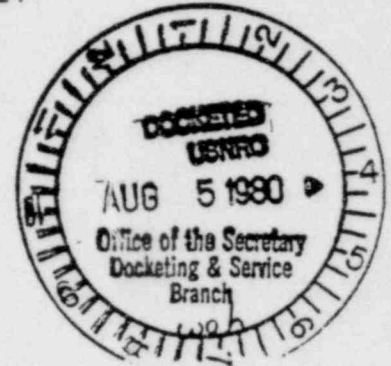


UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of )  
Providence Hospital )  
3200 Providence Drive )  
Anchorage, Alaska 99504 )

Byproduct Material  
License Nos. 50-17838-01  
EA-80-24

ORDER IMPOSING CIVIL MONETARY PENALTIES



I

Providence Hospital, 3200 Providence Drive, Anchorage, Alaska, (the "licensee"), is the holder of Byproduct Material License No. 50-17838-01 (the "license") issued by the Nuclear Regulatory Commission (the "Commission"). License No. 50-17838-01 authorizes the licensee to receive, acquire, possess, and transfer radioactive materials in accordance with the conditions specified therein, and is due to expire on March 31, 1983.

II

A special inspection of the licensee's activities under the license was conducted on January 28 and 29, 1980, at the licensee's facility in Anchorage, Alaska. As a result of this inspection, it appears that the licensee has not conducted its activities in full compliance with the conditions of its license and with the requirements of the Nuclear Regulatory Commission's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations. A written Notice of Violation was served upon the licensee by letter dated May 7, 1980, specifying the items of noncompliance in accordance with 10 CFR

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2.201. A Notice of Proposed Imposition of Civil Penalties dated May 7, 1980, was served concurrently upon the licensee in accordance with Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282) and 10 CFR 2.205, incorporating by reference the Notice of Violation, which stated the nature of the items of noncompliance and the provisions of Nuclear Regulatory Commission regulations and license conditions.

An answer dated May 31, 1980, to the Notice of Violation and the Notice of Proposed Imposition of Civil Penalties was received from the licensee.

### III

Upon consideration of the answers received and the statements of fact, explanation, and argument in denial of the allegations of noncompliance and in protest of the imposition of penalties contained therein, as set forth in Appendix A to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the items of noncompliance designated in the Notice of Violation should be imposed, except for Item 3, which is remitted.

### IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282) and 10 CFR 2.205, IT IS HEREBY ORDERED THAT: The licensee pay civil penalties in the total amount of One Thousand

Five Hundred Dollars within twenty-five days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States, and mailed to the Director of the Office of Inspection and Enforcement.

V

The licensee may, within twenty-five days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Secretary to the Commission, U.S.N.R.C., Washington, D.C. 20555. A copy of the hearing request shall also be sent to the Executive Legal Director, U.S.N.R.C. Washington, D.C. 20555. If a hearing is requested, the Commission will issue an order designating the time and place of hearing. Upon failure of the licensee to request a hearing within twenty-five days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection.

VI

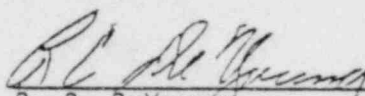
In the event the licensee requests a hearing as provided above and a hearing is held, the issues to be considered at such hearing shall be:

- (a) whether the licensee was in noncompliance with the Commission's regulations and the conditions of the license as set forth in the Notice of Violation

referenced in Section III above, with the exception of Item 3, which is remitted; and,

- (b) whether, on the basis of such items of noncompliance, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

  
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R. C. DeYoung  
Deputy Director  
Office of Inspection  
and Enforcement

Dated this 5 day of Aug, 1980  
at Bethesda, Maryland

Attachment:  
Appendix A, Evaluations  
and Conclusions



Appendix A to Order Imposing Civil Penalties  
Evaluations and Conclusions

For each item of noncompliance and associated civil penalty identified in the Notice of Violation (dated May 7, 1980), the original item of noncompliance is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's responses to each item (two responses dated May 31, 1980) is presented.

Statement of Noncompliance

1. 10 CFR 20.207(b), "Storage and control of licensed material in unrestricted areas," requires that licensed material in an unrestricted area be tended under constant surveillance and under the immediate control of the licensee. 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas," limits the radiation level in an unrestricted area from a radioactive source such that an individual could not receive a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above requirements, after removing ten iridium-192 seeds from a patient on December 29, 1979, a licensee physician placed the seeds in an unlocked lead container and moved them to an adjacent anteroom where several relatives were waiting to see the patient. The physician then returned to the patient's room for approximately 30 minutes to perform necessary post removal tasks, leaving the iridium seeds unattended.

Subsequently, the ten iridium-192 seeds totaling approximately 3.0 mCi were determined to be lost. On January 29, 1980, an NRC inspector found 9 of the seeds under the access stairway to the hospital truck pier adjacent to the dumpster. He also found one seed in a vacuum cleaner. Hospital personnel had access to the areas where the seeds were found. The dose rate from the seeds exceeded two millirems per hour at one foot.

This violation constituted an occurrence related to health and safety.

(Civil Penalty - \$1,000)

Evaluation of Licensee Response

This item of noncompliance contains two parts involving the separate requirements of 10 CFR 20.207(b) and 20.105(b). The licensee denies the part of the citation pertaining to 10 CFR 20.207(b), "Storage and Control of licensed material in unrestricted areas." Essential elements of this citation are: (a) Was NRC licensed radioactive material involved? (b) Was the material unattended? and (c) Was the area an unrestricted area?

The answers to (a) and (b) are yes, but the licensee maintains that the anteroom in question was actually a restricted area, with access controlled by the hospital staff. This position is further strengthened by photographs of signs posted in the area declaring the area a restricted area and announcing the presence of radioactive material. It thus appears that the anteroom in question was likely a restricted area.

However, the licensee did lose ten iridium seeds which were eventually found in an unrestricted area. Nine iridium-192 seeds remained for a period of time, possibly as long as 31 days, in the unrestricted area under the steps adjacent to the truck pier outside the hospital. This area is an unrestricted area as defined in 10 CFR Part 20, and the material there was not "tended under constant surveillance and under the immediate control of the licensee." Also, a single seed was found in a vacuum cleaner located in another unrestricted area, and had likely been there for a considerable time.

There also was a period of time when all 10 iridium-192 seeds were in the hospital, in all probability on the floor and in vacuum cleaners. During this period, the seeds again were likely neither in a restricted area nor were they under the control of any individual who is authorized by the NRC license to use these radioactive materials.

The licensee also denies the second part of the citation pertaining to 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas." Essential elements of this citation are: (a) Was NRC licensed radioactive material involved? (b) Did radiation levels exist which if an individual were continuously present in the area could result in his receiving a dose in excess of two millirems in any one hour or in excess of 100 millirems in any seven consecutive days? and (c) Was the area involved an unrestricted area?

This item of noncompliance relates to the ten seeds subsequent to their loss. In response to (a) above, there is no question that the one seed found in the vacuum cleaner in use in the hospital and the nine seeds found under the steel steps adjacent to the truck pier outside the hospital were NRC licensed material. They were part of a shipment of iridium-192 seeds received at Providence Hospital on December 24, 1979 from Alpha Omega Services, Paramount, California. They were used in treatments at Providence Hospital and subsequently lost.

With respect to (b), above, the nine seeds found under the stairway adjacent to the truck pier outside the hospital emitted radiation levels of 16 millirems/hr at one foot. Therefore, if an individual were continuously present, it could result in his receiving a dose of 16 millirems in one hour if he were located one foot away from the nine seeds. This is greater than 2 mrem in any one hour. In addition, if an individual were continuously present for seven consecutive days, it could result in his receiving a dose in excess of 100 millirems. In either event, the levels of 10 CFR 20.105(b) were exceeded.

Finally, with respect to (c), above, both areas where the iridium seeds were eventually found were unrestricted areas.

The licensee questions the application of 20.105(b) in the circumstances of this case. The licensee suggests that the use of the word "or" in the regulation allows the licensee to meet either requirement imposed (i.e., 2 millirems per hour or 100 millirems in any consecutive seven day period) and thus meet the regulation.

This argument is irrelevant because, at the dose rate actually measured at one foot, both the requirements of the regulations and hence the regulation itself, were violated.

The licensee further questions the application of this regulation in the circumstances of this case in that the licensee seems to imply that the application of the regulation requires an analysis of the actual exposures in each instance. This is not so. The regulation prohibits certain radiation levels. If the potential exists for individuals to be exposed to the radiation levels at or above those specified in the regulation for the time period prescribed, the regulation is violated. Whether personnel exposure in fact occurred is irrelevant. In this case, the licensee had no idea where the iridium seeds were located. The seeds could have adhered to clothing or been placed in a pocket resulting in significant exposures at contact. The Staff reported radiation levels at one foot to provide a measure of the levels involved. This instance had the clear potential to expose individuals for times and at levels in excess of the regulation and this determines the violation. The language of the Statements of Consideration issued with the regulation is clear in this regard:

These levels are believed to be sufficiently low to assure that there is no reasonable probability of individuals in unrestricted areas receiving exposures in excess of 10 percent of the permissible levels for restricted areas under any circumstances. (24 Fed. Reg. 3527, May 12, 1958, Emphasis supplied.)

The licensee further challenges the citations against 10 CFR 20.105(b) and 10 CFR 20.207(b) on the ground that the sources were lost and therefore compliance with those regulations was not required. Every licensee is responsible for meeting the requirements of Part 20 in any of the activities it conducts with materials under license. If the licensee misplaces or loses the licensed material, that loss constitutes an act of possession, use, transfer and the regulatory requirements of Part 20 apply to the lost material. Any other approach has the illogic of permitting the licensee to commit a transgression in fact, i.e., a loss, without there being any legal violation. The regulations were not promulgated with that intent. "The intention of the section [i.e., §20.207] is to assure that proper controls are maintained over licensed radioactive material at all times." (40 Fed. Reg. 26679, June 15, 1975, Emphasis supplied). And so the licensee errs when it argues that materials lost are not materials subject to regulations, i.e., materials possessed, used or transferred.

The licensee in his response also describes various parts of the NRC regulations such as the maximum annual dose permitted to an individual member of the general public, 20.105(a); permissible radiation levels permitted on packages of radioactive materials during transportation, 10 CFR Part 71; and requirements for posting and controlling high radiation areas, 10 CFR 20.203(c). None of those regulations have any bearing on citations for 20.105(b) and 20.207(b).



Conclusion

Noncompliance with 10 CFR 20.207(b) and 10 CFR 20.105(b) existed for the period of time when the seeds were lost at the hospital. The information presented by the licensee does not provide a basis for modification of this enforcement action. The item as stated in the Notice of Violation is an item of noncompliance.

Statement of Noncompliance

2. 10 CFR 20.201(b), "Surveys," requires each licensee to make such surveys as may be necessary for him to comply with the regulations in this part. As used in the regulations in this part, "Survey" means an evaluation of the radiation hazards incident to the use of radioactive materials.

Contrary to this requirement, surveys conducted during the period of January 15, 1980 to January 29, 1980, subsequent to the loss of the iridium-192 seeds, were not adequate to detect radiation levels in unrestricted areas in excess of the limits specified in 10 CFR 20.105(b).

This violation contributed to an occurrence related to health and safety.

(Civil Penalty - \$500)

Evaluation of Licensee Response

The licensee denies this item of noncompliance. Essential elements in this citation are: (a) Was NRC licensed material involved? (b) Was a survey required? (c) With what part of the regulations was the survey intended to ensure compliance? (d) Was a survey made? and (e) Was the survey adequate to ensure compliance with the regulations? With respect to (a), the radioactive material involved was the same 10 iridium-192 seeds described earlier. In response to (b) and (c), a radiation survey was required by 10 CFR 20.201(b), and the survey was intended to ensure compliance with 10 CFR 20.105(b). In response to (d), a survey was made by the licensee.

However, with respect to (e) above, the licensee argues that its surveys were adequate and no violation of 20.201(b) took place. A survey is of little value if it is not adequate to accomplish the desired end. In this case, the intent of the survey was to detect 10 iridium-192 seeds encased in a single nylon ribbon approximately six inches long, containing a total of approximately 3.0 millicuries of iridium-192. That quantity of radioactive material (10 seeds) will result in radiation dose rates of approximately 18 millirems per hour at one foot, approximately 4 millirems per hour at two feet, and approximately 1 millirem per hour at 4 feet. The survey was also to ensure compliance with the limits expressed in 20.105(b) which are 2 millirems in any one hour (2 millirems per hour in this case) and 100 millirems in any 7 consecutive days which calculates to be approximately 0.6 millirem per hour if a continuous, uniform rate of delivery is assumed. Thus the radiation levels which the survey was intended to detect are well defined.



The licensee in his response takes the position that his surveys were made with a standard portable Geiger-Mueller counter, and that his surveys did not detect the seeds. Since the NRC inspector used a more sensitive instrument and was successful in locating the sources, the licensee says, in effect, the NRC is requiring that all licensees procure these more sensitive instruments.

Conventional portable Geiger-Mueller instruments measure normal natural radiation background at less than 0.1 millirem per hour and the meter indicates full scale on the most sensitive range at 0.5 millirem per hour. Thus, the instruments available to the hospital were sufficiently sensitive to detect the radiation levels of interest in this situation. For example, one seed would indicate a dose rate of approximately 2 millirems per hour at one foot.

In any loss such as this, there is always the possibility that the radioactive material has fallen to the floor, and has been picked up or moved about during cleaning and other housekeeping activities. Thus, floors, cleaning equipment and waste receptacles are prime candidates for survey. Providence Hospital in a letter to the NRC dated January 22, 1980 described surveys of the patient's rooms, the incinerator, mops and linen, laundry and adjacent areas. That letter further mentions the possibility that the seeds may have been transferred in some way to the general hospital hallways, swept up and discarded. However, this possibility evidently was not followed up. A radiation survey with the instruments possessed by the hospital would have easily detected the seeds while they were in the vacuum cleaner bag, and a careful radiation survey of the area around the dumpster outside the hospital would have detected the seeds. A careful radiation survey with the hospital's instruments should have detected the one seed in the vacuum cleaner. One seed emits a radiation level of about 1.8 millirems per hour at one foot, which would be off-scale on the most sensitive range of the Hospital's instrument. Even assuming some shielding by the vacuum cleaner, such radiation levels should be detectable with a standard Geiger-Mueller instrument.

One of the licensee's survey instruments was actually used to finally locate the seeds under the steel stairway outside the hospital. Using that instrument a hospital employee quickly found and recovered 9 seeds in the nylon ribbon.

The licensee contends that the NRC position in this situation will require all licensees to obtain very sensitive instruments. That is not the case. The instrument used is only one aspect of a survey. The Geiger-Mueller instruments owned by the hospital were adequate for the required survey when used properly. As stated by the licensee in his response, the NRC has accepted those instruments in previous inspections. The NRC will also accept those standard Geiger-Mueller instruments as adequate in future inspections. Such instruments are standard in medical institutions across the United States. However, adequate instruments do not ensure adequate surveys unless properly used.

#### Conclusion

The licensee's existing instrumentation was adequate for the required surveys. We conclude that, if diligent radiation surveys had been conducted, the seeds

would have been found by the licensee. Thus, we conclude that the radiation surveys that were conducted by the licensee were not adequate. The item as stated in the Notice of Violation is an item of noncompliance.

#### Statement of Noncompliance

3. 10 CFR 20.402(a), "Reports of theft or loss of licensed material," requires that each licensee report by telephone to the Director of the Nuclear Regulatory Commission Inspection and Enforcement Regional Offices listed in Appendix D [of Part 20] immediately after its occurrence becomes known to the licensee, any loss or theft of licensed material in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

Contrary to the above requirement, although it was determined on January 15, 1980 that ten iridium-192 seeds were lost, the appropriate Regional NRC Office was not notified until January 17, 1980.

This is an infraction. (Civil Penalty - \$200)

#### Evaluation of Licensee Response

The licensee denies this item. The discrepancy in the seed count was noted on January 15, 1980. After some search and survey, the hospital attempted to notify the Region V office of the NRC in Walnut Creek, California of the loss by telephone, within 24 hours, on January 16, 1980. The hospital was not successful in reaching the Region V office. The call placed by the hospital went to a Federal Government Switchboard which is not manned except during normal daytime working hours. The hospital was unaware of the correct 24 hour number currently in use by the Region V office for such notifications. This was so even though the correct number had been published in the Federal Register on November 5, 1979. See 44 FED. Reg. 63515. Therefore, the actual notification was not received by the NRC until January 17, 1980.

The licensee states that there is no definition of "immediate" in the NRC Regulations. That "immediate" notification should be prompt and in no event later than 24 hours is supported by Section 20.403 where immediate notification is required in some cases, and 24 hour notification is required for less significant matters. A reading of that Section leads to the conclusion that "immediate" notification should be made in less than 24 hours. The licensee, in fact, attempted its first notification within 24 hours but was unsuccessful due to the circumstances discussed above.

The licensee argues incorrectly that no substantial hazard could result to persons in the unrestricted area from the loss of 3 millicuries of iridium-192. While the radiation dose rates at some distance are not excessive, the possibility exists of the seeds adhering to clothing, being placed in a pocket, or otherwise ending up on or near the surface of a body. Such a situation could result in injury to that person. Loss of the iridium seeds was a situation which could result in substantial hazard and therefore required immediate notification of the NRC under 10 CFR 20.402(a).

Finally, the licensee appears to ascribe some significance to the arrival of the NRC inspector at the licensee's facility, twelve days after notification. The purpose of notification is not necessarily to permit the immediate dispatch of an NRC inspector. Its purpose is in fact, to permit an assessment of the incident to be made and to insure that the licensee is responding properly. A proper response by the licensee in this instance would have included surveys adequate to find the lost seeds. When the licensee's response on this area proved inadequate, an inspector was sent to the facility to review the situation.

#### Conclusion

Although the violation occurred, Providence Hospital did make an effort to make the required notification and did actually notify the NRC within 48 hours. On this basis, the \$200 civil penalty is remitted.