14786

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 15, 1994

James P. Gleason, Chairman
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory
Commission
Washington, D.C. 20555

Thomas D. Murphy
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory
Commission
Washington, D.C. 20555

Dr. Peter S. Lam
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory
Commission
Washington, D.C. 20555

In the Matter of
Indiana University School of Medicine
Byproduct Material License No. 13-02752-08
Docket No. 030-09792-CivP

Dear Administrative Judges:

Enclosed are the following documents requested by the Atomic Safety and Licensing Board pursuant to the Board's March 11, 1994 Memorandum and Order (Hearing Request):

1. Notice of Violation and Proposed Imposition of Civil Penalty, dated October 7, 1993.

2. Licensee's response, dated October 29, 1993.

3. NRC Inspection Report No. 030-097 92/92001 (DRSS) for the inspection on December 14, 1992 through January 13, 1993.

Sincerely,

Michael H. Finkelstein

Michael H. Finkelstein
Counsel for NRC Staff

Enclosures: As stated

cc: Service List

D507

Enclosure 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

October 7, 1993

Docket No. 030-09792
License No. 13-02752-08
EA 93-111

Indiana University School
of Medicine
IUPUI Administration AO 104B
ATTN: Chancellor Gerald Bepko
355 Lansing Street
Indianapolis, IN 46202

Dear Chancellor Bepko:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $5,000
(NRC INSPECTION REPORT NO. 030-09792/92001(DRSS))

This refers to the inspection conducted on December 14, 1992, through January 13, 1993, at the Indiana University Medical Center. The inspection included a review of the circumstances surrounding a teletherapy misadministration which occurred on November 13, 1992. The report documenting this inspection was sent to you by letter dated January 27, 1993. During this inspection a violation of NRC requirements was identified.

An enforcement conference was held on May 26, 1993. The report documenting the conference was sent to you by letter dated June 8, 1993. You reported the event to the NRC Operations Center on December 3, 1992. Subsequently, you submitted a written report dated December 17, 1992.

On November 13, 1992, a 31 month old patient diagnosed with stage IV neuroblastoma was scheduled, on an emergency basis, to receive 300 centigray (cGy) to the left orbit to reduce swelling behind the left eye. The written directive specified that the dose be delivered to one port in two 150 cGy fractions, for a total of 300 cGy. The dosimetrist who performed the dose calculations misinterpreted the written directive and calculated the dose as 300 cGy per fraction, for a total dose of 600 cGy, a 100 percent increase over the prescribed dose.

The error was transferred to the patient chart which was provided to the staff physician (authorized user) who initially prepared the written directive. Prior to the first treatment, the

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

authorized user reviewed and initialed the patient chart but did not identify the error. Two radiation therapists also reviewed the patient chart and the initial directive. A total of 300 cGy was delivered to the patient on November 13, 1992, and another 300 cGy was delivered on November 14, 1992.

On November 16, 1992, a medical physicist reviewed the initial directive, the calculations, and the treatment delivered and did not identify the error. On December 2, 1992, a student radiation therapist identified the error while performing a routine chart summary.

The violation described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involves a substantial failure of the quality management program to ensure that the written directive contained the total dose, dose per fraction, treatment site, and the overall treatment period as required by 10 CFR 35.2. Additionally, the quality management program did not have a procedure to verify dose calculations in cases where the prescribed dose is three fractions or less. The violation contributed to the occurrence of a misadministration on November 13, 1992. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violation is categorized at Severity Level III.

We acknowledge your corrective actions which included revising the written prescription form to promote uniformity of information provided by physicians, revising the quality management program to address dose calculation checks for doses administered in three fractions or less, reissuing the revised quality management program for review by all affected Radiation Oncology staff members, and reviewing the NRC videotape entitled, "Good Practices in Co-60 Teletherapy."

To emphasize the importance of adequate implementation of the quality management program for teletherapy administrations, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $5,000 for the Severity Level III violation.

The base value of a civil penalty for a Severity Level III violation is $2,500. The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was escalated 50 percent for identification. Although the student radiation therapist identified the misadministration during a routine chart summary review on December 2, 1992 and the licensee notified the NRC Operations Center pursuant to 10 CFR 35.33, the NRC identified the violation of the quality management program. In regards to corrective actions, the base civil penalty was mitigated 50 percent for the reasons stated above.

In addition, the base civil penalty was escalated 100 percent for your poor past performance. A similar misadministration previously occurred which was the subject of our May 1990 special inspection.

The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 100 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence.

Your response should also address the following concerns: (1) a lack of staff sensitivity to deviations from the standard treatment plan of 300 cGY per fraction for brain therapies; and (2) inconsistencies in the format for written directives.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure:
Indiana State Board of Health
Mack Richard, Radiation Safety Officer,
Indiana University Medical Center
DCD/DCB (RIDS)

DISTRIBUTION
SECY
CA
JTaylor, EDO
HThompson, DEDS
JLieberman, OE
LChandler, OGC
JGoldberg, OGC
RBernero, NMSS
CPaperiello, NMSS
Enforcement Coordinators
RI, RII, RIV, RV
FIngram, GPA/PA
DWilliams, OIG
BHayes, OI
EJordan, AEOD
PSantiago, OE
Day File
EA File
DCS
State of Indiana
RAO:RIII
SLO:RIII
PAO:RIII
IMS:RIII
PUBLIC

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Indiana University Medical Center
Indianapolis, Indiana

Docket No. 030-09792
License No. 13-02752-08
EA 93-111

During an NRC inspection conducted on December 14, 1992, through January 13, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty is set forth below:

10 CFR 35.32(a) states, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a)(1) and (3), the quality management program must include written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any teletherapy radiation dose; and (2) final plans of treatment and related calculations for teletherapy are in accordance with the written directive.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation and containing, for teletherapy, the following information: the total dose, dose per fraction, treatment site, and overall treatment period.

Contrary to the above, as of January 13, 1993, the licensee's quality management program for teletherapy dated January 16, 1992, did not have a procedure for: (1) ensuring the written directive contained the total dose, dose per fraction, treatment site, and the overall treatment period and (2) verifying the dose calculations for administrations of three fractions or less to confirm that the final plans of treatment are in accordance with the written directive. Consequently, on November 13, 1992, the licensee's authorized user signed and dated a written directive for a teletherapy treatment that failed to include the overall treatment period and the licensee failed to verify the dose calculations, since the treatment called for less than 3 fractions, to ensure the final plans of treatment were in accordance with the written directive.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - $5,000.

Pursuant to the provisions of 10 CFR 2.201, Indiana University Medical Center (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205,

regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

Dated at Glen Ellyn, Illinois
this 7th day of October 1993

October 29, 1993 Enclosure 2

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

RA		RC	
DRA		EIC	
DRP		SGA	
DRS		OI	
DRSS		PAO	
DRMA			

FILE

Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

CHANCELLOR

On October 7, on behalf of Indiana University Medical Center, I received a letter which included a "Notice of Violation and Proposed Imposition of Civil Penalty" (Docket No. 030-09792). By my letter of October 19 I indicated that we would file a response through the office of Dean Walter Daly of the Indiana University School of Medicine. This letter contains that response on behalf of Dean Daly and my office.

As the attached document, entitled "Reply to a Notice of Violation" suggests, we deny the validity of the cited violation. Inasmuch as we dispute the validity of the cited violation, we have opted to protest the imposition of a civil penalty and have included a separate document entitled "Answer to a Notice of Violation." These two documents were prepared and reviewed by physicians, physicists, legal counsel, and radiation safety personnel. Dean Daly and I have reviewed these documents and support the information and conclusions contained in them.

Should you have any questions regarding this response, please contact either me, Dean Daly, or our Radiation Safety Officer, Mr. Mack L. Richard. We hope that we can reach a mutually satisfactory resolution of this case and look forward to hearing from you.

Sincerely,

Gerald L. Bepko
Chancellor

GLB/db
Attachments

cc: W. Daly, M.D., Dean, IU School of Medicine
S. Kleit, M.D., Associate Dean of Clinical Affairs
N. Hornback, M.D., Chairman, Department of Rad. Oncology
B. Batteiger, M.D., Chairman, RRSC
G. Sandison, Ph.D., Chief Physicist, Rad. Oncology
J. Kelly, University Counsel
M. Richard, M.S., Radiation Safety Officer
D. Uhl, Hospital Administration
NRC Region III Office

ministration Building 104
th Lansing Street
apolis, Indiana
46202-2896

317-274-4417
Fax 317-274-4615

REPLY TO A NOTICE OF VIOLATION

I. NRC Assertion #1 - The written directive did not include the overall treatment period: This assertion is incorrect. A copy of the page which includes the written directive for the patient dated November 13, 1992 is attached (Attachment 1). In the written directive, the number of fractions is written as "2 fx" which means the treatment period is to include two fractions or treatments. This is our interpretation of the overall treatment period.

The definition of what is required in a written directive for teletherapy as defined in 10 CFR 35.2 does not include the requirement to record the total number of fractions. The reason that our authorized users do record the number of fractions is to meet the requirement for recording the overall treatment period. The term "overall treatment period" is not defined in the regulations or in Regulatory Guide 8.33. Inasmuch as the NRC has not provided any guidance on this definition and no information had been received prior to this inspection, it is inappropriate for the NRC to arbitrarily cite a violation over a term which was not discussed during the investigation or the Enforcement Conference. Regardless of how this term is interpreted, it had no impact on the treatment delivered on November 13, 1992.

II. NRC Assertion #2 - Failure to verify the dose calculations because the treatment called for less than 3 fractions: This assertion is also incorrect as stated. In fact, three different individuals attempted to verify that the treatment to be delivered was in accordance with the written directive. These individuals included the prescribing physician/authorized user and two radiation therapists. Unfortunately, none of the three individuals identified a calculational error made by a dosimetrist shortly before this emergency treatment. Their failure to identify the error was related to the wording of the written directive rather than a failure to follow proper procedure.

The November 13, 1992 treatment was in fact an <u>emergency</u> treatment. The significance of this fact has been consistently misunderstood or ignored by the NRC. The treatment planning was started at approximately 4:30 p.m. and a number of individuals remained after normal working hours to deliver the treatment. Both the QA/QC Program and the QMP discuss extenuating circumstances which include emergency treatments. In this case, a further check would have required the delay of the treatment until an additional staff member could return to the clinic and perform an additional check. Given the patient's medical condition, such a delay was not in the best interest of the patient. Furthermore, given the root cause of the problem (discussed in the following paragraphs), there is no assurance that an additional check would have detected the initial error.

It is true that the current Quality Assurance/Quality Control (QA/QC) Program and the Quality Management Program (QMP) do not include specific verification procedures for treatments of less than four fractions. The reason for that fact is quite simple. None of the Radiation Oncology staff could recall ever prescribing or reviewing a treatment plan which called for less than four treatments on the ^{60}Co teletherapy unit in either the distant or recent past; therefore, when the QMP was developed, specific verification procedures for such short term treatments were not included. IUMC should not be penalized for not including verification procedures for less than four treatments in the QMP when such treatments rarely if ever occur. Furthermore, the NRC has never raised this particular issue during past reviews of our QA/QC Program and had not pointed out such a deficiency in our QMP which was submitted more than 1.5 years ago. Contrary to the NRC's inference that they independently discovered this omission in the QMP, it was actually concurrently discovered by our staff and the NRC inspector.

III. Area of concern #1 (from page 3, paragraph 4 of the NOV cover letter) - a lack of staff sensitivity to deviations from the standard treatment plan of 300 cGy per fraction for brain therapies: This concern apparently came from statements made in the initial misadministration notice (which was based upon a preliminary review of the circumstances surrounding the misadministration) forwarded to the NRC. After a more thorough review of the overall treatment program, the assumptions and statements made in that notice were determined to

be incorrect. While the treatment delivered in this misadministration was within the normal range for the brain, there is not a "lack of sensitivity" to variations from 300 cGy per fraction. In fact, many brain treatments which are not 300 cGy per fraction are prescribed and delivered appropriately. This concern has already been addressed in an attachment to a March 23, 1993 letter from Mr. Mack Richard to Mr. Charles Norelius. The relevant portion of that correspondence is included with this report as Attachment 2.

IV. Area of concern #2 (from the same document as listed in the preceding paragraph) - inconsistencies in the format for written directives: This concern which we feel is the root cause of the November 13, 1992 misadministration is discussed elsewhere in this reply.

V. Additional Information (Reason for violation, corrective steps taken, and date of full compliance) - We have not challenged the fact that a misadministration occurred on November 13, 1992. Contrary to the assertions of the NRC, the proposed violations, whether they are valid or not, did not cause the misadministration. Based upon our extensive review of the misadministration, the root cause of the misadministration was the inconsistent format of written directives by the authorized user and resident physicians. As noted in Attachment 1, the written directive has always been written out in a "long hand" fashion. Thus, two physicians could write the same written directive in a different way. It was this inconsistency which led to the initial misinterpretation by the dosimetrist and made it difficult for individuals checking the calculations afterward to identify the error. To alleviate this problem, the form utilized to record the written directive has been extensively revised and now requires the authorized user or resident physician to enter specific information in a more consistent manner. A copy of this revised form is included as Attachment 3. This form was put into effect on a trial basis in May, 1993 and has been revised slightly based upon suggestions by the radiation oncology staff.

The QMP has been revised to include an independent check of the treatment time calculations prior to the initiation of treatments of four fractions or less except in the case of emergency treatments. This change was officially reviewed and approved at the September 14, 1993 meeting of our Radionuclide Radiation Safety Committee (RRSC). A copy of the revised QMP has been forwarded to the Department of Radiation Oncology for dissemination to their staff and incorporation into their standard procedures. The revised QMP has also been forwarded to the Region III NRC Office in accordance with 10 CFR 35.32(e). Furthermore, a recently issued NRC videotape entitled "Good Practices in Co-60 Teletherapy - A Procedural Review" has been viewed by all Radiation Therapists.

Attachment 1

RADIATION TREATMENT PLAN

DATE	FIELD DESIGNATION	AIM; TOTAL DOSE, #FRACTIONS, AREA TREATED BEAM ORIENTATION, SPECIAL CONSIDERATIONS
11/13	A Ant. orbit	300 cGy in 2 days (150 cGy/day) thru a ... ant. field ... eye block using CO-60 to a depth of 3 cm

Total Dose
Dose/fraction
Anatomical Area
Overall treatment period

11-13-92

	dictations	M.D.	DATE
drawings ☐	Initial		
clin photos ☐	Completion		

PRESCRIPTION SUMMARY

RT	ANATOMIC AREA	UNIT	ENRGY	e-	DOSE TX	NO TX	C.D. REEVAL STOP AT	DATE	INIT	COMMENTS

The responses to the three concerns specified on page 2 of the inspection report are provided in the same order as listed on said report.

1. It is the goal of the physics staff to check all calculations before they are used for patient treatment; however, such checks are not always possible, usually for one of two reasons. Occasionally, a member of the physics staff is not immediately available to do an independent check before the treatment is initiated, particularly for emergent treatments. At other times, patient measurements are made at the time the patient is positioned for his/her first treatment. In this case, the treatment is usually given as soon as the calculations have been completed. In either of these cases, every attempt is made to have the calculations checked before the second treatment is administered.

The aforementioned procedures are not altered when there are four or fewer treatments. In fact, when staff is available, the treatment is delayed a few minutes, when possible, while the calculations are checked. However, when no physics personnel are available to verify the calculations, treatment cannot be delayed for long periods of time. This most often occurs when the patient is treated without being previously scheduled (i.e. the patient is seen for the first time and treated immediately). It also occurs in emergent cases where the patient treatment commences near the end of the day or after normal working hours.

It is important to balance these checks (and the delays which may occur in attempting to perform them) with the comfort and the care being provided to the patient. Careful judgment must be exercised to prevent compromising patient care for the sake of performing such calculational checks.

The assumption that there is a "lack of sensitivity" to deviations from "standard" treatment plan of 300 cGy (rads) per fraction for brain treatments is an over-generalization. There are brain treatments delivered accurately on the ^{60}Co unit for which the tumor dose is not 300 cGy. The "lack of sensitivity" may have been related to way the prescription (written directive) was written and/or interpreted rather that the assumption that this was a "standard" brain treatment.

2. In the past, the radiation oncology physicians would write prescriptions (written directives) in a narrative format. That being the case, some physicians might indicate the total dose followed by the dose per fraction while others might write the same prescription in the reverse order. Members of the Radiation Oncology Department including physicians, therapists, and physicists have reviewed the layout of the form utilized by the physicians for writing prescriptions. Based upon that review, the form has been revised into a columnar format. The intent of this revision is to provide a more consistent method of writing prescriptions, thus reducing the likelihood that individuals reading said prescriptions will misinterpret them.

Attachment 3

NAME: ______________ HOSP#: ______________ SVC: ______________

ANATOMICAL SITE:	FIELD	DOSE/FX	# FX	TOTAL DOSE	MACHINE/ISOTOPE	ENERGY
		x	=			
	FRACTIONATION: Daily B.I.D. T.I.D. Other					
DESCRIPTION:					Resident Signature & Date: Staff Signature & Date:	

ANATOMICAL SITE:	FIELD	DOSE/FX	# FX	TOTAL DOSE	MACHINE/ISOTOPE	ENERGY
		x	=			
	FRACTIONATION: Daily B.I.D. T.I.D. Other					
DESCRIPTION:					Resident Signature & Date: Staff Signature & Date:	

ANATOMICAL SITE:	FIELD	DOSE/FX	# FX	TOTAL DOSE	MACHINE/ISOTOPE	ENERGY
		x	=			
	FRACTIONATION: Daily B.I.D. T.I.D. Other					
DESCRIPTION:					Resident Signature & Date: Staff Signature & Date:	

ANATOMICAL SITE:	FIELD	DOSE/FX	# FX	TOTAL DOSE	MACHINE/ISOTOPE	ENERGY
		x	=			
	FRACTIONATION: Daily B.I.D. T.I.D. Other					
DESCRIPTION:					Resident Signature & Date: Staff Signature & Date:	

DOSE SUMMARY:	INITIAL LETTER MD: DATE: COMPLETION LETTER MD: DATE:

ANSWER TO A NOTICE OF VIOLATION

Indiana University Medical Center (IUMC) hereby protests the imposition of a civil penalty as stipulated in the NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY (Docket No. 030-09792) dated October 7, 1993 and requests total remission of same. The reasons for this protest are contained in the following paragraphs.

IUMC does not deny that a misadministration occurred on November 13/14, 1992 and in fact notified the NRC both by telephone and written correspondence in accordance with 10 CFR 35.33. IUMC considers any deviation from the normal treatment parameters to be potentially serious in nature regardless of whether or not a misadministration occurs. The Department of Radiation Oncology has had a Quality Assurance Committee for several years which examines any deviations as to their cause and possible solutions to prevent recurrence. Thus, IUMC does not consider this misadministration a trivial issue and significant steps have been taken to prevent the recurrence of such an incident.

As noted in our "REPLY TO A NOTICE OF VIOLATION" (page 2, section V, paragraph 1), the root cause of this misadministration was related to how authorized user/physicians write prescriptions (written directives) for patient treatments. Implemented changes in how prescriptions are written should significantly reduce the likelihood of future misadministrations.

IUMC challenges the validity of the cited violation and the assertions within that cited violation as they apply to this misadministration. This challenge is based upon the following three premises:

1. The proposed violation did not cause this misadministration since the written directive did include the overall treatment period. Nevertheless, the presence or absence of the documentation of the overall treatment period would have no bearing on the initial interpretational error made by the dosimetrist or the subsequent oversights by individuals who were verifying the correctness of the treatment.

2. As mentioned in our "REPLY TO A NOTICE OF VIOLATION" (page 1, section II, paragraph 2), this treatment was performed on an emergency basis. This fact causes the standard verification procedure to change depending upon the availability of staff. Neither the Quality Control/Quality Assurance Program (QA/QCP) nor the Quality Management Program (QMP) include specific procedures for verification when less than four treatments are prescribed. This deficiency in the QMP has been rectified. However, because the treatment in question was an emergency, no change in the subsequent chart checking procedures would have resulted.

3. Regardless of the final outcome of our "REPLY TO A NOTICE OF VIOLATION", IUMC challenges the categorization of the proposed violation as a Severity Level III violation. As stated above, the misadministration occurred due to inconsistencies in the format of the written directive. It was not caused by a "programmatic weakness in the implementation of the QMP" as stated in 10 CFR 2, Supplement VI, C, 6. The QMP was followed and the appropriate checks were made. Even if it were finally adjudged that the violation is correct, it is more appropriately categorized as a Severity Level IV violation as stated in 10 CFR 2, Supplement VI, D, 3. Specifically, it does not represent a programmatic weakness in the implementation of the QMP, the failure was isolated to this single event, and the consequences were limited and did not adversely affect the patient.

IUMC also disagrees with some statements made in the cover letter which accompanied the Notice of Violation. Those statements and our responses are as follows:

1. The statement on page 2, paragraph three, "The violation contributed to the occurrence of a misadministration on November 13, 1992." is incorrect based upon the preceding information.

2. In the final paragraph on page 2, the NRC takes credit for identifying the proposed violation of the QMP. We would remind the NRC that the QA/QCP was submitted several years ago. During none of the NRC's subsequent review and revision was any weakness in our program pointed out to us. Likewise, our QMP was submitted to the NRC approximately 1.5 years ago in accordance with 10 CFR 35.32(f)(2). Since that submission, IUMC has received no indication that the QMP was deficient. In reality, the "less than four treatment" deficiency was detected concurrently by the NRC and IUMC as a result of this misadministration. Escalation of enforcement based on the NRC's claim of identifying the deficiency is inappropriate.

3. In the first paragraph on page 3, the NRC escalates the base civil penalty by 100 percent for "poor past performance." This was apparently due to a misadministration which occurred in May of 1990, some 2.5 years before the most recent one. The NRC claims that these misadministrations were "similar". Upon examination of the details of the May, 1990 misadministration, the only similarities were that they were both brain treatments and the dose per fraction was doubled. The dissimilarities include an emergency treatment versus treatment during normal working hours, a short-term versus a more conventional long-term treatment, and a single port treatment versus a multiple port treatment. All elements considered, there appears to be no relationship between the causes of the two misadministrations. The reason for escalation also infers that the NRC's sole evaluation of past performance relates to the number of misadministrations which have occurred and been reported over an undefined period of time. We would point out that the May, 1990 misadministration was discovered through our QA/QCP. Until January of 1992, most licensees were not required to have any type of QMP; therefore, comparing our performance to that of other licensees is not appropriate (i.e., other licensees may have had misadministrations which went undetected (and not reported) due to the fact that they had no QMP).

Another salient point regarding performance is related to the number of treatments delivered over a given time period. While a QMP helps reduce the possibility of misadministrations, normal statistical probabilities would predict that the potential for misadministrations will increase with the number of patient treatments due to human error. In our particular instance, our Radiation Oncology Department treated approximately 1418 patients including some 52,000 separate treatments with external beam therapy during the time interval between the two misadministrations. 518 of those patients (approximately 15,000 separate treatments) were specifically treated with ^{60}Co teletherapy. One patient with two ports in error is a very small percentage of the overall number of treatments and should not be sufficient to escalate a civil penalty based upon "poor past performance."

We wish to address one final point. On May 26, 1993, representatives of IUMC were invited to an Enforcement Conference to discuss two apparent violations which were cited as a result of the NRC inspection which was carried out as a result of the November 13, 1992 misadministration. At that Enforcement Conference, we specifically challenged the apparent violations. On October 7, 1993, IUMC's Radiation Safety Officer (RSO) was notified by telephone that a Notice of Violation (NOV) was being forwarded to the Chancellor of the university, that a civil penalty was being proposed, and a press release would be issued to the local media. The RSO requested that a copy of the NOV be transmitted to him via facsimile and the NRC complied with his request.

Upon review of the NOV, the RSO discovered that the violation being cited in the NOV was completely different from the violations discussed at the Enforcement Conference. The NRC attempts to justify their actions by alluding to a sentence in the May 19, 1993 inspection report which states, "Be advised that the characterization of the apparent violations may change as a result of further NRC review." This statement does not state that the apparent violations themselves may change. The NRC apparently feels that this statement technically relieves them of any obligation to discuss changes in the violations. IUMC is concerned that

citing a violation, proposing a civil penalty, and issuing a press release on a violation which is of highly questionable validity, has no bearing on the misadministration, and contains assertions which were not discussed during the Enforcement Conference may not be in the best interests of either the university or the NRC.

IUMC understands that the issuance of information regarding misadministrations to the news media is part of the enforcement process. Our concerns are not with this policy itself; rather, it is with the timing for the release of the information. It is our opinion that unless there is imminent danger associated with a licensee's continuation to treat patients, the release of information to the news media should only occur when the final resolutions to all issues relative to the misadministration have been reached. This would prevent an inadvertent defamation of a licensee's character should the final outcome be different from what was originally proposed and would also eliminate the need for either the NRC or the licensee to issue another press release. We respectfully request the NRC to consider these suggestions for future enforcement actions.

Finally, we understand the pressures under which the NRC must operate. Be that as it may, we request the NRC exercise reasonable discretion when imposing enforcement actions against licensees to assure that such actions are indeed warranted. IUMC continually strives to provide the best patient care possible and comply with all NRC regulations and our license conditions. The final outcome of this issue will not change those facts.

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-09792/92001(DRSS)

Docket No. 030-09792

License No. 13-02752-08 Category G(3) Priority I

Licensee: Indiana University School of Medicine
541 Clinical Drive
Indianapolis, IN 46202-5111

Inspection At: Indiana University Medical Center
Department of Radiation Oncology
535 Barnhill Drive
Indianapolis, IN

Inspection Conducted: December 14, 1992 through January 13, 1993

Inspector: Toye L. Simmons — 1/15/93
Toye L. Simmons
Radiation Specialist
Date

Reviewed By: B. J. Holt — 1/15/93
B. J. Holt, Chief
Nuclear Materials Inspection
Section 1
Date

Approved By: Roy J. Caniano — 1/12/93
Roy J. Caniano, Acting Chief
Nuclear Materials Safety
Branch
Date

Inspection Summary

Inspection on December 14, 1992 through January 13, 1993 (Report No. 030-09792/92001(DRSS))
Areas Inspected: This special, announced safety inspection was conducted in response to a teletherapy misadministration reported to the NRC on December 3, 1992. The inspection included a review of the teletherapy misadministration, the radiation therapy program and selected aspects of licensed teletherapy activities as described in Section 6 of this report.

Results: Of the areas inspected, two apparent violations were identified:

- Failure to employ a calibrated dosimetry system when performing a full calibration of the teletherapy unit, 10 CFR 35.632(a), Section 6;

- Failure to equip the radiation monitor in a teletherapy room with a backup power supply, 10 CFR 35.615(d)(2), Section 6.

Three concerns were identified:

- Lack of provisions in the licensee's Quality Assurance/Quality Control procedures or in the Quality Management Program for a dose calculation review by a physics staff member for treatments consisting of less than four fractions. (Section 5)

- Lack of staff sensitivity to deviations from the standard treatment plan of 300 cGY per fraction for brain therapies. (Section 5)

- Inconsistencies in the format for the written directive. (Section 5)

In addition, one unresolved issue was identified:

- The apparent inadequate review of the calculated treatment dose which resulted in a misadministration. (Section 5)

DETAILS

1. Persons Contacted

* B. Batteiger, M.D., Chairman of Radiation Safety Committee
J. Montebello, M.D., Radiation Oncologist
M. Richard, Radiation Safety Officer
* J. Mason, Assistant Radiation Safety Officer
* S. Frost, Physicist, Radiation Oncology
R. Powers, Dosimetrist
S. Roberson, Radiation Therapy Technologist
J. Connett, Radiation Therapy Technologist

* Indicates those present at the exit meeting held on December 15, 1992

2. Inspection History

Activities conducted under License No. 13-02752-08 have been reviewed by the NRC twice within the past two years. One violation was identified during a routine inspection conducted on September 11, 1991 involving the repair of a teletherapy unit by an individual not specifically licensed. As a result of the inspection findings a Confirmatory Action Letter was issued to the licensee on September 20, 1991, to confirm that the following actions would be taken:

a. All proposed work to be performed on the teletherapy units will be discussed with the NRC Region III office.

b. Results of manufacturer's operation check of the Alcyon unit performed after University personnel replaced timer relays will be forwarded to the Region III office within 30 days.

c. Results of the manufacturer's operation check of the Picker unit following repairs by University personnel will be submitted to Region III within 30 days.

A special safety inspection was conducted May 21-23, 1990 following a reported teletherapy misadministration. A patient received a radiation dose to the brain 33% greater than that intended. One violation of NRC requirements was identified: failure to perform monthly checks of the electrical beam stops for the Alcyon II teletherapy unit as required by 10 CFR 35.634(d)(4). In addition, programmatic weaknesses in the license's quality assurance program were identified. As a result of this inspection, the licensee upgraded its quality assurance program and amended License No. 13-02752-08 to include the attached procedure entitled "Quality Assurance/Quality Control Procedures for Administration of External Beam Radiation Therapy" (QA). (Attachment 1)

3. Licensed Program

On September 26, 1973, Indiana University was issued NRC License No. 13-02752-08 for possession and use of up to 6600 curies of cobalt-60 as sealed sources, to be used in an AECL Eldorado teletherapy unit for treatment of humans. The license was last amended in its entirety on October 6, 1989, and currently authorizes possession and use of 7000 curies of cobalt-60 in a Picker Corporation Model 6296 teletherapy unit and 6670 curies of cobalt-60 in a Thomson CGR Medical Corporation Model Alcyon II unit.

The Picker unit is used exclusively for whole body and partial body irradiation of bone marrow transplant patients, at the rate of about one patient per month. The Alcyon unit is used primarily for head and neck treatments, currently at a rate of about 15 patients per day. Although authorized, the licensee no longer uses the Alcyon to irradiate blood or blood products.

The quantities, type and use of radioactive material are as authorized on the license.

No violations of NRC requirements were identified.

4. Teletherapy Misadministration Event Summary

On the afternoon of November 13, 1992, a 31 month old patient diagnosed with stage IV neuroblastoma was scheduled, on an emergency basis, to receive 300 cGy (rads) to the left orbit to reduce swelling behind the left eye. The written directive specified that the dose be delivered to one port in two fractions, i.e. 150 cGy per fraction for a total of 300 cGy. The dosimetrist who performed the dose calculations misinterpreted the written directive and calculated the dose per fraction as 300 cGy with a total dose of 600 cGy, a 100% increase over the intended dose. The error was transferred to the patient chart which was provided to the authorized user who prepared the written directive. Prior to the first treatment, the authorized user reviewed and initialed the patient chart but did not identify the error. The treatment was delivered by two therapy technologists.

On November 14, 1992, the second and final fraction was delivered.

On November 16, 1992, a medical physicist reviewed the dose calculation and the treatment data but also failed to find the error.

On December 2, 1992, during a routine patient chart summary review, a student technologist discovered that the written directive and the delivered dose did not correspond and informed the appropriate licensee personnel. The licensee notified the NRC Operations Center of the teletherapy misadministration pursuant to the requirements in 10 CFR 35.33. This was followed up as required with written notification. (Attachment No. 2). The licensee also notified the patient's guardians and the patient's referring physicians of the misadministration.

The NRC inspector verified that the licensee informed the patient's referring physicians as required. According to the referring physicians, the patient's guardians have been notified and the patient has not suffered adverse affects as a result of the misadministration.

5. Teletherapy Misadministration Evaluation

The apparent root cause of the misadministration was an error made during the dose calculation resulting from a misinterpretation of the written directive. The dosimetrist interpreted the written directive as requesting 300 cGy "times" two fractions instead of 300 cGy "in" two fractions.

Condition 14 of NRC License No. 13-02752-08 references the licensee's QA procedures contained in a letter dated August 27, 1990, entitled "Quality Assurance/Quality Control Procedures for Administration of External Beam Radiation Therapy". Item 4 states that prior to the initiation of treatment, a staff physician shall review and initial the treatment chart. By initialling the patient chart, the staff physician is verifying that he/she has reviewed the written prescription, the calculated dose per fraction, the anatomical area to be treated, and the treatment machine and beam energy to be utilized. (Attachment 2)

10 CFR 35.32(a)(3) and (a)(5) state, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written polices and procedures to meet the following specific objectives: (1) that final plans of treatment and related calculations for teletherapy are in accordance with the respective written directive and (2) that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

The licensee established and implemented a written QMP as required by 10 CFR 35.32 on January 16, 1992. (Attachment 3) The QMP is very similar to the QA procedure which was implemented in 1990. Item 4 of the QA procedure is identical to Section III (B) of the QMP. The staff physician (authorized user) who signed the written directive also initialled the patient chart prior to treatment indicating that he had reviewed the written prescription, the calculated dose per fraction, anatomical area to be treated and the unit to be used. However, the information written on the patient chart for his review clearly indicated that the dose per fraction was incorrect. The staff physician's review appears to have been inadequate. An inadequate review of the calculated dose per fraction is contrary to the licensee's QA procedures and may have resulted in the failure of the QMP to meet the objectives of 10 CFR 35.32 (a)(3) and (a)(5) as previously stated. The NRC is in the process of reviewing this matter for its applicability to the requirements of the License and the regulations. Therefore this issue is considered to be unresolved at this time.

The NRC inspector identified concerns which apparently contributed to the occurrence of this misadministration. These are described below:

- Item 5 of the QA procedure and Section III (A) of the QMP state, in part, that a physics staff member shall review the accuracy of all dosimetric calculations prior to the initiation of treatment if possible or before 25% of the dose is administered or before the fourth treatment is delivered, whichever is less restrictive. Neither document provides for a physicist's review when the treatment length is less than four fractions as in the case discussed in this report.

- The Alcyon cobalt-60 teletherapy unit is used primarily for whole brain treatments. The standard plan for these treatments is 300 cGy per fraction. When the five individuals involved with this case saw the customary "300" in the written directive, the dose calculation and on the patient chart, it was viewed as a standard administered dose.

- Typically there are seven resident physicians and five authorized users who may write a treatment prescription/written directive at the licensee's facility. Each physician documents the information contained in the written directive in a different style. Since there is little consistency in the format of the written directive, misinterpretations can occur.

One unresolved issue and three concerns were identified.

6. Other Areas Inspected

The inspection included a review of selected aspects of licensed activities associated with the routine teletherapy program including: organization, staffing, personnel qualifications materials, facilities and equipment, external exposure control and monitoring, teletherapy unit calibration and posting. No problems were noted except as described below.

10 CFR 35.632(a) and (c)requires, in part, that the licensee perform full calibration measurements using the dosimetry system described in 35.630(a) to measure the output for one set of exposure conditions. 10 CFR 35.630(a) requires the licensee to have a dosimetry system which has been calibrated by an accredited calibration laboratory every two years or calibrated as stated within the previous four years and intercompared at an intercomparison meeting with another dosimetry system that has been calibrated within the past twenty-four months. In December 1991 a full calibration was performed on the Picker Model 6296 teletherapy unit. The dosimetry system used had not been calibrated within two years nor had it been intercompared with a calibrated dosimetry system as required. The failure to use a calibrated dosimetry system while performing a full calibration of a cobalt teletherapy unit is an apparent violation of 10 CFR 35.632. The inspector reviewed records of the monthly spot checks performed following the full calibration and

concluded that the information, i.e. output, obtained from both the full calibration and the spot checks was consistent. In addition, several spot checks had been performed with a calibrated dosimetry system.

10 CFR 35.615 (d) requires the licensee to install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

10 CFR 35.615(d)(2) states that a radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system. A device identified by the licensee as a battery backup system to the radiation monitor in the Picker Model 6296 teletherapy room was tested by the inspector to determine operability of the monitor on an independent power supply. The radiation monitor functioned properly while plugged into the wall socket, however, when attached solely to the backup battery the monitor was inoperable. The failure to equip the radiation monitor in the Picker teletherapy room with a power supply separate from the power supply to the teletherapy unit, that would permit continuous monitoring of the beam status is an apparent violation of 10 CFR 35.615(d)(2).

Two apparent violations of NRC requirements were identified.

7. Exit Meeting

At the conclusion of the inspection on December 15, 1992, the inspector met with those individuals identified in Section 1 of this report. The inspector summarized the scope and findings of the inspection and the likely informational content of the inspection report. The licensee did not identify any of the information covered as proprietary.

The licensee discussed its preliminary corrective action which included the establishment of a task group to review and revise the form utilized for the written directive. All Radiation Oncology personnel have been informed of the misadministration and have been instructed to carefully read written directives and thoroughly review patient chart information.

Attachments:
1. Licensee's QA Procedures
2. Licensee's 10 CFR 35.33 Report
3. Quality Management Program

QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES
FOR ADMINISTRATION OF EXTERNAL BEAM RADIATION THERAPY

. The simulator technologist shall read the physician's written description of the anatomical area to be treated (as documented on the prescription sheet) before starting to simulate the patient.

2. Each prescription entry shall be initialed and dated by the physician making the entry. If the physician is not a staff physician (e.g. a resident), a staff physician shall initial and date the entry to indicate his/her approval. For patients who start their treatment during normal working hours, this shall be done before initiation of treatment.

3. For patients who start their treatment after normal hours (i.e. on an emergent basis) and the first treatment is prescribed and initiated under the direction of a resident physician, the verbal staff physician approval for this treatment shall be documented on the prescription sheet by the resident physician. A staff physician shall approve, initial, and date the prescription before the patient receives his/her first treatment during normal working hours.

4. Prior to the initiation of treatment, a staff physician shall review and initial the treatment chart. By initialing the patient chart, the staff physician is verifying that he/she has reviewed the written prescription, the calculated dose per fraction, the anatomical area to be treated, and the treatment machine and beam energy to be utilized.

5. Dosimetric calculations and transcription information will be reviewed y a physics staff member prior to treatment initiation if possible. Otherwise, the review shall be performed before 25% of the prescribed dose is administered or before the fourth treatment, whichever is less restrictive. This review shall be performed by a physics staff member other than the one who performed the original calculations unless extenuating circumstances exist (e.g. staff shortages or emergency treatments).

6. The treatment charts of all patients under treatment will be reviewed weekly by a member of the physics staff and a staff radiation oncologist.

7. The above provisions do not apply to total body irradiations done on patients who are about to receive bone marrow transplants. The dose to each anatomical area is checked with entrance and exit dose measurements made with a diode during the course of treatment.

8. All other treatment machine checks and radiation safety practices shall be carried out as specified in the current teletherapy license application, relevant regulations of 10 CFR 35, and specific license conditions.

Revised August, 1990

Attachment No. 1

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 159
541 Clinical Drive
Indianapolis, IN 46202-5111
(317) 274-4797

December 17, 1992

U.S. Nuclear Regulatory Commission
Region III Office
799 Roosevelt Road
Glen Ellyn, IL 60137

Gentlemen:

Attached please find a written report of a therapeutic misadministration which was reported to the NRC Operations Center via telephone on December 3, 1992. The telephone report and this written report are submitted as required in 10 CFR 35.33. A copy of the report has also been provided to the affected patient's guardian. Ms. Toye Simmons of the Region III Office performed an investigation of this misadministration on December 14 and 15, 1992.

Should you have any questions regarding this matter or the attached report, please do not hesitate to contact me. Thank you for your assistance in this matter.

Sincerely,

Mack L. Richard

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

Attachments: 1

cc: W. Daly, M.D.
B. Batteiger, M.D.
N. Hornback, M.D.

ATTACHMENT No. 2

DEC 1 [illegible]

TELETHERAPY MISADMINISTRATION REPORT

1. Indiana University School of Medicine - NRC license No. 13-02752-08

2. Prescribing Physician - Joseph Montebello, M.D.

3. Description of Event - On November 13, 1992 in the late afternoon, a 31 month old patient was referred to the Department of Radiation Oncology for treatment of a stage IV neuroblastoma (brain tumor). A Radiation Oncology resident wrote a prescription for a total dose of 300 centigray (rads) to be delivered in two fractions of 150 cGy each on the Thomson CGR ^{60}Co teletherapy unit. The first treatment was to begin on the same day (November 13, 1992) and the second treatment delivered the following day (November 14, 1992). Due to the pressure being exerted on the patient's left eye by the brain tumor, this was considered an emergency treatment. A Radiation Oncology staff physician (the prescribing physician listed above) checked and signed the prescription which had been written by the resident physician.

The prescription was forwarded to a dosimetrist for appropriate calculation of treatment time. The dosimetrist misinterpreted the written prescription and performed calculations which indicated that the patient should receive 300 cGy per fraction for a total dose of 600 cGy. This information was recorded on the treatment record and forwarded to the prescribing physician for approval. The prescribing physician reviewed the provided information; however, he did not notice the dosimetrist's misinterpretation. The prescribing physician initialed the treatment record indicating his approval for the treatment to commence. The treatment record was forwarded to the radiation therapist for review and initiation of treatment. At that point two radiation therapists reviewed the treatment record and the initial prescription; however, they did not notice the discrepancy between the prescription and the information recorded on the treatment record. A total of 300 cGy was delivered to the patient on November 13, 1992 and another 300 cGy was delivered on November 14, 1992. All information regarding each treatment was documented on the treatment record.

After the final treatment was delivered, a staff medical physicist reviewed the initial prescription, the calculations, and the treatment delivered; however, the discrepancy was again overlooked. On December 2, 1992, a student radiation therapist was performing a routine chart summary and noticed the discrepancy.

4. Effect on the Patient - Aside from the desired effect of reducing the pressure on the left eye caused by the tumor, no other effect was noted.

5. Cause of the Event - The most likely cause of this event is related to the fact that delivery of 300 cGy per fraction is relatively common for brain tumors. This mindset evidently caused the dosimetrist and others who checked the information provided them to overlook the deviation from what they considered the normal treatment parameters.

6. Improvements and Actions Taken to Prevent Recurrence - This incident has received considerable attention by all Radiation Oncology personnel. All involved have been reminded of the necessity to read prescriptions carefully and assure that all checks are made consistently and thoroughly. Members of the Radiation Oncology staff (physicians, physics staff, and radiation therapists) are reviewing the forms utilized for writing pre-

scriptions to determine if specific improvements in those forms may help to alleviate any confusion regarding the information provided in the initial prescription.

- Appropriate Notifications - The Radiation Safety Officer (RSO) notified the NRC Operations Center via telephone at approximately 8:58 a.m. on December 3, 1992. A Radiation Oncology staff physician notified the patient's guardians and the referring physician via telephone at approximately 5:00 p.m. on December 2, 1992. Both were informed that the radiation dose delivered to the patient was 100% higher than originally intended. The effect on the patient from the error was also discussed with both parties.

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 159
541 Clinical Drive
Indianapolis, IN 46202-5111
(317) 274-4797

January 16, 1992

U.S. Nuclear Regulatory Commission
Region III Office
799 Roosevelt Road
Glen Ellyn, IL 60137

Gentlemen:

The letter serves as written certification that the attached quality management program entitled "QUALITY MANAGEMENT PROGRAM - TELETHERAPY has been implemented under NRC license number 13-02752-08. It is our understanding that this quality management program supercedes the previous program entitled "QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES FOR ADMININSTRATION OF EXTERNAL BEAM RADIATION THERAPY" which was submitted as a license amendment dated August 27, 1990 and approved by the NRC via license amendment No. 15 on November 8, 1990. Should you have any questions regarding this program, please do not hesitate to contact this office.

Sincerely,

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

Attachments: 1

Attachment No. 3

I. Patient Simulation - The simulator technologist shall read the physician's written description of the anatomical area to be treated (as documented on the prescription sheet) before starting the simulation process.

II. Prescription/Written Directive

A. Before the first teletherapy treatment is delivered, the patients shall have a written prescription entered in the radiation therapy treatment chart by a physician. The prescription shall be initialed and dated. If the physician is not an authorized user, an authorized user shall initial and date the entry to indicate his/her approval. This shall apply to all patients who receive their first treatment during normal working hours.

B. Patients who start their treatment after normal hours (i.e. on an emergent basis) may have the first treatment prescribed and initialed solely by a physician working under the direction of an authorized user. The verbal approval by the authorized user for this treatment shall be documented on the prescription sheet by the physician. An authorized user shall approve, initial, and date the prescription before the patient receives his/her first treatment during normal working hours.

III. Patient Treatment Planning

A. If possible, prior to the initiation of treatment, each treatment record shall be reviewed by a physics staff member. The review shall include the adherence of the calculated treatment fields to the treatment plan delineated by the physician in the prescription, the accuracy of all dosimetric calculations, and the accuracy of all information transcribed to the daily treatment record. In all cases, the above review shall be performed before 25% of the dose is administered or before the fourth treatment is delivered, whichever is less restrictive. This review shall be performed by a physics staff member other than the one who performed the original calculation unless extenuating circumstances exist (e.g. staff shortages or emergency treatments).

B. (Prior to the initiation of treatment, an authorized user shall review and initial the treatment chart.) By initialing the patient chart, the authorized user is verifying that he/she has reviewed the written prescription, the calculated dose per fraction, the anatomical area to be treated, and the treatment machine and beam energy to be utilized. This shall be done for all patients who start treatments during normal working hours. For patients who emergently start their treatment after normal working hours, this shall be done before the first treatment is delivered during normal working hours.

IV. Patient Treatment

A. Prior to the treatment of each patient, the therapist administering the treatment shall verify the patient's identity by two methods and confirm that the patient is the individual designated in the

treatment chart (i.e. asking the patient his/her name, comparison of patient to face photo in chart, comparison of name in chart to hospital i.d. wristband, or any other appropriate method).

B. Prior to delivery of each treatment, the therapist delivering the treatment shall confirm that the radiation fields to be treated are in accordance with the written prescription in the patient's therapy chart.

C. Each patient treatment shall be entered in the daily treatment record by the therapist who delivered the treatment. Therapists involved in the delivery of the treatment shall initial the treatment record to indicate that the treatment was delivered as recorded in the treatment record.

V. Treatment Reviews

A. Unless extenuating circumstances exist, the treatment charts of all patients under treatment will be reviewed weekly by a member of the physics staff and a staff radiation oncologist.

B. The above provisions of the weekly chart check and independent physics review of all calculation information do not apply to patients who receive total body irradiation for bone marrow transplant. In those cases, the dose to each anatomical area is checked with entrance and exit dose measurements made with a diode during the course of treatment.

C. All other treatment machine checks and radiation safety practices shall be carried out as specified in the current teletherapy license application, license conditions, and relevant regulations of 10 CFR 35.

VI. Clarification of Prescriptions/Written Directives - Any therapist who does not understand how to carry out a written directive shall seek clarification from a radiation oncology physician, physicist or the chief therapist.

VII. Annual Audit of Quality Management Program - A member of the Radiation Safety Office shall perform an annual audit of this quality management program. Results of this audit will be reviewed by the Radionuclide Radiation Safety Committee (RRSC) and documented in the RRSC meeting minutes.