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

OFFICE OF THE
SECRETARY

March 3, 1994

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OFFICE OF SECRETARY
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BRANCH

MEMORANDUM FOR: B. Paul Cotter, Jr.
Chief Administrative Judge
Atomic Safety and Licensing Board Panel

FROM: John C. Hoyle, Assistant Secretary

SUBJECT: REQUEST FOR HEARING SUBMITTED BY
INDIANA UNIVERSITY SCHOOL OF MEDICINE

Attached is a request for a hearing dated February 15, 1994 and submitted by the Indiana University School of Medicine (Docket No. 30-9792) in response to an "Order Imposing Civil Monetary Penalty" issued by the NRC Staff on January 18, 1994. The Order was published in the Federal Register at 59 Fed. Reg. 4123 (January 28, 1994). (Copy Attached)

The request for hearing is being referred to you for appropriate action in accordance with 10 C.F.R. Sec. 2.772(j).

Attachments: as stated

cc: Commission Legal Assistants
OGC
CAA
EDO
NMSS
OE
Chancellor Gerald L. Bepko

DS02

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

February 15, 1994

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

'94 MAR -3 [illegible]

Subject: Request for an Enforcement Hearing

Gentlemen:

CHANCELLOR

IUPUI

Upon review of your ORDER IMPOSING CIVIL MONETARY PENALTY (Docket No. 030-09792, License No. 13-02752-08), it is the opinion of a number of individuals within the Indiana University School of Medicine that a hearing should be held to resolve a number of issues related to this matter, including, among others, independent checks for emergency treatments. I am guided by these opinions. Based upon a discussion between our Radiation Safety Officer, Mr. Mack Richard, and the Director of Enforcement of the Region III NRC Office, Mr. Robert DeFayette, it is our understanding that the hearing may be held on or near the IUPUI campus.

Inasmuch as we have a number of conference rooms which can accommodate a fairly large number of people, we would be happy to provide the necessary facilities for this hearing. Furthermore, several of university personnel may be involved in providing testimony, and it would be difficult for them to travel a great distance to participate in the hearing.

Some key university personnel will not be available February 28 through March 4, 1994, and March 25 through April 1, 1994; therefore, we respectfully request that the hearing not be scheduled during those time periods. If our proposal to hold the hearing on the IUPUI campus is acceptable, please contact our Radiation Safety Officer, Mr. Mack Richard, who will make the proper arrangements. In addition, please let Mr. Richard know of any special equipment (e.g tape recorders, overhead projectors, etc.) which will be needed.

Should you have any questions, please contact either myself or Mr. Richard. We look forward to hearing from you and hope that such a hearing will give us an opportunity to show that the proposed civil penalty is not appropriate.

Sincerely,

Gerald L. Bepko
Chancellor

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cc: Assistant General Counsel
for Hearings and Enforcement

Regional Administrator,
NRC Region III

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a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Theodore R. Quay, Director, Project Directorate V: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Christopher J. Warner, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 10, 1994, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407.

Dated at Rockville, Maryland, this 25th day of January 1994.

For the Nuclear Regulatory Commission.

Sheri E. Peterson,

Project Manager, Project Directorate V, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 94-1954 Filed 1-27-94; 8:45 am]

BILLING CODE 7590-01-M

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

Indiana University School of Medicine; Indianapolis, IN; Order Imposing Civil Monetary Penalty

I

Indiana University School of Medicine (licensee) is the holder of Byproduct Material License No. 13-02752-08 issued by the Nuclear Regulatory Commission (NRC or Commission) on September 26, 1973. The license was amended in its entirety on October 6, 1989, and is due to expire on November 30, 1994. The license was most recently amended on April 9, 1992. The license authorizes the licensee to possess Cobalt-60 sealed teletherapy sources for medical use described in 10 CFR 35.600 and for irradiation of blood and blood products in accordance with the conditions specified therein.

II

An inspection of the licensee's activities was conducted on December 14, 1992, through January 13, 1993. The results of this inspection indicated that the licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the licensee by letter dated October 7, 1993. The Notice states the nature of the violation, the provisions of the NRC's requirements that the licensee had violated, and the amount of the civil penalty proposed for the violation. The licensee responded to the Notice by a letter dated October 29, 1993. In its response, the licensee disputes the validity of the cited violation. Further, the licensee takes exception to the NRC Staff's application of the civil penalty adjustment factors in the areas of identification and licensee performance.

III

After consideration of the licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *It is hereby ordered that:*

The licensee pay a civil penalty in the amount of $5,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of the Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and

(b) Whether, on the basis of such violation, this order should be sustained.

Dated at Rockville, Maryland this 18th day of January 1994.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

Appendix

Evaluation and Conclusion

On October 7, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection on December 14, 1992, through January 13, 1993. Indiana University School of Medicine responded to the Notice in a letter dated October 29, 1993. In its response, the licensee disputes the validity of the cited violation. Further, the licensee takes exception to the NRC Staff's application of identification and licensee performance civil penalty adjustment factors. The NRC's evaluation and conclusions regarding the licensee's requests are as follows:

Restatement of Violation

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 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 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 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 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.

Summary of Licensee's Response to the Violation

The licensee disputes the validity of the cited violation, the assigned Severity Level, and the NRC root cause analysis, as follows:

1. The licensee asserts that the proposed violation did not cause the misadministration even though the written directive did include the overall treatment period. In the written directive for the patient treated November 13, 1992, the number of fractions is written as "2 fx" which means the treatment period is to include two fractions or treatments. This is the licensee's interpretation of the overall treatment period. The licensee asserts that the term "overall treatment period" is not defined in the regulations or in Regulatory Guide 8.33. According to the licensee, 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. The licensee notes that the treatment was performed on an emergency basis and that this fact causes the standard verification procedure to change depending upon the availability of staff. According to the licensee, while 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, no change in the subsequent chart checking procedures would have resulted because the treatment in question as an emergency.

The licensee also asserts that it verified the dose calculations in that the prescribing physician/authorized user and two radiation therapists attempted to verify that the treatment to be delivered was in accordance with the written directive. According to the licensee, while some of these individuals identified the calculational error made by the dosimetrist, their failure to identify the error was related to the wording of the written directive rather than the failure to follow proper procedure.

3. The licensee challenges the categorization of the proposed violation as a Severity Level III violation. The licensee asserts that the misadministration occurred due to inconsistencies in the format of the written directive, and that the QMP was followed and the appropriate checks were made. According to the licensee, the violation would be more appropriately categorized at Severity Level IV since it does not represent a programmatic weakness in the implementation of the QMP, the failure was isolated to the single event, and the consequences were limited and did not adversely affect the patient.

4. The licensee disagrees with the NRC's statement that, "The violation contributed to the occurrence of a misadministration on November 13, 1992."

NRC Evaluation of Licensee's Response to the Violation

This enforcement action focuses on the licensee's failure to develop and implement an adequate QMP. As a result of the misadministration, the NRC performed a detailed review of the licensee's QMP during the followup inspection and enforcement deliberations. The result of this detailed review was that the NRC identified substantial deficiencies. The inspection determined that the licensee's written QMP did not have procedures for: (1) Ensuring that 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. The licensee has not provided any information to demonstrate that its written QMP addressed these procedures. These deficiencies represent a programmatic (as opposed to isolated) failure in the implementation of the QMP; therefore, the violation was categorized at Severity Level III in accordance with the NRC Enforcement Policy, Supplement VI.C.8 (57 FR 5792).

NRC has defined the term "overall treatment period" in the Statement of Considerations for the QMP rule (56 FR 34104). According to the Statement of Considerations, "the phrase 'overall treatment period' was added to emphasize that the treatments will end after the specified number of weeks, unless the treatment period is revised by the authorized user prior to continuing." Therefore, the treatment period is a unit of time and not the number of fractions as used in the licensee's definition.

The licensee argues that three different individuals (the authorized user and two radiation therapists) attempted to verify that the treatment to be delivered was in accordance with the written directive, and that the failure to identify the error was related to the working of the written directive rather than a failure to follow proper procedure. However, the same authorized user had created the written directive that same afternoon. Therefore, it is extremely unlikely that his failure to identify the error was related to the wording of his own written directive. The licensee's QMP procedure required that the authorized user review and initial the treatment chart to verify that he had reviewed the written prescription and the calculated dose per fraction. As noted in the inspection report, the information written on the patient chart clearly indicated that the dose per fraction was incorrect. It appears that the authorized user initialed the chart and that his review was cursory or inadequate.

Moreover, the violation focuses on the fact that, while the licensee's QMP requires that a physics staff member review the accuracy of all dosimetric calculations for treatments that are delivered in four or more fractions, it has no equivalent provision for treatments that are delivered in less than four fractions. Had such an independent review been required by the Licensee's QMP and performed in this case, the error could have been avoided.

The licensee's QMP waived review of dose calculations by the physics staff member for extenuating circumstances such as staff shortages and emergency treatments. Neither

the QMP regulations nor the accompanying regulatory guide suggest that this independent review may be waived for staff shortages or emergent treatments, such as those that must be performed after working hours. A footnote to 10 CFR 35.32(a)(1) states, "if, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive." Neither 10 CFR 35.32(a) nor the footnote permit the waiving of the independent review of the dosimetric calculations due to the emergent nature of a treatment. The independent verification is especially important during times when the licensee is more subject to error such as with staff shortages and emergent treatments.

Based on the above, the NRC concludes that the violation did occur as stated, and that there was not an adequate basis for a reduction of the severity level.

Summary of Licensee's Request for Mitigation

1. Identification

The licensee asserts that the NRC improperly takes credit for identifying the proposed violation of the QMP because the QMP was submitted to the NRC approximately 1.5 years ago in accordance with 10 CFR 35.32(f)(2); and, since that submission, the licensee has received no indication that the QMP was deficient. According to the licensee, the "less than four treatment" deficiency was detected concurrently by the NRC and the licensee as a result of this misadministration; and therefore, escalation of enforcement based on the NRC's claim of identifying the deficiency is inappropriate.

2. Licensee Performance

The licensee asserts that the NRC improperly escalated the base civil penalty by 100 percent for "poor past performance" and notes that this was apparently due to a misadministration which occurred in May of 1990, some 2.5 years before the most recent one. According to the licensee, while the NRC claims that these two misadministrations were "similar", the only similarities were that they were both brain treatments and the dose per fraction was doubled. The licensee notes that 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. According to the licensee, there appears to be no relationship between the causes of the two misadministrations. The licensee indicates that this escalation implies 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. The licensee points out that the May 1990 misadministration was discovered through its QA/QCP and, until January of 1992, most licensees were not required to have any type of QMP; therefore, comparing the licensee's performance to that of other licensees is not appropriate (i.e., other licensees may have had misadministrations which went undetected due to the fact that they had no QMP).

The licensee asserts that 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 the licensee's particular instance, its 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. Five hundred and eighteen (518) of these patients (approximately 15,000 separate treatments) were specifically treated with cobalt-60 teletherapy. According to the licensee, 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."

NRC Evaluation of Licensee's Request for Mitigation

1. Identification

Licensees may not expect, or rely on, NRC to identify safety problems or violations for them. The Enforcement Policy provides that the purpose of the identification factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance. By the licensee's own admission, it did not detect the problems noted in the violation during the 1.5 years that its QMP has been in existence, nor is there any evidence that the licensee identified the specific problems noted in the violation before NRC did. For example, these problems are not noted in the licensee's December 17, 1992 misadministration report, which includes a section entitled, "Improvements and Actions Taken to Prevent Recurrence."

Based on the above, the NRC concludes that 50 percent escalation of the base civil penalty is warranted for NRC identification.

2. Licensee Performance

The NRC Enforcement Policy states that prior performance refers to the licensee's performance normally (1) within the last two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer. On this case the period covered by the last two inspections is applicable, i.e., two inspections prior to the inspection at issue. The two previous inspections to be considered are the inspection conducted on September 11, 1991, and the inspection conducted on May 21–23, 1990.

The NRC did not compare the licensee's performance with other licensees. The Enforcement Policy provides that the effectiveness of previous corrective action for similar problems is a consideration in assessing the licensee performance factor. The May 1990 inspection was conducted to review the circumstances surrounding a teletherapy misadministration. The physicist performing the treatment dose calculation misinterpreted the physician's written prescription. The error continued undetected despite at least four separate opportunities for the dosimetry and physician staffs and several opportunities for the technologists to identify the problem. In its misadministration report of May 24, 1990, the licensee noted that loss of objectivity was a causative factor in that the various QA checks had not been performed as an independent review. The licensee's corrective action was to turn an existing requirement that the authorized user initial the chart before the treatment begins into a full QA check involving a review by the physician of, among other things, the calculated dose per fraction. A memorandum entitled "Chart checking of treatment doses and calculations" was circulated to emphasize to physicians and other key personnel the importance of vigilant and critically minded checking of doses and dose calculations. Thus, the NRC concludes that the root causes of the misadministrations are sufficiently similar to warrant escalation for past performance.

The licensee also argues good past performance in that a very small percentage of its treatments were misadministrations. On the contrary, the NRC is concerned that the licensee was performing a high volume of treatments with a deficient QMP.

Based on the above, 100 percent escalation of the base civil penalty is warranted for poor licensee performance.

NRC Conclusion

Based on its evaluation of the licensee's response, the NRC staff concludes that the violation did occur as stated, and that neither an adequate basis for a reduction of the severity level nor for mitigation of the civil penalty has been provided by the licensee. Accordingly, NRC concludes that a civil monetary penalty of $5,000 should be imposed by order.

[FR Doc. 94-1870 Filed 1-27-94; 8:45 am]
BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee Open Committee Meeting

According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that meetings of the Federal Prevailing Rate Advisory Committee will be held on—

Thursday, Feb. 17, 1994
Thursday, Feb. 24, 1994
Thursday, Mar. 10, 1994
Thursday, Mar. 24, 1994

The meetings will start at 10:45 a.m. and will be held in Room 5A06A, Office of Personnel Management Building, 1900 E Street, NW., Washington, DC.

The Federal Prevailing Rate Advisory Committee is composed of a Chairman,