$4,950.00
37-701-4	Symmetry Phantom	275.00
37-701-5	Depth Dose Phantom	485.00
30-490-8	Diode Detector, ^{60}Co to 4 MeV. . ea.	210.00
30-493-8	Diode Detector, 6-8 MeV .....ea.	225.00
30-494-8	Diode Detector, 10 MeV .....ea.	225.00
81-701	Printer Paper, 5 rolls/pkg	30.00
87-701-2200	220 Volt Power Converter	200.00

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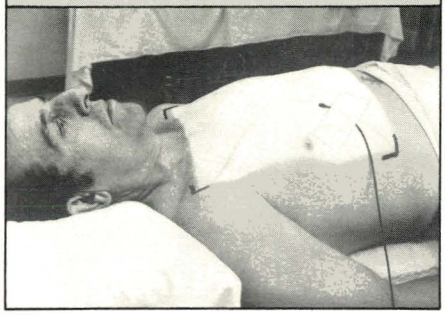
5-686 371A

For Therapy Dosimetry...

Look what our tiny new diode detector provides you

Detector is shown
ACTUAL SIZE
including ^{60}Co
build-up cap



Detector can be taped
in any position on patient.

±1% ACCURACY.

- **Instant patient dose data without correction factors.**

  Determines exposure gradients of mantle fields, strip techniques, tangential breast and wedge fields. Replaces TLD for irregular field measurements.

- **"Sensitive organ" measurements (eyes, rectum, mouth).**

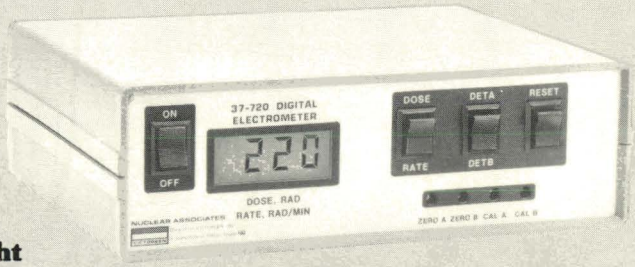
- **Rapid checks of equipment output.**

Available in 3 energy ranges.
Compatible with most electrometers.

To complete your system...

Low-Cost Digital Electrometer

- **Reproducibility: ± 1%**
- **Range: 0-2000 Rad or Rad/minute**
- **Accepts 1 or 2 detectors**
- **Battery Operated • Compact • Lightweight**



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(OVER)

Diode Detector*

The miniaturized Diode Detector has proven its reliability and dependability in the clinical environment for the past 10 years. The detector, when coupled with a good electrometer, offers a unique combination of high accuracy (± 1%), ruggedness, small size, immediate readout and simple operation. Calibrated at its center, the diode gives the dose wherever it is placed. It can be taped to the patient's skin to obtain data for TDR values, eliminating time-consuming TLD measurements. Irregular field dosimetry is easily performed with this high-output detector. No temperature or pressure corrections are necessary. Typical diode applications include the clinical measurement of tangential breast fields, lens of the eye, gonadal dose, mouth, rectum, prostate and vaginal fields.

Slightly modified depth-dose data and the equivalent square field size may be employed to convert "surface" dose to a desired depth dose (below the diode) at points of interest, on and off the axis. Dose measurements of this type can serve as a practical substitute for tedious irregular field dose calculations (e.g., mantle fields). The method is especially useful for verifying routine mid-line tumor doses, picking up small errors in the dose delivery where experience has shown that spurious measurements become evident immediately.

It operates in a shorted junction mode requiring no bias voltage. The output is six times greater than standard 0.6cc ion chambers. Three energy-response ranges are available: ^{60}Co-4 MeV, 6 MeV, and 10 MeV. An integral build-up cap at the end of the flexible 30-foot cable establishes equilibrium and serves as a filter for low-energy radiation.

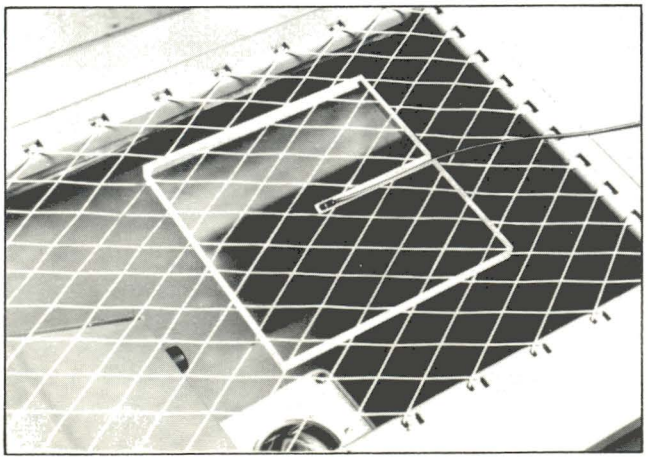
An optional Detector Holder is available. This 7″ × 7″ × ½″ thick clear acrylic plate is routed to hold the diode in a level, reproducible position during field measurements.

Detector Specifications:

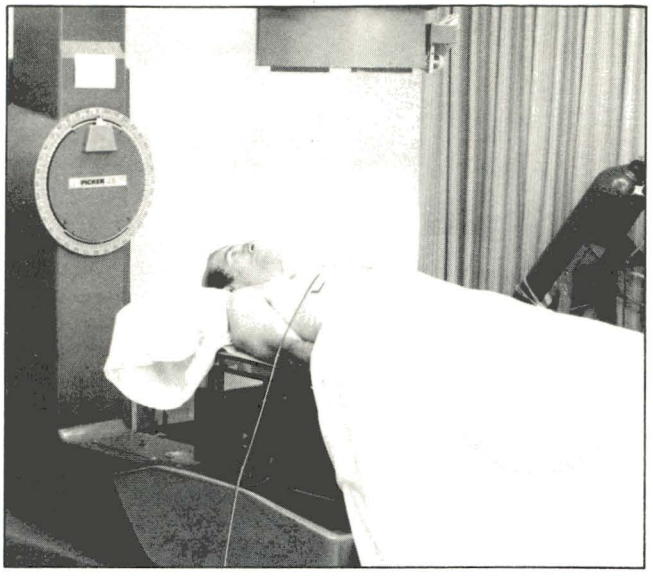
Accuracy: ± 1%.
Energy Response Ranges: ^{60}Co-4 MeV, 4-8 MeV, 9-10 MeV.

Detector Diameter:	**(30-490)**	^{60}Co–4 MeV	7.0 mm
	(30-493)	6–8 MeV	7.2 mm
	(30-494)	10 MeV	7.5 mm

Sensitive Volume: 0.200 mm^3 typical.
Operational Mode: Shorted junction.
Output Range: 75 to 90 × 10^7 rads/coulomb.
Linearity: ± 1.0% of full scale.
Output: 2 × 10^{-11} amperes/R/min.
Detector Cable: 30 feet long. BNC termination.
Build-Up Cap: Integral with detector.



Optional holder positions the diode for direct measurements of therapy machine output.



Detector and 30-foot cable allow direct skin dose measurements.

Therapy Dosimetry System

The Therapy Dosimetry System combines a compact, solid state electrometer and the Diode Detector to offer a low-cost, dependable means of checking therapy machine output. It is not intended for use as a primary calibration instrument. The unit is also excellent for depth-dose studies in phantoms and for field use, allowing accurate and reproducible dose and dose-rate data to be obtained without any warm-up or temperature equilibration.

Measurements are read on a large digital display with a range of 0-2000 Rad or Rad/minute. The electrometer accepts either 1 or 2 diode detectors which are selected by a front-panel switch. Calibration and zero controls are also readily accessible on the front panel.

Digital Electrometer Specifications:

Accuracy: ± 5%. Reproducibility: ± 1%.
Range: 0-2000 Rad or Rad/minute.
Readout: ½-inch digital display.
Front Controls: ON-OFF, Dose-Rate, Det.A–Det.B, Reset, Trimpots for Zero and Calibration for Detectors A and B.
Rear Connections: Det.A and Det.B Input.
Power: Standard 9-volt alkaline battery.
Size: 2¾″ high × 6″ wide × 6¼″ deep.
Weight: 2 lbs.

30-490	**Diode Detector.** ^{60}Co to 4 MeV	$210.00
30-493	**Diode Detector.** 6 to 8 MeV	225.00
30-494	**Diode Detector.** 10 MeV	225.00
30-492	Optional Holder for diode detector	20.00
37-720	Digital Electrometer	745.00

*"Properties of a Diode Dosemeter for Radiotherapy" by Laurence Gray, M.S. Available on request.

St. John's Hospital

800 East Carpenter
Springfield, Illinois 62769
217/544-6464

Medical Physics

November 5, 1987

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

Subject: Comments on Proposed Rules "Basic Quality Assurance in Radiation Therapy"

Dear Gentlemen:

I am opposed to the proposed rule changes in their entirety. There appears to be a number of assumptions in proposing these rules; the first, that the number of misadministrations is significant, second that this number can be reduced by legislation and thirdly the economic impact of these proposed changes is insignificant.

Using statistics provided in the document one can show that approximately seven misadministrations per year out of a total of 180,000 procedures per year result in an incidence rate of approximately 0.004%. Even allowing a factor of 10 or 20 more misadministrations than reported results in an incidence rate of less than 0.10%. I find these numbers remarkably small.

The second assumption is that the number of misadministrations can be reduced by a revision of the rules. The analysis of misadministrations indicates three fundamental problems; inadequate training, inattention to detail and lack of redundancy. I believe that rule revisions may correct inadequate training and may effect the level of redundancy but will not effect the level of attention of an individual doing a particular task. Consequently, misadministrations will still occur as a result of generalized mistakes, specifically someone not paying attention. Consequently, it is my opinion that these rule revisions will not substantially reduce the number of misadministrations.

The third assumption is that these rule revisions will have insignificant economic impact. This is concluded apparently by comparing the expected additional cost of these revisions to the average gross annual receipts of an institution. A more appropriate comparison may be between the expected additional cost and the

expected number of reduced misadministrations. In this analysis I suspect that the cost per reduced misadministration would be considerably high, primarily due to the small number of misadministrations presently.

There are a number of excellent documents available addressing issues of quality assurance in radiation therapy published by the AAPM or the ACR. I believe these documents establish a standard of care and consequently create liability for practioners in the field not following these standards. I feel that legal liability is a far greater motivating factor than these proposed revisions and as a result these revisions would have little effect on practioners who are currently not following standards of care. Unfortunately, these revisions would effect all practioners in the field and as a result would be too expensive for the anticipated gains.

Thank you for the opportunity to comment.

Sincerely,

Ray Capestrain

Ray Capestrain, M.S.
Medical Physicist

RC:tmc

Richard L. Cole Jr. M.D.
11275 Pabellon Circle
San Diego, CA. 92124
November 4, 1987

Dear Sirs:

The following opinions are regarding the proposed NRC changes to CFR part 35 which relate to changes in radiation therapy and radiopharmaceutical regulatons. The comments are made in response to the proposals published in the Friday, October 2, 1987 Federal Register. All the opinions below are related to the proposals printed on page 36948 in the middle column.

Section 35.39 (b) states: "A physician may not prescribe administration of a radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without personally examining the patient and the patient's chart, and consulting with the referring physician if reasonably available."

I have three comments regarding this sentence:

1) This would be an unreasonable restriction of 5 uCi I^{131} doses for thyroid RAIU (radioactive iodine uptake) studies. The restriction would be less objectionable if it applied only to iodine doses over a certain level such as 10 uCi. If enacted as stated, this sentence would make most RAIU studies more trouble than they are worth.

2) Also "consulting with the referring physician", may be unnecessary, especially if the referring physician has requested the therapy in writing.

3) I believe a clarification would be helpful in the first part of the sentence, "A physician may not prescribe administration ... ". Does "physician" here refer to the authorized user only or to a physician under supervision of the authorized user?

Sincerely,

Richard L. Cole Jr. M.D.

William S. Middleton
Memorial Veterans'
Hospital

2500 Overlook Terrace
Madison WI 53705

Veterans Administration

In Reply Refer To:

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC

Richard J. Hammes
Nuclear Pharmacist
November 3, 1987

Dear Sir:

These are my comments on the proposed rule, 10CFR Part 35, titled "Basic Quality Assurance in Radiation Therapy".

With regard to radiopharmaceutical therapy, the magnitude of the problem does not justify new rules. According to NRC statistics, there were only six misadministrations between November 1980 and July 1984 while there were an estimated 110,000 therapeutic doses administered. This is an exceptionally low error rate. Furthermore, three of those misadministrations resulted from misreading the label and, presumably, not assaying the dose before administration. This is already a violation of current regulations and making additional rules is not likely to correct the problem. In addition to this general objection to the proposed rules, I have some specific comments to be addressed before the rules are finalized.

1) With regard to 35.39, including all iodine radiopharmaceuticals, both diagnostic and therapeutic is extremely burdensome. This would include radiopharmaceuticals such as iodohippurate and albumin in addition to the more dangerous sodium iodide. It makes more sense to set a patient dose activity level above which the more stringent therapeutic requirements would apply. 500 microcuries would be apppropriate since below this activity the potential for adverse effects is extremely low, but most diagnostic imaging could proceed efficiently.

2) 35.39 a. If the intent here is to require written approval of orders by the authorized user, it is overly restrictive. It is a rare institution where the authorized user does the ordering and almost all radiopharmaceuticals are ordered by telephone to facilitate expeditious delivery, often for use the same day or the next day. There is very little to be gained by placing obstacles in the ordering process. The regulations should concentrate on the administration end of the chain.

3) 35.39 b. These are reasonable requirements for therapeutic administration but totally unreasonable for diagnostic administrations.

4) 35.39 c. The requirement to assay the dose before administration should be reiterated. This assay should be cross-checked with the prescription and the label. The assay should be done twice; first by the person who prepares the dose and second by the person who administers the dose. The administration of therapeutic amounts should be restricted to physicians and pharmacists.

Sincerely,

Richard J. Hammes

Richard J. Hammes, RPh., MS.,
Board Certified Nuclear Pharmacist

"America is #1—Thanks to our Veterans"

UNIVERSITY OF WISCONSIN
CLINICAL SCIENCE CENTER
DEPARTMENT OF RADIOLOGY
600 HIGHLAND AVENUE
MADISON, WISCONSIN 53792

MICHAEL A. WILSON, M.D., CH.B., F.R.A.C.P.
ASSOCIATE PROFESSOR RADIOLOGY AND MEDICINE
CHIEF, NUCLEAR MEDICINE
(608) 262-7014

5 November 1987

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

SUBJ: Comments to Proposed 10 CFR Part 35 Changes

(1) 35.39(a) I am confused by this section as I believe it is implicit that if the license orders radiopharmaceuticals it has the approval of the authorized user in that it is a designate of the user that is ordering the radiopharmaceutical.

2. 35.39(b) This section I find too all-inclusive. I performed 1136 diagnostic and therapeutic iodine studies as defined in the proposed changes in FY-1987 (July 1, 1986 - June 30, 1987) and this represented 23% of the total Nuclear Medicine workload. Of these 49 were iodine therapies (10-150 mCi), 32 were diagnostic metastatic surveys - (8 mCi), 39 diagnostic uptakes (4-10 uCi), and 1002 iodohippurate studies (100-200 uCi), and 14 blood volumes (<100 uCi iodinated albumen).

It can be seen the majority are diagnostic tests (96%). The largest contributions were the renal studies (particularly for transplantation), and in each case the thyroid burden is very low. The need to personally examine the patient and chart, and consult with the referring physician is unreasonably demanding and not warranted medically in the diagnostic studies. Such a requirement is a waste of time.

I would be happy if the same demands were placed on patient studies where significant radioiodine doses were used (say >1 millicurie or even >250 microcuries).

Yours sincerely,

MICHAEL A. WILSON, M.D.
Chief, Nuclear Medicine Service
Associate Professor, Radiology & Medicine

VICTOREEN

NUCLEAR ASSOCIATES

A Division of VICTOREEN, INC.

100 VOICE ROAD • CARLE PLACE, NY 11514-1593

Writer's Phone:
516-741- 7614

November 4, 1987

Secretary of the Commission
U.S. NUCLEAR REGULATORY COMMISSION
Washington, DC 20555

Attn: Docketing and Service Branch Re: 10 CFR Part 35
Basic Quality Assurance in
Radiation Therapy

A potential problem with Cobalt 60 teletherapy equipment is the accuracy and performance of the timer which determines the treatment time.

Until recently, Cobalt 60 teletherapy systems only utilized mechanical "count-down" timers.

This mechanical "count-down" timer is manually set by the technician. The timers are usually set by manually moving the minute and second hands to the desired treatment time. It would be entirely possible to make a human error of mis-setting the timer -- a setting of 2½ minutes could be set as 3½ minutes, and vice-versa.

Once a count-down timer starts in motion, it is not possible to determine if an error was made in the timer setting. Under the present system of timer settings, unless there is a back-up count-up timer, it is impossible to ever know if an incorrect time was set.

Another potential problem with mechanical timers is a "sticky", or intermittent movement.

Attached are two papers which describe the importance of timer settings and a potential mechanical problem with a mechanical count-down timer.

It is, therefore, suggested that, in the proposed ruling of "Basic Quality Assurance in Radiation Therapy", it be stipulated that Cobalt 60 machines that only have "count-down" timers include in their quality assurance a method of a "count-up" or verification timer.

The "count-up" or Verification Timer, is commercially available, simple to install on existing equipment, and relatively inexpensive.

Sincerely,

H. Glasser
General Manager

HG:dl
Enc.

'87 NOV -9 P2:25

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Accuracy in patient setup and its consequence in dosimetry*

Ponnunni K. I. Kartha, Anthony Chung-Bin, Thomas Wachtor, and Frank R. Hendrickson

Department of Therapeutic Radiology, Rush University and College of Medicine, Chicago, Illinois 60612

(Received 18 November 1974)

Analysis of 5575 settings on a computer-monitored Theratron-80 ^{60}Co unit demonstrates that human error does occur in treating patients with radiation. The errors are due to inaccurate setting of such parameters as field size, gantry angle, collimator rotation, treatment time, etc. The error rate per parameter was found to be about 3%, and more than two-thirds of the patients monitored with the PDP 11/45 computer had at least one error at some stage during the full course of treatment. Both the dose and the dose distribution may be affected by these errors and have been studied in a few typical cases. The errors in timer setting have the largest effect on the prescribed dose and may change the probability of local control appreciably.

More than 50% of all cancer patients are benefitted by radiation therapy at some point in the course of their disease. The clinical importance in the accuracy of the dose delivered in treating a tumor has been demonstrated by Shukovsky[1] and by Herring and Compton.[2] Reports[3] have been made of various types of errors when patients are treated with radiation. We have reported previously[4] the results of a study of the errors usually seen in the treatment of patients with radiation owing to calculation errors and/or misreading of prime data. For example, the arithmetical error in the calculation of treatment time has been found to be 5% or more in 10% of the cases. This paper presents the results of a study of errors in the daily setting-up of patients receiving radiation treatments with a computer-monitored Theratron-80 ^{60}Co unit. All of our patient setups are isocentric. The center of the field on the patient's surface is either tattooed or localized with respect to some prominent anatomical landmark. In a few cases, the corners of the fields are also marked. The target volume is then located beneath the surface marking at a depth to place it at the isocenter. The Theratron-80 in our department is used mostly for treating the tumors of the head and neck. The patient-monitoring system[5] includes a PDP 11/45 computer which monitors and records the values of the parameters used in daily treatment of patients: for example, patient identification, field size, gantry angle, collimator rotation, date and time of treatment, beam-on time, etc. This record of the parameters can then be compared with that appearing on the corresponding treatment cards. This was a pilot study to determine the magnitude of setup errors and their implications in dosimetry.

The first step in the analysis of the computer data was to obtain the systematic error in the actual settings of the parameters on patients. We define systematic error[6] as the degree of accuracy with which a certain parameter can be repetitively set on the machine under normal working conditions when patients are set up for treatment. This is measured by the difference between the prescribed and delivered values. Table I shows the systematic error for the field size, gantry angle, collimator rotation, and treatment time. Isocentric techniques have been employed in the setting-up of patients for treatment, and currently the dose rate from our Theratron-80 unit at 10-cm depth for a 10 × 10-cm field at 80-cm source-axis distance (SAD) is 1 rad/sec.

The second step in the analysis of the data was to find the frequency of accidental errors. We define accidental errors[7] as erroneous settings of the parameters due to some sort of oversight. They are recognized by their relatively large deviations from their intended values. The arbitrary criteria we chose in defining an error as accidental are given in Table II. The treatment card of each patient was compared with the computer printout data for the course of treatment to find the incidence and magnitude of the accidental error. These errors were then analyzed, and the results are given in Table II. The number of patients monitored in this detailed analysis was 98, and 5575 parameter settings were involved. At least one misset parameter was found in the

TABLE I. Systematic error in field, gantry, collimator, and timer settings.

Field size		Gantry		Collimator		Timer	
Set within	% of cases	Set within	% of cases	Set within	% of cases	Set within	% of cases
1 mm	81.4	1°	81.0	1°	89.1	1 sec	86.1
2 mm	93.5	2°	97.2	2°	95.3	2 sec	90.9
3 mm	95.1	3°	97.6	3°	97.3	3 sec	93.1

TABLE II. Accidental errors of various types in 5575 settings and frequency of each in percentage of the total.

Parameter	Criteria used for accidental error	Number of setups	Accidental errors	Percentage
Field size	1 cm or more	2364	78	3.3
Gantry	15° or more	1064	23	2.2
Collimator rotation	10° or more	1136	26	2.3
Treatment time	0.5 min or more	1011	36	3.6
Total		5575	163	2.9

treatment course of 69 patients, two or more missets in that of 22 patients, and a maximum of five missettings in that of 3 patients. Where multiple errors occurred, they were found to involve the missetting of the same parameter in all cases save one. The average number of erroneous treatments delivered in a full course where multiple missettings occurred was found to be about 10%.

The third step in our analysis was to compare the isodose patterns for a few treatment plans with and without a 10% error rate. The treatment plans were generated by computer with the use of the radiation treatment planning system of Sterling.[9] Those considered were the following: a pair of wedged fields for maxillary antrum tumors; a pair of posterior-oblique fields in treating laryngeal tumor with bilateral cervical lymph nodes; a parallel-opposing pair in treating tumor in the larynx, etc. Missettings in positioning the wedge, field size, gantry, and collimator were considered in generating the isodose distribution. These errors made minimal difference in the dose distribution. The area enveloped by the 90% isodose line (100% being at the isocenter) changed less than 5% with these errors.

The fourth step in our analysis was to estimate the real change in dose between what was prescribed for the patient and what was actually delivered. In the case of patients where missetting of parameters occurred, the tumor dose at the isocenter was calculated according to the computer printout data of parameters and compared with that in the treatment card. The cumulative error in dose in the full course of treatment of the patient was thus found. 25 rads was the maximum error found owing to the missetting of the field size. The maximum error, as a result of the missetting of the timer, was found to be 145 rads. From the published work of Shukovsky,[1] showing the probability of local control for superglottic squamous cell carcinoma vs nominal standard dose (NSD), an error of 50 rets can result in a change of local control by 20%. We suspect that the change in dose between what is prescribed and what is delivered owing to the missetting of the timer may be of this order of magnitude and, hence, a serious concern.

Accidental errors do occur while patients are being given radiation treatment. This study does not deal with all the different types of errors; however, we have found that among the measured parameters that have been misset, timer setting has the largest effect on the prescribed dose and may change the probability of local control appreciably. Computers can help us prevent these errors from occurring in clinical dosimetry provided all machine parameters, particularly the time, can be digitized, which would thus enable verification of the patient setup before the commencement of daily treatment.

*Presented at the Radiological Society of North America Meeting, November 1973.

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[6]Systematic error here is meant to include both constant and random errors (see Ref. 8). These types of legitimate errors arise from fluctuating conditions, personal errors, errors in judgement, and instrument capability.
[7]Accidental error here is meant to include those types of illegitimate errors such as blunders, errors of computation, and chaotic errors (see Ref. 8).
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Technical Innovation

ACCURACY IN RADIOTHERAPY TREATMENT

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Radiotherapy has proved very effective in the management of cancer. There is increasing evidence that the dose–response curve is rather steep. Therefore, accurate doses are important clinically. At present there is not enough data to support that this degree of accuracy is achieved in clinical radiotherapy all the time. Our data on patient monitoring and verification suggest that timer or monitor setting has the largest effect on the dose and may be significant.

Radiotherapy, Accuracy in patient setup, Computer monitoring and verification, Dosimetry.

INTRODUCTION

More than 50% of all cancer patients benefit from radiation therapy at some point in the course of their disease. The clinical importance in the accuracy of the dose delivered in treating a tumor has been demonstrated by Shukovsky[7] and by Herring and Compton.[2] This concept that small variations in dose might result in a significant increase in tumor control or failures has been supported by the data of Morrison,[6] Stewart and Jackson[9] as well as Luk and Castro.[5] Reports have been made of various types of errors when patients are treated with radiation.[8] We have reported,[3] previously, the results of a study of errors usually seen in treatment of patients with radiation, owing to calculation errors and/or misreading of prime data, such as percentage depth dose or tissue–air ratio: for example, the arithmetical error in the calculation of treatment time in minutes in the case of a ^{60}Co unit or monitor units in the case of a 4 MV Linear Accelerator has been found to be 5% or more in 7.1% of the cases. This result is reported from a study analyzing the treatment cards of 4718 patients who were treated in our Department during the period 1971–75. The errors were corrected promptly during our daily check of treatment cards.

METHODS AND MATERIALS

The present paper pertains to the recent study of errors found in the daily setting of patients receiving radiation treatments with a computer-monitored Theratron-80 ^{60}Co unit and a 4 MV Linear Accelerator. All of our patients are set up isocentrically. The center of the radiation field on the patient's surface is either tattooed or localized with reference to some promient anatomical landmark. In few cases, the corners of the fields also are marked. The target volume then is located beneath the patient's surface at a certain depth to place it at the isocenter. The monitoring system includes a PDP 11/45 computer which monitors and records the values of the parameters used in daily treatment of patients: For example, patient's identification in terms of a physics number, field size, gantry angle, collimator rotation, date and time of treatment, beam on time, etc. After setting up the Patient for a given treatment field, the technologist types in the physics number and the field number, in the case of multiple fields, on a Hazeltine Terminal. The computer then verifies the parameters with those of the first treatment and informs the operator of the correctness of the setup. The computer also questions the operator to correct the parameters, if there is deviation in any of them from those of the first treatment. This enables the technologist to correct the parameters if they were set up incorrectly on any particular day. The beam then is turned on for the daily dose. The beam on time, in terms of seconds, in the case of the ^{60}Co unit or in terms of the monitor units in the case of the 4 MV Linear Accelerator is recorded by the computer at the end of the treatment for the particular field. This is followed for all the fields that are treated for all individual patients. Thus, one is able to get all the

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parameters for the individual patient through the full course of treatment. These recorded parameters by the computer then can be compared with those appearing on the treatment cards of individual patients. Thus, the study enables one to determine the magnitude of setup errors and their implication in dosimetry.

RESULTS AND DISCUSSION

We have reported,[4] previously, that more than 95% of the setups do not make significant errors, either in field size, gantry rotation, collimator rotations or timer setting. Errors of small magnitude introduced in the repetitive setting up of the machine for the daily treatment of patients were named "systematic errors". The systematic error here is meant to include both constant and random errors. These types of legitimate errors arise from fluctuating conditions, measurement uncertainties, errors inherent in approximations and instrument capability. These errors do not make appreciable differences between what was prescribed for the patient and what actually was delivered. These errors, therefore, do not introduce significant errors in patient dosimetry.

The second type of error is termed the accidental error. Accidental errors are erroneous settings of the parameters resulting from some sort of oversight. They are recognized by their relatively large deviation from their intended values. Accidental error here is meant to include those types of illegitimate errors, such as errors larger than usual uncertainties, errors of computation and chaotic errors such as those resulting from use of inappropriate data. Since the computer verifies all the parameters before turning the machine on for treatments except the real beam on time, the accidental errors introduced in parameters, such as field size, gantry rotation and collimator rotation should be very minimal. Tables 1 and 2 show the frequency of accidental errors in the field settings on the ^{60}Co and 4 Mv Linear Accelerator. The arbitrary criteria used in defining an error as accidental for field setting was 1 cm or more. It is obvious from these tables that the missetting of the dial for field size was very minimal. The cumulative error in dose resulting from the missetting of the field size, therefore, was not significant in the full course of treatment of the patient. We believe that the reason for minimal missetting of the field size was the result of the monitoring and verification of this parameter by the computer prior to turning on the beam. The frequency of accidental error in the timer and monitor setting of the two teletherapy units also are given in Tables 1 and 2. The arbitrary criteria used in defining an error as accidental was 30 sec for the timer setting and 30 units for the monitor setting. The frequency of accidental error for the timer was about 3%. This agrees with the result reported in our initial study.[1,4]

The frequency of accidental error for the monitor setting in the case of the 4 MV Linear Accelerator was found to be about half of that on the Theratron 80. The time period of the patients treated on both the machines was the last quarter of 1975. We believe that the reason for the larger accidental error for the Theratron 80 might result from the absence of a digital time setting device for that machine. We also estimated the real change in dose between what was prescribed for the patient and what actually was delivered as a result of the missetting of the timer during a full course of treatment. The maximum error for the entire course of therapy as a result of the missetting of the timer was found to be 150 rad. The maximum error as a result of the missetting of the monitor setting was 185 rad. This change in dose owing to the missetting of the timer or monitor may be of the order of 50 ret and might cause an ap-

Table 1. Accidental errors in 1032 settings on 25 patients treated with the Theratron 80 during the last quarter of 1975

Parameter	Criteria used for accidental error	Number of steups	Accidental error	%
Field size	1 cm or more	688	1	0.15
Treatment time	30 sec or more	344	11	3.20

Table 2. Accidental errors in 3972 settings on 70 patients treated with the 4 MV Linear Accelerator during the last quarter of 1975

Parameter	Criteria used for accidental error	Number of setups	Accidental error	%
Field size	1 cm or more	2648	24	0.91
Monitor unit	30 or more	1324	19	1.44

preciable change in the probability of local control. This is especially important when the intent of treatment is curative.

CONCLUSION

The results of our study reveal that accidental errors do occur while patients are being given radiation treatment. If the patient setup parameters were monitored and verified by the computer prior to turning on the beam, the technologist could pick up the daily setup errors and thereby minimize such errors. The frequency of errors in timer setting could be minimized by digitizing the timer. We believe that computer monitoring and verification of daily setup parameters have significant roles in modern radiotherapy to achieve the desired degree of accuracy in clinical dosimetry.

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Note: The underscoring of sentences in this printing is not part of the original article but was added by Nuclear Associates to call attention to the importance of timer settings.

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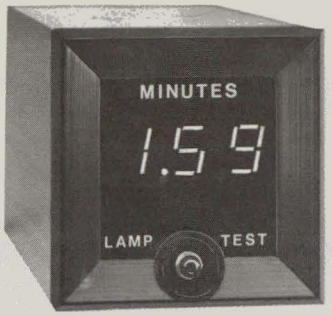

"Several errors were identified as a one-minute missetting of a timer."

This statement appears on page 62 of the BRH report,* "Nationwide Survey of Co-60 Teletherapy; Final Report—August, 1980." The report further states (pg. 63):

"Another problem area identified in the survey involved exposure timing errors. Even though they represented a small fraction of the exposures, the occurrence of such errors in a clinical setting could result in significant changes in dose administration. Therefore, it is important to minimize their occurrence and provide a means of alerting the operator when such errors have occurred."

The Verification Timer helps avoid these problems.

*HHS Publication (FDA) 80-8130, available from BRH.

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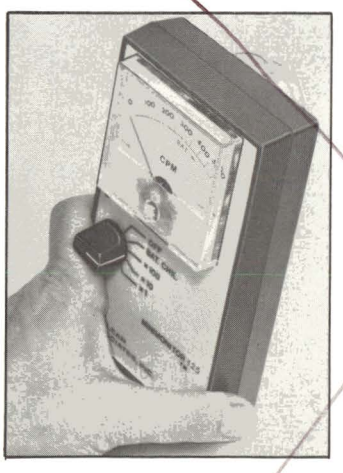

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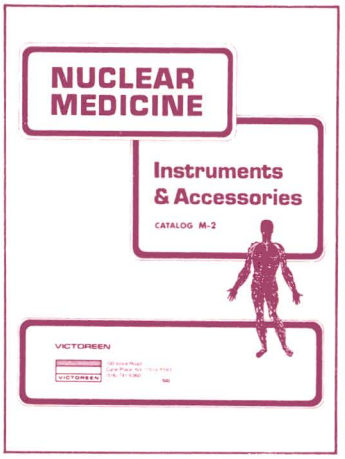

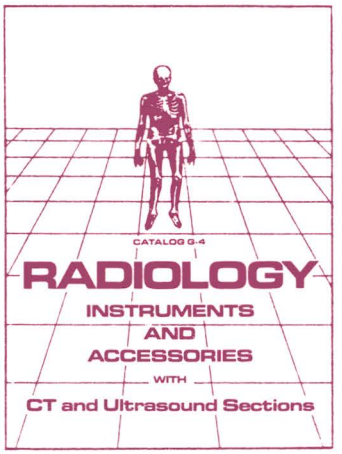

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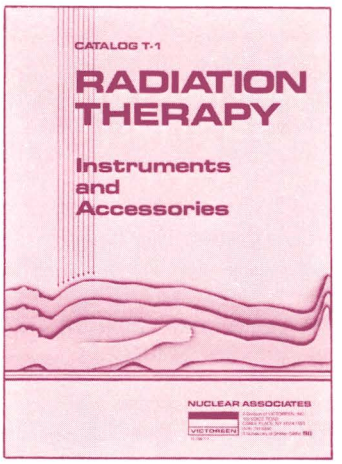

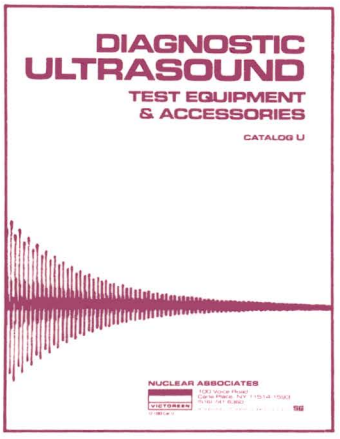

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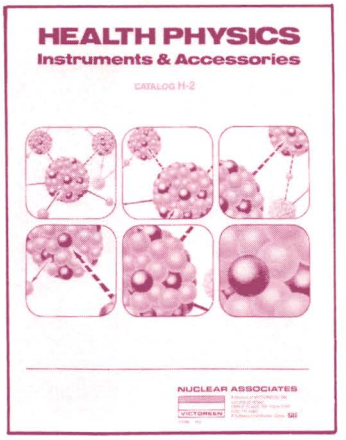

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October 30, 1987

Federal Register Vol. 52, No. 191 of Friday, October 2, 1987

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

Attn: Docketing and Service Branch

Gentlemen:

We wish to comment on the proposed changes to 10CFR35 relative to basic quality assurance in radiation therapy and comprehensive quality assurance in medical use and the standard of care as printed in the Federal Register, Vol. 52, No. 191 of Friday, October 2, 1987. I feel that many of the items you have proposed are already included as part of a good quality control program in most facilities and institutions. To this end, I feel that they should be included in your rules and regulations. I do wish to comment on a couple of the proposed items which I feel may involve a great deal of staff time and institutional expense with little or no reduction in the possibility of misadministrations.

Section 35.432: Subsection A requires that a licensee shall measure the source strength of sources before first use and annually therafter. I feel that measuring source strength before first use is a good policy. However, since institutions are required to do semi-annual leak/wipe tests to assure the integrity of the source, I am not sure that the added personnel exposure is worth what small additional information may be gathered by repeating the measurement of the sourch strength at annual intervals. The NRC in its explanation of why the rule changes are recommended has already noted that manufacturers usually provide better source strength information than can be provided at the hospital or treatment facility. It also recommends that the licensee should use the source strength that it believes to be the most accurate, which may mean taking that of the manufacturer over that measured in house. To this end, it seems that repeating measurements in house on an annual basis would have little or no validity.

Section 35.452: The NRC is considering requiring two individuals to independently make physical measurements of the patient to ascertain those parameters necessary for accurate dosimetry. In many institutions the constraint on personnel is already such that to make another person available at the time of simulation to duplicate the measurements might put a real strain financially and physically on the institution. Perhaps a better requirement would be to have an individual make two independent measurements using different techniques to ascertain the information that is needed.

Section 35.454: Check of dose calculations. Several institutions would not have more than one person with the expertise to do manual calculations or to double check computer calculations. To this end, it may again be more advantageous to have one person use two independent means to verify that all of the data is correct.

Section 35.633: Independent check of full calibration measurements. The commission is requiring that a second teletherapy physicist perform a full calibration on the equipment within one month after a full calibration is performed by the institution's physicist. It is also required that this second physicist use a complete dosimetry system different than that used by the first physicist. This imposes a financial burden upon the institution as well as the problem of locating an additional teletheraphy physicist who has the time and the equipment to make such a visit within the one month interval. This is a case where there is also a major financial burden on the institution. Perhaps the government should consider financing such an endeavor if it is to be required. Until recently the centers for radiological physics which were funded through the Federal government provided such services to all institutions within their area. There was also a small fee to the institutions receiving such services to help defray cost. Due to the large expense of this program, it has been discontinued. If a second check is desired, it should be reinstituted through such a program as this. There is also no real need for such a check to be done within one month of the full calibration of the equipment. If a second check is required, the check should be able to be performed once per calendar year. Also, I fail to see the need of having a second full dosimetry system in order to do this. Since dosimetry systems are calibrated once every two years and institutions often have a reference system to use in conjunction with the bench system, it seems that an institution that has more than one physicist in house should be able to perform the second check on their own equipment without the added expense of bringing in an outside person and transporting in their equipment.

Section 35.654 (Note: mislabelled 35.354 on page 36949 of the Federal Register): Checks of dose calculations and measurements of dose. Concerning computer generated doses, there may not be more than one individual in an institution who is proficient in the use of the treatment planning computer. A double check should be able to be made by that individual by doing a separate verification that all of the data that was entered was appropriate. Also, for most cases it is very possible to do a single point dose calculation within the treatment volume to ascertain if the doses are within the prescribed limits. Since this is a completely separate method of calculating the dose, there is no reason why this point check cannot be performed by the same person who ran the computer program.

A general comment on quality assurance and general criteria. The commission has commented that the commission could impose a performance requirement under which licensees would be required to implement a quality assurance program that would provide absolute assurance that there will be no misadministrations. The implications of this statement go beyond belief. There is no way that one can implement any kind of a program that would provide absolute assurance that there would be no misadministrations. The goal is to reduce the number of misadministrations to as low a level as possible. However, when dealing with individuals, it is absolutely impossible to guarantee that there will never be any error.

How much does a quality assurance program cost per patient or per year? It is difficult to put an exact number on such a question. One can more realistically look at staff time involved in such a program. In a community hospital such as ours, we devote one hour per day when all technologists, the radiation therapists, and the radiation physicist have a conference to assure quality assurance. In addition, weekly chart checks are performed on all patients, requiring an additional two to three hours of staff physicist time. Weekly portal films are done on all patients to assure that the treatment fields are those being treated as were designed and set up during patient simulation. The therapist or physicist often goes into the treatment room to be assured that portals are lined in conformity with the desires set forth in the treatment planning process. These procedures alone probably account for 1.5 to 2.0 FTE. In addition, there is the amount of time spent in preventative maintenance, calibrations, and other quality assurance tests performed on the units. These often include daily QA checks of the therapy unit prior to commencing daily patient treatments.

The NRC has indicated that the reasons for considering these changes is the fact that there were 27 misadministrations in the time interval from November 1980 through July 1984. However, it is also estimated that there were 100,000 teletherapy patients treated in this 3.7 year interval and 50,000 brachytherapy patients treated per year, total of 555,000 patients treated. This results in a misadministration rate that is less than 0.005%. The question is whether or not the time and effort being expended is really going to result in any significant decrease in this total percentage of misadministrations.

I appreciate the opportunity of sharing these views with you and look forward to being notified as to when there will be public hearings on these matters.

Sincerely,

Herbert W. Mower, Sc.D.
Senior Radiation Physicist

HWM/i/MS

The University of Texas Medical Branch at Galveston

77550

Medical School
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals at Galveston

ANTHONY R. BENEDETTO, PH.D.
ASSOCIATE PROFESSOR

NUCLEAR MEDICINE DIVISION
RADIOLOGY DEPARTMENT
(409) 761-2921

October 30, 1987

Secretary of the Commission
US Nuclear Regulatory Commission
ATTN: Docketing and Service Branch
Washington, DC 20555

SUBJECT: Proposed Rule, 52 FR 36942

The purpose of this letter is to respond to the Proposed Rule that was published 2 October 1987 at the subject Federal Register citation. This Proposed Rule would amend 10 CFR Part 35 to implement quality assurance programs not previously required, and it would expand certain existing guidelines. Since many of my comments are in response to the comments in the Supplementary Information section, my citations for that section will be by Federal Register page, column, and paragraph numbers.

I am furnising these comments in my role as a private citizen; my views do not necessarily reflect those of any organization of which I may be an officer or member. I am a nuclear medicine physicist with many years of experience as Radiation Safety Officer in broad-license institutions, and I am certified by the American Board of Science in Nuclear Medicine and the American Board of Radiology.

Page 36943, col 3, para 4: I couldn't find anything in the Proposed Rule that implements the independent verification of calculations for radiopharmaceutical therapy. Was this intentional? You may wish to consider a new definition that would clearly define what constitutes independent verification. For example, in a teaching institution, faculty physicians (authorized users) almost always check calculations made by residents and fellows. If a faculty physician makes the initial calculation, must the independent verification be made by an authorized user, or can it be made by a resident or fellow? In institutions where there is only one authorized user, what other types of individuals would be acceptable as independent verifiers? If a physician performs the

'81 NOV -4 P3:10

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calculations, can a physicist or other nuclear medicine scientist provide the independent verification? NRC should specifically address the issue of physicians-in-training, and NRC should give guidelines about general qualifications of independent verifiers, perhaps with some examples. Licensees should be required to get approval for the independent verification process if their schemes are different from those given in Part 35 (or an accompanying Regulatory Guide).

Page 36944, col 1, para 1 and 10 CFR Part 35.39: NRC is justifiably concerned about diagnostic radiopharmaceuticals that deliver unusually high organ doses. It would seem possible to make the proposed Part 35.39 more generic by specifying organ doses above which a diagnostic radiopharmaceutical would come under the scope of this Part, e.g., one gray. For example, we do not permit residents and fellows to prescribe the 5 mCi metastatic survey dosage of I-131 sodium iodide; an authorized user must prescribe these dosages. Such a generic organ dose guideline would eliminate the necessity of revising Part 35 every time a new radiopharmaceutical is introduced.

Page 36945, col 1, last para: The statement is made that the necessary records are "usually" kept by most licensees. If there are licensees who don't keep appropriate records, it is either because they don't know what records are necessary, they know but don't care, or they know and don't agree with the way other facilities keep their records. If it is important to maintain certain records, NRC should clearly specify the information that is required and the format in which it must be provided. Exceptions should be allowed only by specific request and NRC prior approval.

Page 36945, col 2, para 4: NRC requested comments on documentation of the independent verification of computer calculations. It would seem reasonable that a data input worksheet be prepared for each patient, and that a computer used for treatment planning calculations print out the values that were actually entered. Many software packages may not provide this information at this time, so a phase-in may be necessary. The input worksheet and the computer printout should be initialed and dated by the verifier, and both documents should be placed into the patient's clinic chart as a permanent record. NRC may wish to consider the retention period of many of these new documentation requirements at this time. In general all of the patient-related documents should be permanent portions of the record. Instrumental spot-checks probably could be discarded after 10 or 20 years.

Page 36945, col 3, para 2 and 10 CFR Part 35.65: In the Supplementary Information section, the term "obvious" is vague, maybe intentionally so, but it nonetheless leads to

differing interpretations by the user and by NRC. The wording in the proposed Part 35.65 fairly neatly circumvents this issue.

Page 36945, col 3, last para: NRC requests comments on a requirement for two independent measurements of patient parameters. This seems like a good idea. If implemented, the measurements should be recorded on two separate worksheets, so that the second measurer won't be influenced by seeing the first set of measurements. Both sets of measurements should then be transcribed onto a third piece of paper that would display the measured values side by side so that discrepancies are readily seen. NRC may wish to consider stipulating what percentage variation between the two measurements is acceptable, and it should also consider requiring the set of measurements actually used for treatment planning to be clearly identified. NRC should also specifically address whether measurements performed by a non-physician, e.g., physicist, are acceptable as either the primary or secondary measurements.

Page 36946, col 2, para 3: NCR requested comments on whether two completely independent treatment plans should be calculated. Historical data indicate that these sorts of errors are rarely the cause of misadministrations. Given the relative scarcity of immediately available physicist support, it would seem impractical to implement this requirement. If a physician verifies the calculations of a physicist, it would seem acceptable for the physician to simply initial the essential components of the treatment plan, e.g., verify input values, verify the reasonableness of the machine parameters prescribed by the plan.

Page 36946, col 2, para 5: No teletherapy machine should be used to deliver clinical doses if the operating parameters have not been characterized fully in a calibration, whether in the annual calibration or in a special calibration performed just for an unusual machine setup.

Page 36946, col 3, para 1: I agree that double-checking of brachytherapy source identities is not necessary, especially in light of ALARA and the small number of misadministrations attributed to this source of error. Perhaps NRC could consider urging source manufacturers to design sources with unique x-ray "signatures" so that the activity of the source could be identified from the x rays.

Page 36946, col 3, last para: NRC should consider how to treat multiple-physicist staffs in regard to treatment planning verification and instrument calibration. If one physicist member of such a staff performs a calculation or calibration, may another physicist member of the staff perform

the independent verification? So long as two different measurement systems are used, can they both be owned by the licensee?

Part 35.39(a): A restriction against all chemical forms of iodine is too restrictive. For example, orthoiodohippurate is administered in dosages of the range of 150-300 uCi and is never supplied in stock vials of enough millicuries to cause serious harm. Likewise, I-125 human serum albumin for blood volume measurments is provided in microcurie stock vials and the potential for large organ doses is miniscule. As suggested earlier in this letter, perhaps NRC should adopt an organ dose action level rather than a chemical identity restriction. Another option would be to stipulate, as we have done in our clinic, that any non-Tc99m dosage greater than 1 mCi must be prescribed by an authorized user.

Part 35.39(b): In our institution we will not perform a nuclear medicine diagnostic or therapeutic study unless the referring physician sends us a consultation form describing pertinent clinical history and the study he/she feels is appropriate. Such a written consultation between the referring physician and the nuclear medicine or radiation therapy physician should be acceptable if it contains a clear identification of the patient, brief clinical history, the requested study/treatment, and the name and telephone number of the referring physician. We combine our consultation form with our radiopharmaceutical prescription form, so that all of this information is on one sheet of paper.

Part 35.43(d): If worker instruction is required, the nature of the instruction should be spelled out in more detail and the frequency with which it must be presented should be prescribed. NRC may wish to consider to adding any such requirement for instruction to Part 19.

Part 35.302: This paragraph should reiterate the measurement of the activity in a dose calibrator prior to and immediately following administration. It should also require a visual check of the radiopharmaceutical. In the instance of the IV and intracavitary forms of P-32, for example, the colloidal form is a cloudy green color and the IV form is clear.

Part 35.432(a): It is not clear whether the sources should be assayed in units of activity or of exposure rate; this should be specified. Except for I-125 seeds, most brachytherapy sources are procured in rather small lots and it would not seem onerous to require a check of each individual source; the only other indication of a source being too hot or too cold might be that Geiger counters located near the source safe act peculiarly when the source is being removed from or returned to the safe.

Part 35.354(c): Arithmetic checks should be made by a person other than the one who performed the initial calculations. This might get complicated if multiple individuals performed the daily calculations--can any one of these do the weekly check? Should these weekly checks be made by more senior personnel, such as supervisory technologists or physicists?

Thank you for this opportunity to provide my comments on this Proposed Rule. In general, it seems like a step in the right direction. NRC may wish to consider whether teletherapy regulations continue to be cost-effective given the gradual decline in the number of radioisotope teletherapy machines in clinical use due to their replacement by accelerators.

Sincerely,

Anthony R Benedetto

Anthony R. Benedetto, Ph.D.

The University of Iowa

Iowa City, Iowa 52242

The University of Iowa Hospitals and Clinics
Department of Radiology

(319) 356-2188
If no answer, 356-1616

1847

October 22, 1987

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

Dear Sir:

I would like to comment on portions of your proposed rule "Basic Quality Assurance in Radiation Therapy" for inclusion in 10 CFR Part 35. My comments concern only those portions of the proposed rule dealing with radiopharmaceuticals.

35.39 (a) states that "A license (sic) may not order any radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without approval of the authorized user." Does "radiopharmaceutical of iodine for diagnosis" include I-125 fibrinogen, I-125 RISA, I-131 RISA and I-131 iodohippurate? Also, I routinely order I-131 sodium iodide for diagnosis and therapy to have in stock in anticipation of future use. In such cases when an authorized user is not available at the time of ordering, receipt may be delayed for one or more days; a delay in receipt and treatment may have adverse impacts on the patient's economic and medical interests. Therefore, I suggest deleting this paragraph.

35.39 (b) states that "A physician may not prescribe administration of a radiopharmaceutical of iodine for diagnosis . . . without personally examining the patient and the patient's chart . . . ." Does this proposed rule also apply to I-125 fibrinogen, I-125 RISA, I-131 RISA, and I-131 iodohippurate? Also, physician examination of the patient and the patient's chart does not appear to be necessary in many cases involving non-imaging studies using I-131 sodium iodide (e.g., thyroid uptake measurements only). I suggest deleting the words "for diagnosis."

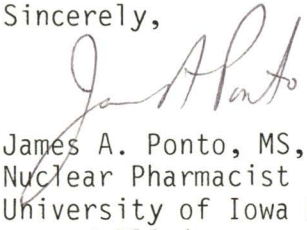
35.39 (b) states that "Prescriptions for these byproduct materials must be in writing and must include the patient's name, the radiopharmaceutical, dosage, and route of administration." This proposed requirement is unnecessary in that state laws governing the practice of medicine and pharmacy require these pieces of information on prescriptions already. Furthermore, when practice is based in institutions (hospitals), these requirements are included in JCAH standards of practice. I suggest deleting this paragraph.

35.39 (c) and 35.302 both state that comparison of the written prescription and the radiopharmaceutical label is required prior to administration. 10 CFR 35.53 already requires that a licensee measure the activity of each pharmaceutical dosage before medical use. The proposed rule does little to enhance the requirement already in place. I believe, however, that this step may be the single most important aspect of avoiding a misadministration. Thus, the current policy in our department is that measurement of each dosage of I-131 for diagnostic imaging or therapy must be verified by a second individual. Therefore, I suggest that this paragraph be revised to state that dosage calibration or measurement of I-131 sodium iodide intended for imaging or therapy or other radiopharmaceuticals intended for therapy be verified by a second individual.

35.43 (b) states that the authorized user "has personally made, dated, and signed a written prescription in the patient's chart. . . ." Certainly the authorized user (or physician working under the supervision of the authorized user) must write a prescription for administration of therapy. However, in the case of radiopharmaceuticals, this prescription is rarely part of the patient's chart; typically, the original prescription order remains in the nuclear medicine files. Nonetheless, the intended information (i.e., radiopharmaceutical, amount of activity administered, route of administration) is incorporated into the patient's chart by means of dictated reports and/or handwritten notations. Therefore, I suggest deleting the phrase "in the patient's chart" in reference to written prescriptions for radiopharmaceuticals.

Thank you for consideration of my comments.

Sincerely,



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TELEPHONE 795-2400

October 30, 1987

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

Attn: Docketing and Service Branch:

Dear Mr. Secretary:

I am writing in reference to the proposed rules in the Federal Register, Volume 52, 191, Friday, October 2, 1987. In part 35-Medical Use of Byproduct Material, section 35.39 the first sentence reads in part: "A physician may not prescribe administration of a radiopharmaceutical of Iodine for diagnosis or therapy or any radiopharmaceutical for therapy without personally examining the patient..".

While I fully support the need for examining patients prior to therapy with radiopharmaceuticals I question the need for examining patients prior to the use of Iodine for diagnostic purposes, possibly with one exception. When higher doses of radionuclide are used in seeking metastatic thyroid carcinoma there might be some justification for examining the patient, however, in our institution at least, patients for this procedure will have had a total thyroidectomy before this examination is ordered. I certainly can see no need for examining the patient who is having an I-131 uptake examination or a renogram since the amounts of activity used are so minimal. There certainly can be no justification for requiring examination of patients prior to the use of I-123 for diagnostic purposes.

If adopted and enforced, this would become a very time consuming non productive exercise without improvement in patient care and safety.

I would strongly recommend that this paragraph be amended to exclude Iodine for diagnostic purposes from this restriction.

Your consideration of this proposal is appreciated.

Very truly yours,

John W. Carrier

John W. Carrier, M.D.
/ls

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October 26, 1987

The Secretary of the Commission
United States Nuclear Regulatory Commission
Washington, D.C. 20555
ATTENTION: Docketing and Service Branch

RE: Proposed Rules by the Nuclear Regulatory Commission in Ten CFR Part 35 as Noted in the Federal Register Volume 52, Number 191, Friday, October 2, 1987, Page 36948

Dear Sir:

You proposed in Subpart B - General Administrative Requirements, paragraph 35.39 on ordering, prescribing, and administering certain radiopharmaceuticals that "a physician may not prescribe administration of a radiopharmaceutical of iodine for diagnosis...without personally examining the patient and the patient's chart, and consulting with the referring physician if reasonably available."

The way that this is worded would require such a procedure for small tracer administrations of radioiodine-131 as well as standard radiopharmaceuticals such as I-131 hippuran, etc. I do not believe that this is a reasonable restriction for diagnostic amounts of radioiodine containing pharmaceuticals. It will unnecessarily delay and complicate the diagnostic medical care of the patient without any evident benefit. There is no evidence in man of a clinically harmful effect of tracer amounts of radioiodine-131.

I would strongly urge that you modify the proposed changes in paragraph 35.39 to exclude the diagnostic use of radioiodine-131 or radioiodinated radiopharmaceuticals. Your proposed changes for therapeutic administrations would seem reasonable.

Very sincerely yours,

Harry R. Maxon III, M.D.
Professor and Director

HRM/jcc

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Basic Quality Assurance in Radiation Therapy

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed Rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations concerning the medical use of byproduct material to require its medical licensees to implement certain quality assurance steps that will reduce the chance of therapy misadministrations. This proposed action is necessary to provide better patient safety and a basis for enforcement action in cases of therapy misadministration. The amendment is intended to reduce the chance and severity of therapy misadministrations. The proposed regulations would primarily affect hospitals, clinics, and individual physicians. In an advance notice of proposed rulemaking published elsewhere in this issue of the Federal Register, the NRC is also requesting comments on the need for a comprehensive quality assurance program requirement.

COMMENTS: Comments must be received by 12/1/87. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

pub. 10/2/87

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

Copies of the regulatory analysis and the comments received on this rule may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the regulatory analysis are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

SUPPLEMENTARY INFORMATION:

I. BYPRODUCT MATERIAL IN MEDICINE

Use for Patient Care

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. An estimated 10 million diagnostic nuclear medicine procedures are performed in this country annually. In therapeutic nuclear medicine, larger

quantities of radiopharmaceuticals are administered to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 30,000 procedures are performed each year.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy primarily to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 100,000 patients receive cobalt-60 teletherapy treatments from NRC and Agreement State licensees each year. Smaller sealed sources with less radioactivity are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. Licensees perform approximately 50,000 brachytherapy treatments annually.

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Many states, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized

by the Atomic Energy Act.) They issue licenses for the medical use of byproduct material, and currently regulate about 5,000 licensees. In non-Agreement States, the NRC has licensed 2,200 medical institutions (mostly hospitals and clinics) and 300 physicians in private practice. These licenses authorize certain diagnostic and therapeutic uses of radioactive materials.

II. NRC'S REGULATORY PROGRAM

NRC's Policy Regarding the Medical Use of Byproduct Material

In a policy statement published February 9, 1979 (44 FR 8242), the NRC stated:

> "1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
>
> "2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
>
> "3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

The NRC has the authority to regulate the medical use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that

properly trained and adequately informed physicians will make decisions in the best interest of their patients.

NRC's Responsibilities in the Medical Use of Byproduct Material

The NRC draws a line between the unavoidable risks attendant to purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use of byproduct material in medicine. The NRC is obliged, as part of its public health and safety charge, to establish and enforce regulations that protect the public from the latter.

Reports of Misadministrations in Radiation Therapy

The NRC has published a study of the twenty-seven therapy misadministrations that were reported over the period November 1980 through July 1984.[1] The following NRC analysis of these events provides the basis for determining that a need exists for this rulemaking.

The specific causes of the misadministrations, detailed in Table 1, are, of course, related to the treatment modality. Nonetheless, three basic themes run through the reports: inadequate training, inattention to detail, and lack of redundancy.

Improved training of medical personnel who handle and administer byproduct material can reduce the potential for error. Thorough training should also clearly impress on each individual involved in the medical use of byproduct material that a clear communication of concepts

[1]For a copy of this report, write to Kathleen M. Black, Office for Analysis and Evaluation of Operational Data, Nuclear Regulatory Commission, Washington, DC 20555. Ask for report AEOD/C505.

Table 1. Therapy misadministrations reported to NRC from November 1980 to July 1984

Teletherapy
Prescription
Total daily dose was delivered from each port (2)*
Oral and written prescriptions were different (1)
Boost dose of 500 rad/3 da was interpreted as 500 rad x 3 da (1)
Proper body side was not clear (1)
Treatment planning
Tumor depth was incorrectly measured (1)
Tumor depth was incorrectly recorded (1)
Dosimetrist used wrong computer program (1)
Dosimetry tables for wrong unit were used (1)
Arithmetic mistakes were made (3)
Records
Arithmetic mistakes were made (1)
Poor handwriting of numerals caused misunderstanding (1)
Physical measurements
Wedge factors were measured incorrectly (1-53 patients affected)
Application
Field blocks were not used (1)
Brachytherapy
Treatment planning
Dose rate was much higher than first estimated (1)
Application
Wrong sources were loaded in applicator (2)
Source fell out of applicator (1)
Source was improperly seated in applicator (1)
Radiopharmaceutical Therapy
Wrong radiopharmaceutical was administered (2)
Assay date on unit dosage was not read (3)
Patient was improperly identified (1)

*Numbers in parentheses indicate number of events of the type described.

and quantities as well as systematic checks for revealing mistakes early in the process are both essential for the delivery of quality care. All information integral to the process, whether specific to the patient or to the clinic, should be carefully examined for clarity, applicability, and correctness. Each individual involved in the process should be strongly encouraged to ask for clarification if there is any unclear or unexpected step or if an expected step is missing.

Inattention to detail is often the medium in which a misadministration event germinates. NRC recognizes that this problem is not specific to the medical use of byproduct material. Computerized radiation therapy treatment planning may reduce the chance of mistakes in sealed source treatment planning, and "record and verify" systems that check teletherapy unit orientations and settings may reduce the chance of mistakes in teletherapy administration. But even these systems must ultimately rely on quantities that are initially measured, recorded, and entered into memory by individuals.

Lack of redundancy means that there exist no independent mechanism for detecting errors. An independent verification requires examination by a second individual of each data entry, whether a physical measurement or a number copied from a table of values, as well as a check of arithmetic operations for correctness. Redundancy requires that two separate systems produce the same result. For purposes of planning radiation therapy, the best method of early detection of mistakes may be a simple independent check. Independent verification may also need to be incorporated into procedures for measuring radiation parameters, using those measurements for treatment planning, and applying radiation to patients. In radiation therapy or any other endeavor, an independent

outside auditor can detect mistakes in both process design and process application as well as cite areas where a change in the process might reduce the chance for future error.

These observations have led the NRC to some general conclusions regarding quality assurance.

The radiation therapy process should be planned with the realization that individuals are likely to make mistakes. Some simple aids may include using tables and graphs that are clearly titled and easy to read, and use of a uniform written prescription format. NRC inspections have revealed that about ten percent of teletherapy unit calibrations and spot-checks are incomplete. Checklists could be used to assure completeness.

Independent verification must be made integral to the design of the radiation therapy process. All entries and calculations in a treatment plan should be checked by an individual who did not construct the treatment plan. Each patient's chart should be reviewed weekly to check for accumulated dose and implementation of prescription changes. A quality assurance program for the teletherapy unit should include a periodic check of the teletherapy unit output and an occasional detailed examination of the complete teletherapy process, including physical measurements, by an outside expert with an eye towards systematic errors and system improvements.

A program that requires a physical measurement of the dose or amount of radioactivity actually administered to the individual patient would provide assurance that the given dose is the same as the prescribed dose.

Such measurements are now done for radiopharmaceutical therapy and occasionally for some teletherapy cases, but because of expense or unavailability of equipment are not commonplace in sealed source therapy.

Reports of Diagnostic Misadministrations That Result in Doses in the Therapy Range

The NRC has also published a report on misadministrations of diagnostic dosages of iodine-131 that lead to doses in the therapy range.[2] The report was a review of fourteen recent misadministration events in which patients were administered one to ten millicuries of iodine-131 with a resulting thyroid dose of several thousand rads. Many of the events demonstrated that the physician authorized user failed to review the medical history of the referred patient to determine the suitability of a particular clinical procedure. In many cases the referring physician, who is not a nuclear medicine expert, and the nuclear medicine technologist, who is not a medical expert, determine which radiopharmaceutical should be administered. Furthermore, in some events technologists unfamiliar with the clinical procedure prescribed by the authorized user mistakenly administered a dosage that was not requested. It is apparent, therefore, that whenever radiopharmaceuticals capable of producing therapy doses are used, clear nomenclature, independent verification, and adequate training are essential.

Earlier NRC Efforts

This is not the first time the NRC has examined the matter of quality assurance in the medical use of byproduct material. In 1979 the NRC issued some basic quality assurance requirements for teletherapy (see 44 FR 1722,

published January 8, 1979). This rulemaking was precipitated by the inaction of a single licensee. The output of a teletherapy unit was incorrectly calculated and the licensee made no physical measurements to determine whether the calculation was correct. This inaction resulted in cobalt-60 teletherapy being misadministered to 400 patients. The 1979 rule addressed the circumstances surrounding that event but did not critically examine the entire radiation therapy process.

Voluntary Initiatives

The Commission is aware of voluntary initiatives to improve quality assurance. A notable example is the Patterns of Care study managed by the American College of Radiology. In addition to comparing prescriptions, methods of applying radiation, and survival rates for certain diseases at various therapy facilities across the nation, methods of calculating and measuring applied dose rates are examined for accuracy. Such an examination can detect whatever procedural flaws may be present as well as determine the precision and accuracy of day-to-day service.

It is NRC's position that voluntary programs alone may not provide adequate assurance of public health and safety. Serious misadministrations continue to occur. The NRC would be remiss in its responsibilities were it to fail to examine thoroughly all avenues available available to reduce unnecessary exposure from licensed material.

Summary

The NRC believes many misadministrations could reasonably be avoided if certain basic quality assurance steps were included in the radiation therapy process.

Other Actions

The NRC recognizes that the medical use of byproduct material is a complex field, and that preparing regulations to reduce the likelihood of misadministrations must be done carefully. However, the NRC cannot allow the complexity of medical use to prevent it from taking regulatory action when patients are harmed by the incorrect application of byproduct material. The NRC has balanced these competing desiderata by preparing two rulemaking actions for contemporary publication.

This Notice of Propose Rulemaking (NPR) will provide the foundation for a basic quality assurance program that addresses some simple sources of error that have come to light under NRC's misadministration reporting program. Elsewhere in this issue of the Federal Register, the NRC has published an Advance Notice of Proposed Rulemaking (ANPR) that provides the foundation for a comprehensive quality assurance program requirement that addresses broad areas where error can lead to a misadministration.

The NRC believes this two-pronged approach to the problem of misadministrations provides the best balance between the need to assure public health and safety without inadvertently interfering in the delivery of quality medical care.

III. DISCUSSION OF PROPOSED REGULATORY TEXT

The NRC staff has examined literature on the radiation therapy process and consulted with experts practicing in the field of radiation therapy to discuss these quality assurance steps. The NRC believes that the following steps are basic to the radiation therapy process. The

regulations that would require implementation of these steps will provide guidance for improved patient safety and will also provide a basis for NRC enforcement action should these steps not be followed.

§ 35.2 Definitions.

The NRC has added several definitions to the regulations to ensure that the regulatory requirements are clear. The definitions are intended to be similar to those already in use in radiation therapy.

§ 35.39 Ordering, prescribing, and administering certain radiopharmaceuticals

There have been a number of misadministrations in which an unclear oral prescription by the authorized user resulted in the licensee ordering the wrong radiopharmaceutical. Confusing colloidal and soluble phosphorus-32 is a common mistake. The NRC is particularly concerned with the medical use of iodine-131 because of the high thyroid dose that results when a patient with a normal thyroid is misadministered an iodine-131 dosage intended for a patient whose thyroid has been removed.

These misadministrations appear to be precipitated by unclear instructions. This section would require close participation of the nuclear medicine physician in those cases involving the use of radiopharmaceuticals that are clearly hazardous to the patient if misadministered.

In drafting this section the Commission considered applying these requirements to all licensees when using any diagnostic radiopharmaceutical. For the following reasons the scope of the section was limited to therapy radiopharmaceuticals and radiopharmaceuticals of iodine.

There is a clear history of misadministration of these two groups of radiopharmaceuticals, and medical experts generally agree that there is clear potential for harm to patients that receive these misadministrations. For the other radiopharmaceuticals identified in 35.100 and 35.200, the record shows that most misadministrations involve either the conventional administration of a radiopharmaceutical to the wrong patient, or the conventional administration of the wrong radiopharmaceutical to the patient (see "NRC Reports on Misadministrations and Unannounced Safety Inspections," Journal of Nuclear Medicine, v27, n7, p1102, July 1986). Neither of these types of misadministration pose a clear hazard to the patient. To misadminister a diagnostic radiopharmaceutical other than iodine in a manner that would pose a hazard to the patient would, in the most likely circumstance, require administration of at least a full day's inventory of the radiopharmaceutical to the patient.

However, the absence of additional quality assurance requirements for diagnostic radiopharmaceuticals other than iodine should not be interpreted as Commission lack of interest in this matter. The Commission would appreciate public comment on how it might address future diagnostic applications of radioisotopes which, if misadministered, could produce doses in the therapy range.

§ 35.43 Prescriptions and records of medical use for therapy.

The NRC has received one therapy misadministration report in which radiation was administered to a patient who had not been referred for medical use of byproduct material. The NRC believes that a physician

with special training and experience is needed to consult with the primary care physician in cases of referral, and make a determination that a clinical procedure that requires radiation dose to the patient is indicated.

When a decision has been made to treat a patient for any malady, whether with radiation, surgery, or drugs, a physician makes a patient chart that includes information about the care provided for the patient. The chart is made for medical and legal reasons. All charts contain the patient's name, the results of laboratory tests and physical examinations, a statement of diagnosis, and a prescription. Charts for teletherapy patients usually include: (1) photographs of the patient's face and the treatment area; (2) the treatment plan (which is comprised of: (a) diagrams of physical measurements of the patient, portal arrangements used to administer the radiation dose, and devices used to modify the radiation beam, (b) calculations made to determine how long the beam must be applied each day to deliver the prescribed dose, and (c) the number of days radiation is to be administered); (3) a record of each daily application of radiation made at the time of application; and (4) records of any physical measurements of radiation or portal verification films made specifically for the patient. Charts for brachytherapy patients include the same type of information, but the diagrams and calculations refer to implanted radiation sources rather than externally applied radiation beams. Each entry in a chart is dated and signed or initialed.

The NRC considered preparing prescriptive recordkeeping requirements for the application of therapeutic amounts of radiation, but believes that the patient charts and calibration records that licensees make and retain usually contain the information needed to demonstrate that the licensee

has implemented a quality assurance program. However, the NRC would appreciate public comment on this matter.

Several therapy misadministrations have been precipitated by unclear prescriptions. In radiation therapy, a different dose is prescribed for each patient, depending on the type and extent of the malady. Therefore, requiring a legible handwritten or typed prescription on the patient's chart appears to be the most efficient way of ensuring clear communication between the prescribing physician and the dosimetrist who makes the calculations to determine how long radiation must be applied to deliver the prescribed dose.

The NRC believes that it is possible that some dosimetrists or technologists may be disinclined to request clarification of instructions and this may lead to misadministrations. Therefore, the NRC would require licensees to specifically instruct workers to request clarification in cases where there may be ambiguity or error.

The NRC is considering prescribing what documentation is needed to demonstrate that an independent check of data transfers and calculations had been made. The NRC has not included such a requirement in the proposed rule, but would appreciate comment on this matter.

§ 35.65 Discrepancies in records and observations.

On occasion licensees have complied with required safety measures, such as performing surveys, yet not taken mitigating or corrective actions that the NRC believes were obviously necessary to assure public health and safety. The purpose of this section is to clearly require licensees to resolve discrepancies in records and observations.

The NRC foresees the possibility of many kinds of discrepancies. The licensee's measurement of the source strength of a brachytherapy source may differ from the manufacturer's reported source strength. A thin patient may present a surface lesion, yet the patient's record may refer to a deep-seated lesion with extensive overlying tissue. A post-mastectomy patient may be referred for a prophylactic treatment with no clear statement prescribing whether the tissue surrounding the site of surgery or the remaining breast tissue is to be treated. The prescription in the chart may not be in accord with the prescription agreed to by the physician, physicist, technologist, and dosimetrist during a treatment planning meeting. Daily tallies of administered dose may not agree with projections made by multiplying the daily dose by the number of treatment days.

If, when faced with an obvious discrepancy, a licensee, physician, physicist, technologist, dosimetrist or other individual fails to take reasonable clarifying, mitigating, or corrective action and the discrepancy results in a misadministration, then a citation will issue under this section.

§ 35.432 Source strength measurements.

The radiation dose rate from a sealed source, which is known as source strength, depends on the amount of radioactivity in the source and the material used to encapsulate it. (See National Council on Radiation Protection and Measurements Report Number 41, "Specification of Gamma-Ray Brachytherapy Sources," Chapter 4.)[3] Manufacturers usually provide source

[3]Copies of this report may be purchased by contacting NCRP Publications, P.O. Box 30175, Washington, DC 20014.

strength information with sources, but the NRC believes that an independent measurement is needed to ensure that the information relates specifically to the source under consideration.

However, the NRC would not require licensees to use these measurements in dose calculations. In some cases, manufacturers are able to provide more accurate measurements of source strength than licensees; the licensee must be free to use the source strength that it believes is the most accurate.

§§ 35.452 and 35.652 Physical measurements of patients.

The NRC knows that dose rates depend to some extent on the tissue volume to be treated and its depth within the patient. These parameters may be determined by physical examination or examination of images such as radiographs, or images from computerized tomography, ultrasound, nuclear medicine, or nuclear magnetic resonance. The NRC considered requiring that two individuals independently make the physical measurements of the patient that are needed for dosimetry purposes, and believes that such a requirement may reduce the chance of misadministrations. The NRC would like comment on this matter.

§ 35.454 Check of dose calculations, and § 35.654 Checks and measurements of dose

Dose calculations are made for each teletherapy and brachytherapy patient before radiation is administered to determine how long the source must be used to deliver the prescribed radiation dose to the treatment volume. Several therapy misadministrations have been precipitated by arithmetic mistakes or incorrect assumptions in dose calculations. An independent check will likely uncover many of these mistakes.

Ideally, teletherapy dose calculations should be checked before radiation is administered, and the NRC expects that most licensees already do this. However, a second person may not always be available to check the dose calculations before therapy begins. The NRC believes that requiring the check to be made before 20 percent of the dose has been administered provides a proper balance between patient safety and administrative flexibility for the licensee.

For most brachytherapy cases, final dose calculations cannot be performed until the sources are implanted in the patient because the exact location of the sources with respect to certain tissues cannot be predetermined. Brachytherapy sources are typically left in place for two to three days. Thus, a 20 percent criterion may be difficult to meet in many cases, because the check would have to be made within hours after the sources are implanted. Thus, the NRC has selected a dose calculation check criterion of 50 percent.

Public comments are invited on the workability of these 20 percent and 50 percent criteria.

There are two usual methods for performing checks of manual dose calculation. Two individuals may independently calculate treatment times and compare results. Alternatively, one individual may make the calculation and then a second individual can examine each entry and arithmetic operation to verify its accuracy.

The NRC considered requiring that licensees perform a manual check of the dose to a single point in the treatment volume predicted by computer-generated dose calculations. However, checks of computer-generated dose calculations pose difficult problems. It is not clear whether nomograms or manual algorithms are available that can be used to

check the accuracy of computer-generated dose calculations. Many computer programs that are used contain steps for calculating the effect on the dose caused by tissue density differences, organ and tissue contours, and radiation field contours. The NRC believes that a manual check of a computer calculation with that many physical correction factors may be beyond the reasonably expected means of many licensees, and may adversely affect the delivery of medical care. Therefore, the NRC has only drafted a requirement that a second individual assure that the correct parameters, such as radionuclide, dose, and physical measurements of patients, were used in the computer-generated dose calculation printout to information in the patient's chart, and examining each relevant piece of information on the calculation printout.

The NRC would appreciate comments on the best method for documenting that these checks have been made.

Regarding the concept of "independent check," the NRC would particularly appreciate comments on whether a second individual should begin with only the prescription, independently calculate the dosimetry and treatment plan, and then compare those results with those of the first individual.

In teletherapy, the arithmetic that sums the daily administration of radiation must also be checked. Radiation is usually administered in daily doses over several days or weeks and each dose is recorded in the patient's chart. A weekly check will assure the daily doses have been summed correctly. In contrast, brachytherapy is administered continuously until the prescribed dose has been given; thus, there is no need for a comparable requirement.

One recent teletherapy misadministration occurred in a case in which an unusual treatment configuration of the teletherapy unit, the beam collimators, and the patient was required. Whereas an arithmetic mistake would likely be obvious in a commonly used configuration because certain calculated values for patients usually fall within small ranges, an unexpected treatment time in an uncommon configuration would likely be attributed to the uncommonness of the configuration rather than triggering an examination of calculations for a dosimetry mistake. Therefore, the NRC believes that a physical measurement of the dose rate should be made if the teletherapy unit settings or beam modifying devices used for a patient fall outside the ranges examined during the last set of full calibration measurements.

The NRC considered requiring physical measurements for brachytherapy but believes the methodology (comprised of a comparison of calculated and measured dose rates) that is needed to make such measurements has not been fully developed. The NRC also considered requiring that two individuals verify that the correct sources were being implanted. This would clearly add to workers' radiation dose, but it is not clear that this would reduce the number of brachytherapy misadministrations.

The NRC knows that some treatments must be administered within hours after a decision has been made to administer radiation therapy. These cases usually involve compression of the spinal cord or superior vena cava, respiratory distress, brain metastases, or severe vaginal bleeding. In such cases, it may not be possible for the licensee to perform an independent check of calculations.

The NRC believes the prescribing physician is best situated to determine whether the time needed to make normal quality assurance checks might

jeopardize the patient's health. This provision is not intended to give licensees a basis for not providing the required quality assurance steps in a timely fashion.

§ 35.632 Full calibration measurements

In one misadministration event, 53 patients received doses of radiation different from the doses that were prescribed because a mistake was made when measuring the effect of certain beam modifying devices on the teletherapy unit output. The NRC believes the revalidation of the effect of these devices on the output is just as important as the annual full calibration itself.

§ 35.633 Independent check of full calibration measurements

All teletherapy dose calculations are based on the output of the teletherapy unit, which is measured each year as part of the full calibration. If a mistake were made in that measurement, all dose calculations would be incorrect. Therefore, the NRC believes there should be an independent check of the output that was determined during the full calibration. The check should be made by a teletherapy physicist because that individual has special training and experience in the measurement of therapeutic radiation.

The check should be made using a measuring system other than the system used in the full calibration. This will better assure that any mistake made in the methodology or the calibration of dosimetry equipment will not go unnoticed. (The term "measuring system" is used in a broad sense here to mean not just the dosimetry equipment, but the personnel,

records, site-specific methodology, and even origin of dosimetry equipment calibration when possible. However, the NRC is not certain that this would be available to all licensees and requests comment on this matter.) The device used to make the output measurement could be one described in § 35.630 "Dosimetry equipment." Alternatively, it could be made using a specialized dosimetry service available by mail. Some organizations supply licensees with precisely calibrated thermoluminescent dosimeters within a device made of "tissue-equivalent" material. The licensee irradiates the device, calculates the given dose, and returns the dosimeters to the organization by mail. By processing the thermoluminescent dosimeters, the organization can measure the given dose and compare that measure to the calculated given dose. This provides assurance that the output has been correctly measured.

IV. ADMINISTRATIVE STATEMENTS

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(3) and (c)(14). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980

(44 U.S.C. 3501, et seq.). Existing requirements were approved by the Office of Management and Budget under approval number 3150-0010.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies may be obtained from Mr. McElroy (see "FOR FURTHER INFORMATION CONTACT" heading).

Regulatory Flexibility Certification

Based on the information available to date, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The NRC has issued approximately 2,500 medical licenses under 10 CFR Part 35. Of these, approximately 2,200 are held by institutions, and approximately 300 physicians in private practice. Most of the institutional licensees are community hospitals. The size standards adopted by the NRC (50 FR 50241, December 9, 1985) classify a hospital as a small entity if its average gross annual receipts do not exceed $3.5 million, and a private practice physician as a small entity if the physician's annual gross receipts do not exceed $1 million. Under these size standards, some NRC

medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

The number of medical licensees that would fall into the small entity category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The primary objective of the rule is to require licensees that provide radiation therapy service to implement certain quality assurance steps that will reduce the chance of therapy misadministrations. The NRC believes that most licensees already perform these steps in order to assure the provision of quality medical care. Therefore, there should not be a significant economic impact on these small entities.

The Commission has prepared a preliminary regulatory analysis for this regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the regulation will not result in significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room, 1717 H Street N.W., Washington, DC. Single copies are available from Mr. McElroy.

Because of the widely differing conditions under which licensees covered by this proposed regulation operate, the Commission specifically seeks public comment from small entities. Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates: (1) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually; (2) how the regulation would result in a significant economic

burden on the licensee as compared to that on a large licensee; (3) how the regulations could be modified to take into account the licensee's differing needs or capabilities; (4) the benefits that would be gained or the detriments that would be avoided to the licensee, if the regulations were modified as suggested by the Commenter; and (5) how the regulation, as modified, would still adequately protect public health and safety. The Commission is particularly interested in comments on whether individuals with special training and experience (such as treatment technologists, dosimetrists, and radiation therapy physicists) are readily available in the marketplace, either as full-time employees or as a contract service.

Backfit Analysis

The staff has determined that a backfit analysis is not required for this rule because these amendments do not apply to 10 CFR Part 50 licensees.

V. LIST OF SUBJECTS IN 10 CFR PART 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

VI. TEXT OF PROPOSED REGULATIONS

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1954, as amended, and 5 U.S.C. 553 the NRC is proposing to adopt the following amendments to 10 CFR Part 35.

Part 35 - Medical Use of Byproduct Material

1. The authority citation for Part 35 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273): §§ 35.11, 35.13, 35.20(a) and (b), 35.21(a) and (b), 35.22, 35.23, 35.25, 35.27(a), (c) and (d), 35.31(a), 35.39, 35.43, 35.49, 35.50(a)-(d), 35.51(a)-(c), 35.53(a) and (b), 35.59(a)-(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)-(f), 35.75, 35.80(a)-(e), 35.90, 35.92(a), 35.120, 35.200(b), 35.204(a) and (b), 35.205, 35.220, 35.302, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a) and (c), 35.410(a), 35.415, 35.420, 35.432, 35.454, 35.500, 35.520, 35.605, 35.606, 35.610(a) and (b), 35.615, 35.620, 35.630(a) and (b), 35.632(a)-(f), 35.633, 35.634(a)-(i), 35.636(a) and (b), 35.641(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.654, 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b., 68 Stat. 948 as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27(a) and (c), 35.29(b), 35.33(a)-(d), 35.36(b), 35.39, 35.43(b) and (d), 35.50(e), 35.51(d), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406(b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(j), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o., 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In Subpart A--General Information, § 35.2, the following terms are added in alphabetical order:

§ 35.2 Definitions.

* * * * *

"Beam modifying devices" means items such as trays, wedges, compensators, boluses, and blocks that are used to change the radiation dose profile within the patient.

* * * * *

"Computer-generated dose calculation" means a dose calculation that has been made by a computer program with no human action necessary other than the input of patient data, selection of a certain computer program, and the instruction to the computer to begin calculation.

* * * * *

"Manual dose calculation" means a calculation made by an individual using patient data, tabulated data or graphs, nomograms, and a calculator that was not specifically designed or programmed for radiation therapy calculations.

* * * * *

"Patient chart" means a record of the diagnosis and radiation treatment applied to a patient. It may be part of the hospital admission chart prepared for each patient and kept with the patient, or a chart prepared primarily as a result of radiation treatment and kept in the clinic.

* * * * *

"Prescription" means the written instruction to make medical use of byproduct material for the benefit of a specific patient.

* * * * *

"Source strength" means the exposure rate at a specified distance from a source (usually expressed as roentgens per hour at one meter), the amount of radioactivity in a source (usually expressed as millicuries), or the amount of a different radionuclide that produces the same dose rate (usually expressed as milligrams of radium equivalent).

* * * * *

3. In Subpart B--General Administrative Requirements, § 35.39 is added to read as follows:

§ 35.39 Ordering, prescribing, and administering certain radiopharmaceuticals.

(a) A licensee may not order any radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without the approval of the authorized user.

(b) A physician may not prescribe administration of a radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without personally examining the patient and the patient's chart, and consulting with the referring physician if reasonably available. Prescriptions for these byproduct materials must be in writing, and must include the patient's name, the radiopharmaceutical, dosage, and route of administration.

(c) A licensee may not administer a radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without comparing the radiopharmaceutical label and dosage on hand with the physician's prescription.

4. In Subpart B--General Administrative Requirements, § 35.43 is added to read as follows:

§ 35.43 Prescriptions, records, and checks of medical use for therapy.

(a) The authorized user or a physician under supervision of the authorized user shall ensure that, if there is a primary care physician, the patient has been referred for a therapeutic clinical procedure that requires the medical use of byproduct material.

(b) Before beginning a patient's treatment, the licensee shall verify that the authorized user or a physician working under supervision of the authorized user has personally made, dated, and signed a written prescription in the patient's chart that identifies the body part to be treated. Any change in the prescription must also be made in writing in the patient's chart, and must be dated and signed.

(1) For radiopharmaceutical therapy, the prescription must also identify the radiopharmaceutical, the amount of activity to be administered, and the route of administration.

(2) For brachytherapy, the prescription must also identify the sources of radiation and the total tumor dose.

(3) For teletherapy, the prescription must also identify the teletherapy unit to be used, the prescribed dose, and the treatment plan.

(c) Prescriptions and other records made regarding the medical use of byproduct material must be legible and unambiguous.

(d) The licensee shall instruct all workers involved in the radiation therapy process orally and in writing to request clarification from the prescribing physician if any element of a prescription or other record is unclear, ambiguous, or apparently erroneous.

5. In Subpart C--General Technical Requirements, § 35.65 is added to read as follows:

§ 35.65 Discrepancies in records and observations.

A licensee may not use byproduct material for medical use on a patient if there is a discrepancy in records, observations, or physical measurements that may result in a misadministration. A licensee may resume use after resolving the discrepancy.

6. In Subpart F--Radiopharmaceuticals for Therapy, § 35.302 is added to read as follows:

§ 35.302 Administration of radiopharmaceutical dosages.

A licensee shall verify that the prescribed radiopharmaceutical is being administered by comparing the written prescription and the container label.

7. In Subpart G--Sources for Brachytherapy, § 35.432 is added to read as follows:

§ 35.432 Source strength measurements.

(a) A licensee shall measure the source strength of sources before first use and annually thereafter. Sources that are in storage and not being used do not have to be measured; they must be measured before they are placed in service again. For sources manufactured and supplied in lots of nominally identical sources, a sample from each lot may be selected rather than measuring each source.

(b) When performing dose calculations, a licensee may use the source strength reported by the manufacturer rather than using the source strength measured by the licensee.

8. In Subpart G--Sources for Brachytherapy, § 35.452 is added to read as follows:

§ 35.452 Physical measurements of patient.

[Reserved]

9. In Subpart G--Sources for Brachytherapy, § 35.454 is added to read as follows:

§ 35.454 Check of dose calculations.

A licensee shall check dose calculations for accuracy before 50 percent of the prescribed dose has been administered. The check must provide assurance that the final treatment plan will provide the dose prescribed in the patient's chart.

(a) Manual dose calculations must be checked for accuracy by an individual who did not make the calculations.

(b) Computer-generated dose calculations must be checked by examining the calculation printout to assure that the correct parameters and parameter values were used in the calculation. The check must be made by an individual who did not enter the patient data or prescription into the computer.

(c) If the prescribing physician makes a determination to delay treatment in order to perform the checks of dose calculations required by this section would jeopardize the patient's health because of the emergent nature of the patient's condition, the licensee may provide the prescribed treatment without performing the checks; the prescribing physician shall make a notation of this determination on the patient's chart, and the licensee shall perform the checks as soon as practicable.

10. In Subpart I--Teletherapy, § 35.632, the introductory text of paragraph(b) and paragraph(b)(1) are revised to read as follows:

§ 35.632 Full calibration measurements.

* * * * *

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ±3 percent for the range of field sizes, range of distances, and selection of beam modifying devices (for example: trays, wedges, and the stock material that is used for making compensators and boluses) used for medical use;

* * * * *

11. In Subpart I--Teletherapy, § 35.633 is added to read as follows:

§ 35.633 Independent check of full calibration measurements.

(a) A licensee shall have an independent check of the output determined within one month after completion of the full calibration required by § 35.632.

(b) The independent check must be performed by a teletherapy physicist who did not perform the full calibration and made using a dosimetry system other than the one used to measure the output during the full calibration. The teletherapy physicist does not have to be listed as a teletherapy physicist on an NRC or Agreement State license. The dosimetry system may be one described in § 35.630, or it may be another system that provides a similar level of accuracy and precision.

12. In Subpart I--Teletherapy, § 35.652 is added to read as follows:

§ 35.652 Physical measurements of patient.

[Reserved]

13. In Subpart I--Teletherapy, § 35.654 is added to read as follows:

§ 35.654 Checks of dose calculations and measurements of dose.

A licensee shall check dose calculations for accuracy before 20 percent of the prescribed dose has been administered. The check must provide assurance that the final treatment plan will provide the dose prescribed in the patient's chart.

(a) Manual dose calculations must be checked for accuracy by an individual who did not make the calculations.

(b) Computer-generated dose calculations must be checked by examining the calculation printout to assure that the correct parameters and parameter values were used in the calculation. The check must be made by an individual who did not enter the patient data or prescription into the computer.

(c) A licensee shall make a weekly accuracy check of daily arithmetic calculations that have been made in patient's charts.

(d) If the patient's dose calculations include parameters or parameter values that fall outside the range of those measured in calibrating the teletherapy unit, the licensee shall make a physical measurement of the dose rate to be administered to the patient. This measurement must be made before 20 percent of the prescribed dose has been administered.

(e) If the prescribing physician makes a determination that to delay treatment in order to perform the checks of dose calculations or

physical measurements required by this section would jeopardize the patient's health because of the emergent nature of the patient's condition, the licensee may provide the prescribed treatment without performing the checks of dose calculations or physical measurements; the prescribing physician shall make a notation of this determination on the patient's chart, and the licensee shall perform the checks of calculations or physical measurements as soon as practicable.

Dated at Washington, DC, this 29th day of September, 1987.

For the Nuclear Regulatory Commission,

Samuel J. Chilk,
Secretary of the Commission.