cc. (w/c attachment.
JH
FH
KB
SP

Medical-Surgical Division/3M

3M Center
St. Paul, Minnesota 55144-1000
612/733 1110

3M

February 11, 1986

See p 4

C. J. Heltemes, Jr.
Director
Office for Analysis and Evaluation
of Operational Data (AEOD)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Preliminary Case Study Report - Rupture of an Iodine-125 Brachytherapy Source at the University of Cincinnati Medical Center

Dear Mr. Heltemes:

This letter is in response to your correspondence of December 27, 1985, which provided a copy of an AEOD preliminary case study report pertaining to the rupture of an I-125 Seed used for brachytherapy at the University of Cincinnati. Specifically, your letter requested comments on the technical accuracy of the report.

We are pleased to have this opportunity to review the preliminary report. We share the agency's concern about the safe use of all brachytherapy sources, including I-125 Seeds, as reflected in the AEOD report. However, there are technical details in the report which we feel are inaccurate and certain recommendations which are inappropriate.

Specific comments in support of our conclusions are presented below, which are a result of our section-by-section review of the case study report.

EXECUTIVE SUMMARY (Pages 1-5)

3M Comment 1. In paragraph 1 on page 1 of the AEOD report, it is stated that "the 3M Company specification sheet for the seeds indicates that the seeds can be used as removable brachytherapy implants." Indeed, I-125 Seeds as originally manufactured were intended to be reused. This is reflected in the package insert for the model 6702 seed, which specifically indicates that seeds can be used for removable implants. It is our position that reuse of these seeds is

H/6

appropriate and should be allowed to continue, as long as proper reloading techniques are instituted and medical personnel are properly trained in those techniques.

3M Comment 2. On page 4, item number 3 states that "As a result of the iodine-125 seed rupture event at the University of Cincinnati, the 3M Company now voluntarily includes a "warning notice" with the packaging of iodine-125 seeds that implies that the seeds should not be reused." This statement is incorrect, insofar as both the chronology and interpretation of the warning statement are concerned. With regard to timing, the "warning notice" was provided with each shipment of I-125 Seeds as of December 1, 1981 and therefore did not result from the University of Cincinnati incident in 1984. This is the labeling which was promised in a 3M letter of September 23, 1981 to Mr. Earl Wright of the NRC, and constituted 3M's response to an incident at the University of Connecticut involving probable in vivo leakage of ruptured I-125 Seeds model 6701, used as permanent prostate implants. A copy of this 3M letter is presented in ATTACHMENT 1 to this letter.

In 1985, Mr. D. Wiedeman of NRC Region III office contacted 3M to ascertain what the 3M response was specific to the University of Cincinnati incident, which would also prevent similar occurrences at other institutions. A letter dated August 12, 1985 from R. G. Wissink (3M) to Region III indicated that the warning notice was included with each shipment of I-125 Seeds and verified that this warning notice was intended to address any and all damage to seeds, including that resulting specifically "from reuse." A copy of the August 12, 1985 letter to NRC is provided as ATTACHMENT 2.

3M Comment 3. With regard to the first AEOD recommendation listed on page 5, we support the agency's proposal to send an Information Notice to licensees describing the University of Cincinnati event and actions taken to prevent recurrence of similar events. It is our feeling that such a notice would alert licensed institutions to the hazards associated with improper use of I-125 Seeds, and would provide guidance in the areas of proper handling techniques and personnel training. Based on our investigation of the Cincinnati incident we believe that had the seed reloading been conducted in the appropriate environment (i.e. a fume hood with proper monitoring), any contamination would have been limited to the fume hood and possibly the gloved hands of the technician, and certainly would not have involved the entire room and numerous hospital personnel.

3M Comment 4. We strongly disagree with the second AEOD recommendation (page 5), however, that we be required to amend our product labeling to prohibit the reuse of I-125 Seeds. Such action is unwarranted, based on our several years' experience with I-125 Seeds, and would compromise medical care available by significantly increasing cost without concommitant increase in user and patient protection.

During the period from September 1981 to August 1984 (the month in which the Cincinnati incident occurred), 3M delivered 1900 high-activity I-125 Seeds, model 6702, to 41 medical institutions. Although we have no precise knowledge of the reuse frequency of these seeds (i.e. how many seeds were reused and in how many clinical procedures), we do know that many were reused for brain and eye tumors and for research. For this period, no incidents involving seed damage have been reported to 3M. Similarly, our records for sales subsequent to the Cincinnati incident indicate that 1100 model 6702 seeds were sold to 38 institutions; again, we received no reports of seed damage.

The medical use of I-125 Seeds for removable implants, is increasing. The chief thrust for this is the significant decreased exposure to hospital personnel when compared to the historical use of brachytherapy sources. A recent publication by Marchese et al, entitled "Clinical, Physical and Radiobiological Aspects of Encapsulated Iodine-125 in Radiation Oncology," discusses I-125 Seeds as removable implants for brain and eye tumors, in particular. It is noted in the abstract that "encapsulated iodine-125 seeds, because of their soft X-ray emission (28 keV average), greatly simplify the problems of radiation protection and offer the advantage of a more rapid fall-off of dose outside the treatment volume compared to other isotopes in clinical use." For the same reasons I-125 Seeds are being investigated as possible substitutes for afterloaded iridium-192 now used widely in such sites as breast, head and neck, and gynecological cancers. Such use is reported in an article by Genest et al entitled "Iodine-125 as a Substitute for Iridium-192 in Temporary Interstitial Implants". Reprints of these articles are presented in ATTACHMENT 3 to this letter.

The uses of I-125 Seeds cited above most certainly require some reuse in order to make this form of therapy economically feasible with respect to Ir-192 therapy. For example, a typical Ir-192 Seed (0.5 mg Ra eq) costs $2.50. An I-125 Seed of equal therapeutic value (4 mCi) would cost more than 10 times as much, or $31.00 in quantities of 5 or more. A typical I-125 Seed implanted in brain tumors (40 mCi) costs $185 in quantities of 5 or more. We believe strongly that

single use and disposal of such seeds is not cost-effective and could result in treatment being denied to patients who might otherwise benefit from proper reuse of the sources.

In summary, we disagree with the recommendation that "This amendment should ensure that the 3M Company's recommendation that the seeds not be reused is clearly in the warning notice." Any modification to the labeling perceived to be necessary should focus on training of personnel, encourage practice with nonradioactive seeds if reuse is anticipated, dictate appropriate hooded facilities and outline health physics support required.

3.0 ANALYSIS OF THE EVENT

3M Comment 5. The first paragraph in section 3.1, Seed Rupture, (page 11 of the AEOD report) describes I-125 Seeds and refers to the University of Cincinnati's use of "... coaxial after-loading teflon catheters." In fact, these catheters are made of a silicone elastomer, not teflon, and the statement should be revised accordingly.

4.0 LICENSEE AND SOURCE MANUFACTURER ACTIONS

3M Comment 6. The excerpt from the University of Cincinnati response, quoted on page 17, reports that 3M "...has agreed that it would be unwise for any of the high activity iodine-125 (40 mCi) seeds to be reutilized within a hospital since this problem could occur again anywhere." In reviewing the 3M interaction with Cincinnati personnel subsequent to this incident, none of the 3M people involved remembers advising that high activity seeds should NOT be reused. In fact, we were aware that I-125 Seeds were being reused, without incident, at many institutions prior to the Cincinnati incident, as described in 3M Comment 4 above. Our records indicate that personnel at Cincinnati were advised that seeds should not be reused at any institution that doesn't have adequate facilities or health physics support for handling, that removable seeds should not be used at Cincinnati because of their lack of such facilities, and that perhaps seeds should be rented instead of reused.

3M Comment 7. Several errors are present in the scenario described on pages 18 and 19 of the AEOD report pertaining to 3M's use of a warning notice; corrections have been discussed in detail in 3M Comment 2 above.

Subsequent to the Cincinnati incident, 3M upgraded its internal procedures aimed at providing additional control for institutions/uses involving high activity seeds. These activities are described as follows.

1. 3M Customer Service directs all phone inquiries about the use of I-125 Seeds Model 6702 for brain implants to someone in Technical Service.

2. This Technical Service person summarizes 3M's REQUIREMENTS of an institution prior to selling the seeds for such use, which include submission to 3M of 1) a Brain Implant Protocol, 2) an Institutional Review Board (or equivalent) approval of that protocol, and 3) a copy of the Patient Informed Consent form. In the same phone conversation, risks and hazards associated with the handling of the 30-40 mCi seeds are summarized to include the consequences of cutting a seed while removing it from the afterloading catheters (the Cincinnati incident is alluded to but the hospital is not identified).

3. A follow-up Brain Implant Protocol letter is mailed to the customer.

Prior to the Cincinnati incident, a phone call was not always followed with a letter since it was believed that adequate verbal instructions were given to a knowledgeable customer. An example of this pre-Cincinnati letter is presented in ATTACHMENT 4 to this letter. Following the Cincinnati incident, a follow-up letter was always sent. Two examples of such letters are presented in ATTACHMENT 5 indicate how the 3M instruction has evolved. We believe that requiring a radiation safety section in the implant protocol provided adequate assurance that the seeds would not be mishandled if reused. The letters also directed the customer to knowledgeable people who could advise about the proper handling of seeds during reuse.

5.0 FINDINGS

3M Comment 8. We do not disagree with the risks of I-125 Seed rupture, as listed on page 19 of the AEOD report, and believe that these risks are manageable, as discussed on page 19 of the AEOD report ("...could have been mitigated by adequate radiation surveys...") and in 3M Comments 3 and 4 above.

3M Comment 9. We disagree with finding 3 regarding amendment of 3M license to require specific warning notice verbiage, (AEOD report page 20), for reasons noted in 3M Comment 4.

3M Comment 10. We strongly agree with the NRC statement on page 21 that "...it appears that licensee personnel failed to appreciate or understand the potential for a seed to be ruptured by the seed removal operation or the consequence of such a rupture, in that the protocol describing procedures to be followed for temporary implants..." This is based on our (3M) investigation of the Cincinnati event.

6.0 CONCLUSIONS AND RECOMMENDATIONS

3M Comment 11. We support the NRC's recommendation to send an Information Notice to affected licensees, advising them of the hazards of high activity I-125 Seeds and appropriate precautions to preclude a recurrence of the Cincinnati experience.

3M Comment 12. For reasons previously stated (3M Comment 4), we disagree with the agency's recommendations as stated on page 22.

We appreciate the opportunity to review this document. If you have any questions about these comments or require additional information pertaining to I-125 Seeds, please feel free to contact me (at 612/733-6421) or Mr. D. O. Kubiatowicz in our laboratory (612/733-9127).

Sincerely yours,

Jacquelyn D. Bush

Jacquelyn D. Bush
Manager, Regulatory Affairs
Medical-Surgical Division/3M
3M Center, 270-4A-05
St. Paul, Minnesota 55144

JDB:fw

c: R. G. Wissink

Precautions Observed in the Case of Jennifer Heeg
Observations on Precautions Appropriate in Hospital Areas

On 8/27/84 the hospital room of patient J. Heeg was surveyed by Radiation Safety with the following results:

1) The patient was fitted by Radiation Oncology with a lead hat from which no radiation in excess of background levels could be detected from any location using an ion-chamber.

2. Measurements taken with the lead hat removed showed levels of radiation to be below 2 mR/hr. at distances exceeding 18 inches. Similar measurements were made in adjoining areas with no radiation detected.

3) The head nurse and attending nurses were told that no precautions were in order provided that the patient wore her hat at all times when people were present.

4. No sign was posted and no badges were issued.

5 At the conclusion of the implantation period, (10/6/84) monitoring again showed no radiation above 2 mR/hr. despite significant accumulation of radioiodine in the patient. Wipe testing of the patient's hospital room revealed no contamination.

Current Policy Regarding Interstitial Iodine Implantation

The present practice of the Radiation Safety Office is to monitor operating rooms and the equipment used in these procedures: and to survey urine in the case of prostate implants (with a view towards recovering stray seeds). The Radiation Safety Office has been in consultation with involved physicians regarding the necessity of publishing guidelines for use in these situations.

Suggestions for Future Implantation of Iodine Seeds

The following suggestions are offered for future interstitial implantations of radioiodine:

(1) Patients should be administered blocking doses of iodine salts to prevent thyroid uptake in the event that a seed should be compromised while in the body.

(2) Routine, daily urinalysis for radioiodine should be carried out as the most sensitive means of detection of *in vivo* leakage. It is recommended that well-counting be the technique of choice for this assay due to its high sensitivity.

(3) We do not suggest the practice of issuing film badges to nurses under these circumstances since the efficiency of these dosimeters for detecting Iodine-125 is negligible.

Suggestions for Future Implantation of Iodine Seeds

The following suggestions are offered for future interstitial implantations of radioiodine:

HOSPITAL PRECAUTIONS

(1) Patients should be administered blocking doses of iodine salts (SSKI) to prevent thyroid uptake in the event that a seed should leak while in the body, unless such treatment is medically contraindicated.

(2) Routine, daily urinalysis for radioiodine should be carried out as the most sensitive means of detection of *in vivo* leakage. It is recommended that well-counting be the technique of choice for this assay due to its high sensitivity. This function could be carried out by Radiation Safety or Radiobiology.

(3) Urine precautions should be instituted in the case of prostate implants. These precautions should include storage and daily monitoring of urine as well as attendance by radiation safety at the time of catheter removal. Written precautions should be posted in the chart.

4) If *in vivo* leakage is detected, insitute urine handling ecautions (radioiodine cleaning solution, gloves, wipe- esting), air sampling, and thyroid counting for personnel at risk, including the patient.

PRECAUTIONS FOR HANDLING SEEDS

(1) All storage, handling and manipulation of seeds should occur in a fume hood, using dedicated tools. This hood should be fitted with a radioiodine (charcoal) filter, which should be periodically replaced.

(2) Wipe-testing should be the method of choice for monitoring of tools and hood at the conclusion of handling.

(3) Routine thyroid counting should be scheduled for physicians and technicians who handle sources.

(4) Seeds should not be reused.

Release

#13

Wipe tests on 10 ^{125}I seeds upon arrival at Rad. Safety.

Wipe test of patients' bandage and skull cap after implementation.

Wipe test of applicator before & after implantation.

Wipe test of the seeds after they were placed in patient (and thought to be leaking).

Comments on the NRC Document:
RADIATION PROTECTION - THYROID BLOCKING - DRAFT
Eugene L. Saenger, M.D.
April 28, 1983

In 1972 the NCRP formed an ad hoc committee on Thyroid Blocking resulting in the issuance of NCRP Report 55. In addition to three thyroidologists, a nuclear engineer and a public health physician, aid was received from a number of staff members of NRC. The final report was reviewed by the NCRP membership numbering about 65 scientists and physicians. The report recommended a blocking dose of 130 mg of KI (100 mg of I) per day upon advice of public health authorities if the radiation dose to the thyroid approaches 10-30 rad. This daily dose is to be continued under guidance of public health authorities. Sheltering, evacuation and milk surveillance were also discussed as were possible complications of KI therapy. No specific recommendations for stockpiling and distribution were made.

The FDA reviewed, expanded and finalized these recommendations between 1977 and the present.

In March and April 1979 at Three Mile Island there was escape outside of the containment vessel of so small an amount of radioactive iodine that it did not constitute a threat to the population either within the plume or ingestion zones. Since then there has been speculation (at least from this physician's viewpoint) as the possible occurrence of a deficit in release of radioiodines.

Meanwhile the potential use of KI has been criticized in several ways. Aldrich and Blond of the NRC in several publications have indicated that KI is not cost effective in preventing either thyroid nodules or thyroid cancer. Yalow (Yalow RS. Potassium iodide: Effectiveness after nuclear accidents. Science 218: 742, 1982) regards the use of KI as dangerous pointing out that the number of serious iodine effects will exceed the number of thyroid tumors which may be prevented.

The American Thyroid Association although agreeing that chemical blocking of the thyroid gland is a reasonable protective measure if administered under appropriate circumstances recommends that the decision point should be a potential thyroid dose of 100 rad.

An opposite viewpoint has been expressed on a number of occasions by Von Hippel (Von Hippel F. Potassium iodide policy. Science 218: 6, 1982) who believes that KI should be distributed over a radius of 100-200 miles. His argument focuses on his interpretation of equal efficacy of ^{131}I as compared to external x-irradiation in the production of thyroid abnormalities and certain other calculations regarding the dissemination of radioiodines which differ from those of the Reactor Safety Study (RSS).

H/4

The RSS has been critically reviewed on several occasions and was criticized in part as being not sufficiently conservative (NUREG/CR-0400 [see p. A-2 of NRC draft]). Rasmussen, however, pointed out that the RSS prediction was conservative in its preductions in comparison with the actual experience at TMI (Hubner K, Fry S: The Medical Basis for Radiation Accident Preparedness. Elsevier/North Holland, New York, 1980). More recently, Lewis has indicated that the RSS is conservatively biased (Scientific American, March 1980). More recent studies (NUREG 2239) suggest that the major areas of contamination may well involve sectors within a 2-5 mile radius, i.e. that more planning and drills will be useful close to the fence line. A probability is assigned to the ingestion zone of about 1-2 orders of magnitude less than in the plume zone.

The current NRC draft is based on some assumptions that require further discussion and clarification. It is quite unclear why the entire U.S. population needs to be supplied with KI. In addition to the lowered probability of release of radioiodines from the containment vessel (NUREG 2239) it seems likely from the extensive meteorological studies that only a few sectors downwind would be involved. Also it does not seem reasonable that Governmental agencies, either local or Federal, should be required to stockpile and distribute a blocking agent. The governmental agencies do not necessarily plan to furnish transportation for evacuation although they have certainly cooperated well with the private sector and service agencies such as the Red Cross in many crises in the recent and distant past. These points will be analyzed further below but the present draft seems unrealistic in these two important parameters based on relatively recent NRC documents.

Currently we are attempting to purchase the 130 mg KI tablets as OTC preparations in the Cincinnati area. This effort has been unsuccessful. Certainly there are many reasons for this difficulty. At the very low cost and presumably low price, it will be necessary to generate a large volume of sales in order to provide the participating drug companies with a cost effective product. These concerns should not be penalized for their apparent lack of willingness to participate in this effort. It is important to provide some marketing opportunities. For example over the past decade it became necessary for DOE to subsidize the production of pharmaceutical grade DTPA compounds in amounts suitable for therapy of transuranic element contamination because the FDA would not accept the manufacturer's claim of efficacy for other purposes. A similar role for KI hardly seems justifiable although this possibility may require consideration.

In order to make some further estimates of the need for KI based on a given dose, say 20-100 rem to the thyroid, the total population in the vicinity of 36 power reactors was summed from NUREG 1856 as shown in Table 1. Using many of the assumptions in the NRC draft document except for the need to supply the total

U.S. population each with one tablet some further calculations follow.

POPULATIONS AROUND POWER REACTORS
From NUREG 1856* July 1981

Radius	Permanent	Transient	Row Totals
2 mile	99523	18313	117836
5 mile	490601	88479	579080
10 mile	2136016	301854	2437870
Column Totals	2726140	408646	3134786

*Fifty two reactor sites are listed but only 36 supplied population data

As an example derived from the NRC draft document, with a U.S. population of about 200×10^6 persons, the number within a 10 mile radius of 36 reactor sites is 3/200 = 1.5% of U.S. population. It would seem within reason to estimate that no more than this fraction would require KI protection based on the low probability of a release of ^{131}I. To carry these projections further with a probability of a reactor accident of 10^{-5}/yr for 36 reactors listed in the above report, one can calculate the cost as $36 \times 10^{-5} \times 0.015 \times \$200 \times 10^6 = 1080/yr = \$1080.00$ at 10¢ per tablet for a 10 day supply.

It is true that ^{131}I can possibly involve a portion of the ingestion zone but probably not within a period of 24-48 hours which would give sufficient time for sheltering, evacuation, distribution of KI and redistribution of existing milksheds.

Estimate of thyroid nodules: BEIR III (p.301) estimates 12 cases per 10^6 PY per rad. Using the above population within the 10 mile zone, about 3×10^6, and without correction for age, race, sex or latency, an estimate would be $3 \times 10^6 \times 12 \times 10^{-6}$ per rad per year or 36 cases/rad in a given year. Again without corrections about 12 cases/rad/yr might be malignant, about 1-2 cases/rad/year would be fatal.

At a cost of $1080 the cost benefit ratio would be 1080/36 = $30.00 per nodule per rad per year. If one were to multiply these values by an average lifetime of 50 years after exposure, the excess cases prevented would be 36 x 50 years or 1800 and the cost benefit ratio would become 1080/1800 = 60¢/case assuming 100% effectiveness of KI and blocking at 1 rad or less. If 30 rad is used as a threshold cost becomes 2¢/case.

If one were to include the ingestion zone based on Tables 1 and 2 there is a change in the above calculation of a factor of

10-100 that would increase the cost benefit ratio to $6.00-$60.00.

In a period when there are enormous investments in nuclear power plants many of which are not completed for various reasons and great concern by citizens concerning safety, it does not seem useful to engage in debates concerning the protection of the thyroid gland between agencies of the Government. Several steps are recommended to aid in the resolution of this problem:

1. A more thorough study of the effects of policies of other governments, principally those in Europe, should be made preferably by an international conference held here or by individual visits.

2. There should be further studies on stability under different conditions of packaging, climate, storage and other factors of various iodine preparations.

3. In the drills as required in NUREG 0654 study of methods of distribution of iodine compounds as compared to sheltering and evacuation should be carried out.

   Particular attention should be paid to the recommendations of masks, filters, wet towels and other home remedies to filter out airborne iodine compounds in whatever physico-chemical states they exist. These casual proposals, however simple and inexpensive they may seen, offer serious threats to large classes of persons including infants and young children, patients with chronic cardiac and pulmonary diseases, the elderly and persons who are or may easily become emotionally disturbed.

4. A trial of distribution by local authorities as compared with over the counter sales should be carried out in two comparable areas to determine the efficiency and costs to the public of these two different methods.

5. It is essential to define far more precisely than has been done before the population which may be at risk for thyroid exposures above 25 rad at each reactor site.

E.L. Saenger, M.D.
April 28, 1983

(4) [illegible] licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

§ 20.204 Same: exceptions.

Notwithstanding the provisions of § 20.203,

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level twelve inches from the surface of the source container or housing does not exceed five millirem per hour.

(b) Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to § 20.203(c) is not required because of the presence of patients containing byproduct material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the regulations in this part.

(c) Caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than eight hours provided that (1) the materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the regulations in this part and (2) such area or room is subject to the licensee's control.

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.

[illegible]For example, containers in locations such as water filled canals, storage vaults, or hot cells.

§ 20.205 Procedures for picking up, receiving and opening packages.

(a)(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in paragraph (b) of this section shall:

(i) If the package is to be delivered to the licensee's facility by the carrier, make arrangements to receive the package when it is offered for delivery by the carrier; or

(ii) If the package is to be picked up by the licensee at the carrier's terminal, make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) Each licensee who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.

(b)(1) Each licensee, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents, except:

(i) Packages containing no more than the exempt quantity specified in the table in this paragraph;

(ii) Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

(iii) Packages containing only radioactive material as gases or in special form;

(iv) Packages containing only radioactive material in other than liquid form (including Mo-99 Tc-99m generators) and not exceeding the Type A quantity limit specified in the table in this paragraph; and

(v) Packages containing only radionuclides with half-lives of less than 30 days and a total quantity of no more than 100 millicuries.

The monitoring shall be performed as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or eighteen hours if received after normal working hours.

(2) If removable radioactive contamination in excess of 0.01 microcuries (22,000 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee shall immediately notify the final delivering carrier and, by telephone and telegraph, mailgram or facsimile, the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office shown in Appendix D of this part.

TABLE OF EXEMPT AND TYPE A QUANTITIES

Transport group[1]	Exempt quantity, curie (microcuries)	Type A quantity, curie (curies)
I	0.1	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1000
VII	25,000	1000
Special form	1	20

[1]The definitions of "transport group" and "special form" are specified in § 71.4 of this chapter.

[Footnote 1 removed 49 FR 19623]

(c)(1) Each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified paragraph (b) of this section, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirem per hour, or at three feet from the external surface of the package in excess of 10 millirem per hour,

the licensee shall immediately notify by telephone and telegraph mailgram, or facsimile, the director of the appropriate NRC Regional Office listed in Appendix D, and the final delivering carrier.

(d) Each licensee shall establish and maintain procedures for safe opening packages in which licensee material is received, and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

§ 20.206 Instruction of personnel.

Instructions required for individuals working in, or frequenting any portion of a restricted area are specified in § 19.12 of this chapter.

§ 20.207 Storage and control of licensed materials in unrestricted areas.

(a) Licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

(b) Licensed materials in an unrestricted area and not in storage shall be

A [c]

Cleveland Clinic

(A)

Conversation with W.L. Axelson, Region III, Nov. 18, 1986

The underlying disease: Walstroms macroglobalemia, causes excessive proteins in the blood. 57 year old female, considered terminal. treatment considered "palliative". They were trying to zap the bone marrow, head to waist, front and back, side and side. Trying to avoid further blood transfusions. Dr. Saenger knows Walstrom and would ask him about it, about the mode of treatment. The major reason for his interest is the actual cause of death. This clinic treats about 100 patients a day. Last misadministration was in 1982. Pneumonia, kidney failure, toxic dermatitis. Two weeks after she received the misadministration she came into the clinic with blisters on her skin. This caused the doctor to go back and check the dosimetry. Discovered on November 11, didn't report until November 17. They had a dual check, dosimetrist and physicist checked another's work. But the tech who turned on the machine didn't have the responsibility of checking to make sure that the double check took place. This will be fixed, other procedures. We will handle this as we did Henry Ford, with extensive QA/QC changes.

How come 60% exposure if she was only irradiated from the waist up? Very preliminary thing about the skin poisoning -- part of the toxic dermatitis may be the effect of the chemotherapy, thinks Saenger.

The symptoms that you would typically see is pulmonary fibrosis. The literature says the first 3-4 weeks to several months for that.

Saenger will go to the hospital for the special inspection.

The clinic's excuse for not reporting sooner: they didn't know they had to.

The original PNO described the patient as "elderly" -- in fact, she was 57. "Elderly" was the licensee's characterization.

My questions:

(1) Why did it take until Nov. 11 for the hospital to figure out the cause of the burns, when she was in the clinic by October 25 or so?

(2) Are you checking on the possibility that this pneumonia is in fact radiation pneumonitis, which resembles it closely, is sometimes a consequence of radiation to the chest area, and is almost invariably fatal?

H/8

the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone 202/786-0322.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; or (3) information the disclosure of which would significantly frustrate implementation of proposed agency action, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

1. Date: May 28, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in Philosophy and Religion, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

2. Date: May 29, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in Philosophy and Religion, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

3. Date: June 1, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in Philosophy and Religion, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

4. Date: June 3, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in Philosophy and Religion, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

5. Date: June 4, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in Classical, Medieval, and Renaissance Studies, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

6. Date: June 5, 1987.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review Biennial Proposals submitted by state humanities councils to the Division of State Programs, for projects beginning after November 1, 1987.

7. Date: June 8, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review Biennial Proposals submitted by state humanities councils to the Division of State Programs, for projects beginning after November 1, 1987.

8. Date: June 2, 1987.
Time: 8:30 a.m. to 5:30 p.m.
Room: 316-2.
Program: This meeting will review the Summer Seminars for Secondary School Teachers applications in English Literature, submitted to the Division of Fellowships and Seminars Programs, for projects beginning after October 1, 1987.

9. Date: May 28-29, 1987.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review Higher Education Program applications, submitted to the Division of Education Programs, for projects beginning after September 1, 1987.

10. Date: June 1-2, 1987.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review Higher Education Program applications, submitted to the Division of Education Programs, for projects beginning after September 1, 1987.

11. Date: June 1, 1987.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in the fields of the humanities submitted to the Publication Subvention category of the Texts Program, submitted to the Division of Research Programs, for projects beginning after October 1, 1987.

12. Date: May 29, 1987.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review applications in the fields of the humanities submitted to the Publication Subvention category of the Texts Program, submitted to the Division of Research Programs, for projects beginning after October 1, 1987.

Stephen J. McCleary,
Advisory Committee Management Officer.

[FR Doc. 87-10781 Filed 5-11-87; 8:45 am]
BILLING CODE 7536-01-M

NUCLEAR REGULATORY COMMISSION

Abnormal Occurrences for Third Quarter CY 1986; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974, as amended, requires the NRC to disseminate information on abnormal occurrences (i.e., unscheduled incidents or events which the Commission determines are significant from the standpoint of public health and safety). The following incidents at NRC licensees were determined to be abnormal occurrences (AOs) using the criteria published in the Federal Register on February 24, 1977 (42 FR 10950). These abnormal occurrences are described below, together with the remedial actions taken. These events are also being included in NUREG-0090, Vol. 9, No. 3 ("Report to Congress on Abnormal Occurrences: July-September, 1986"). This report will be available in the NRC's Public Document Room 1717 H Street NW., Washington DC, about three weeks after the publication date of this Federal Register Notice.

Nuclear Power Plants

AO 86-15 Differential Pressure Switch Problem in Safety Systems at LaSalle Facility

One of the general AO criteria notes that major degradation of essential safety-related equipment can be considered an abnormal occurrence. In addition, one of the AO examples notes that incidents with implications for similar facilities (generic incidents), which create major safety concern, can be considered an AO.

Date and place—On June 1, 1986, LaSalle Unit 2 experienced a feedwater transient that resulted in low water level in the reactor vessel. The level reached a point where an automatic reactor scram would be expected; however, no such scram occurred. LaSalle County Nuclear Power Station consists of two Units, each utilizing a General Electric

H/10

On July 7, 1986, Region IV issued enforcement letters to the licensees involved as follows:

a. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $40,000 to KG&E. The violation was categorized as Severity Level II (on a scale where Severity Levels I and V are considered the most significant and least significant severity levels).

b. A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $65,000 to PSC. The Civil Penalty consisted of $40,000 for the Severity Level II violation and $25,000 for other less significant violations.

Enforcement conferences were held at the Region IV office on November 25, 1985, with KG&E and January 6, 1986, with PSC to discuss these issues and the corrective actions undertaken by the licensee. The specific corrective actions described by the licensees have been evlauated by the NRC.

The NRC has inspected both sites since the violations were identified and is continuing to review the licensees' corrective actions to assure that all of the issues are satisfactorily resolved.

AO 86-18 Significant Deficiencies in Access Controls at River Bend Station

One of the AO examples notes that any substantial breakdown of physical security, such as access control, that significantly weakened the protection against theft, diversion, or sabotage, can be considered an AO.

Date and place—By letter of August 7, 1986, the NRC issued to Gulf States Utilities (GSU), licensee for the River Bend Station, an enforcement letter containing a Severity Level II violation for serious deficiencies in the plant's safeguards program pertaining to access controls. River Bend Unit 1 is a General Electric-designed boiling water reactor located in West Feliciana Parish, Louisiana.

Nature and probable consequences—The Severity Level II violation involved four examples of failure to adequately control the access of personnel to vital areas. In the most serious example, the licensee incorrectly devitalized the plant auxiliary building access control system for over 17 hours. The other three examples included: (1) improperly removing a hatch cover that allowed uncontrolled vital-island-to-vital-island access; (2) allowing a vital island door to be unsecured and uncompensated for about 30 minutes; and (3) improperly removing a large concrete floor plug which served as a vital-island-to-vital-island barrier. In all four examples, conditions existed whereby an intruder could have obtained unauthorized and undetected access into vital areas from either the protected area or other vital areas. It appeared from interviews with licensee personnel and a review of maintenance records that the floor plug had been removed for several months.

The August 7, 1986 letter also described a second violation of lesser significance involving two examples of inadequate vital area physical barriers. Details of the items that constitute the two violations described above are contained in NRC Inspection Reports 50-458/86-11 and 50-458/86-17, both of which were issued on June 6, 1986.

Cause or causes—The cause of these deficiencies was the failure of management to exercise effective personnel access control and to recognize and correct plant design deficiencies as they related to implementation of the security program.

Actions Taken To Prevent Recurrence

Licensee—In each example identified, the licensee took immediate corrective action to post compensatory guards where required. At the locations where uncontrolled access was identified, the licensee secured the area and conducted a search to confirm that no unauthorized activity has occurred, or conditions existed that would prevent safe plant operation. In the "devitalization incident," the licensee performance-tested all equipment essential for safe shutdown that was not operating during that period. The licensee has revised procedures and trained personnel to be aware of the safeguards implications of work performed by maintenance/operations personnel. Markings have been placed on all plugs, hatches, etc., that form part of the vital area barrier to alert personnel to notify Security before removal. The licensee implemented an engineering review and walkdown to identify any barrier openings that existed. Acceptable barriers have been installed to prevent unauthorized access through these openings.

NRC—An enforcement conference with GSU was held at the NRC Region IV office on June 10, 1986, to discuss these matters and the corrective actions undertaken by them. The August 7, 1986 enforcement letter forwarded a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $65,000. The Civil Penalty consisted of $40,000 for the Severity Level II violation and $25,000 for the other less significant violation. The NRC has inspected the site since the violations were identified and is continuing to review the licensee's corrective action to ensure that the issues are resolved satisfactorily.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

AO 86-19 Therapeutic Medical Misadministration

The general AO criterion notes that an event involving a moderate or more severe impact on public health or safety can be considered an AO.

Date and place—On September 4, 1984, NRC Region III was notified by the University of Cincinnati Medical Center, Cincinnati, Ohio, that an iodine-125 radiation source, which had been implanted in a patient had leaked, causing an unintended radiation exposure of 2,087 rad to the patient's thyroid. The leaking radioactive source was one of eight implanted in a patient August 27, 1984, for treatment of a brain tumor. The eight sources were removed on September 1, 1984.

The event has not been previously reported as an abnormal occurrence because at the time of the incident it was not classified as a medical misadministration as defined in 10 CFR 35.41-35.45. However, a recent reevaluation of the event by that NRC Staff concluded that the event should have properly been classified as a medical misadministration, and reportable as an abnormal occurrence, because the treatment was intended to irradiate only the patient's brain tumor, but because of the leaking source, also irradiated the thyroid. (In the body, iodine is deposited in the thyroid, and therefore, the radiation from the leaking iodine source would be concentrated there.)

Nature and probable consequences—On August 27, a total of eight seeds were placed in thin plastic catheter tubes and were temporarily implanted in the brain of a terminally ill patient. the next day, iodine-125 contamination was detected in the brachytherapy source storage room (BSR). Bioassay results showed that the technicians who had worked with the iodine-125 seeds had measurable uptakes of iodine. When the seeds were removed from the patient on September 1, a radiation survey of the patient's neck revealed a radiation level of 1.5 millirem per hour at two inches from the thyroid, which confirmed the seeds were leaking inside the patient. The patient was then discharged from the hospital with instructions to return for further bioassay analyses.

Subsequently bioassay testing of the patient's thyroid determined that there had been a deposition of 557 microcuries of iodine-125 thyroid. This level of deposition would result in a radiation dose to the thyroid of 2,087 rad. (A rad is

a standard measure of absorbed dose.) Such an exposure would be expected to result in some diminished thyroid function. Drugs are available to compensate for the reduced thyroid function.

The licensee found that the patient's friend and about 80 hospital personnel had received thyroid uptakes of 0.04 to 209 nanocuries; the NRC's maximum permissible thyroid burden for iodine-125 is 720 nanocuries. The 209 nanocuries was received by one of the technicians involved in preparing the iodine-125 seeds, and would result in a thyroid dose of about 0.8 rad. This dose would not be expected to result in any clinically detectable effects. The doses received by the other people were all considerably less than that received by this technician. Followup 24 hour urine bioassay testing of the two technicians involved in preparing the iodine-125 seeds showed a thyroid deposition of 29 nanocuries for one and no detectable activity for the other. The results of thyroid function testing of both individuals were normal.

The hospital personnel who received iodine uptakes included those who had handled or were in close vicinity of the leaking source, those involved in the control and cleanup of the contamination of the BSR, and those who frequented the areas outside of the BSR. In regard to the latter, the licensee found that a positive differential pressure between the BSR and the area outside it had exited for several days following the discovery of contamination in the BSR. This positive pressure contributed to the airborne migration of the iodine-125 into adjacent areas. (The licensee later changed the room to be under negative pressure.)

The licensee's investigation of the contamination incident determined that one of the iodine-125 seeds had been cut, apparently when it was being removed from a catheter tube from a previous patient implanted on August 13–17, 1984. Two technicians were involved in removing the seeds, and reported that after the tubes were removed from the previous patient, they were discolored and the seeds were difficult to see. One technician stated that he believed the damage most likely occurred when the ends of the catheter tubes were cut off with scissors.

The use of high activity iodine-125 seeds as removable brachytherapy sources was a new procedure at the University of Cincinnati. Previous uses (treatment protocols) involved the use of low activity iodine-125 seeds (0.1–1 millicurie) as permanent brachytherapy implants.

Although the contamination of the BSR was extensive, wipe surveys and air samples revealed that the contamination was essentially limited to the BSR. The room was decontaminated and then painted to fix any remaining contamination in place. Subsequent air samples in the room and in adjoining areas showed no detectable radioactivity. Some equipment (i.e., a sink, shelving, and storage safe) were found to have some residual contamination; they were covered in plastic to allow for radioactive decay prior to use.

Cause or causes—The cause of the misadministration was found to be an inadequate procedure used in removing the iodine-125 seeds from the catheter tubes for reuse. Further, there were inadequate radiation surveys performed in the work area where the source preparation was performed. Had adequate surveys been performed, the leaking seed might have been discovered prior to its being implanted in the patient.

Actions Taken to Prevent Recurrance

License—The licensee's Radioisotope Committee recommended that the use of high activity iodine-125 seeds be discontinued for this type of radiation therapy, pending a thorough review of the health physics aspects of their use. The hospital also contructed a new radiation source storage room with a greater distance between the storage area and the source preparation area. A fume hood was also installed in the room.

NRC—Region III conducted a special inspection at the hospital on October 10–12, 1984, to evaluate the circumstances of the source leakage and patient use. A Notice of Violation was issued on December 18, 1984 for two violations, i.e., opening a sealed source and failure to make an adequate survey for the source storage area following the preparation of the iodine-125 seeds for patient use.

Followup inspections have been conducted to determine the adequacy of the licensee's corrective actions.

On September 30, 1986, the NRC issued Inspection and Enforcement Information Notice No. 86–84 ("Rupture of a Nominal 40-Millicurie Iodine-125 Brachytherapy Seed Causing Significant Spread of Radioactive Contamination") to all NRC institution licensees to inform them of this event.

The NRC's Office of Nuclear Material Safety and Safeguards, and the NRC's Region Office, are evaluating what additional measures should be taken by the manufacturer and medical licensees to improve handling procedures for iodine seeds.

The NRC Office for Analysis and Evaluation of Operational Data undertook a review of the incident to determine if there was a generic problem associated with the reuse of high activity iodine-125 seeds in brachytherapy implant protocols, and to assess any associated health and safety problems. The findings and recommendations for action by various NRC offices, were issued in AEOD/C601 ("Rutpure of an Iodine-125 Brachytherapy Source at the University of Cincinnati Medical Center") during August 1986.

Dated in Washington, DC, this 6th day of May 1987.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 87-10823 Filed 5-11-87; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 40-8857]

Everest Minerals Corp.; Draft Finding of No Significant Impact Regarding a New Source and Byproduct Material License

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of draft finding of no significant impact.

1. Proposed Action

The proposed administrative action is to issue a new source and byproduct material license authorizing Everest Minerals Corporation to operate the Highland in situ leach uranium recovery operation located in Converse County, Wyoming.

2. Reasons for Draft Finding of No Significant Impact

An environmental assessment was prepared by the staff at the U.S. Nuclear Regulatory Commission (NRC) and issued by the Commission's Uranium Recovery Field Office, Region IV. The environmental assessment performed by the Commission's staff evaluated potential impacts on-site and off-site due to radiological releases that may occur during the course of the operation. Documents used in preparing the assessment included operational data from the research and development in situ leach operation, the licensee's application dated December 30, 1985, and the Final Environmental Statement for Exxon Corporation (Everest's Highland site) prepared by the Commission staff dated November 1978. Based on the review of these documents

(6)

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region III staff on this date.

Facility: Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH

License No. 34-00466-02
30-394

Licensee Emergency Classification:
____ Notification of an Unusual Event
____ Alert
____ Site Area Emergency
____ General Emergency
_X_ Not Applicable

Subject: THERAPEUTIC MISADMINISTRATION

The licensee reported that an elderly, terminally ill patient was exposed to 2000 rads of radiation rather than the prescribed 1200 rads while undergoing cobalt-60 teletherapy treatment for a blood disease.

The treatment, which covered the patient's upper torso, began October 6, 1986, and ended October 8, 1986. The error was discovered on November 11, 1986, but was not reported to the NRC until November 17, 1986. The delay was apparently due to the licensee's failure to realize that a misadministration of this type requires immediate notification.

The excess exposure resulted from an error in the treatment calculations, and was discovered when the patient was admitted to the clinic with skin complications.

An NRC medical consultant has been notified and will promptly review the misadministration. The hospital is required to submit a written report on the incident, including a description of correction actions, within 15 days of the initial report. Region III (Chicago) has scheduled an onsite inspection to review the incident.

The State of Ohio will be notified.

This information is current as of 12:30 p.m. (CST), November 17, 1986.

CONTACT: D. G. Weideman
FTS 388-5616

W. L. Axelson
FTS 388-5612

C/R Distribution: Chm, Cmr [redacted], GC, CA, ACRS, Historian SECY, Records.

DISTRIBUTION:

H. St.	EDO	NRR	E/W	Willste	Mail:	ADM:DMB
Chairman Zech	PA		IE	NMSS		DOT:Trans only
Comm. Roberts	ELD		OIA	RES		
Comm. Asselstine			AEOD			
Comm. Bernthal						
Comm. Carr	SP _____		Regional Offices			
ACRS						
SECY	INPO _____		NSAC _____			
CA	RIII Resident Office					
PDR	Licensee: _____ (Corp. Office - Reactor Lic. Only)					

8.6112504260 1p

Region III
Rev. November 1985

Release 11/7

86-09-0031

WP
MN
FC
JL

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

November 28, 1986

MEMORANDUM FOR: Chairman Zech

FROM: Victor Stello, Jr.
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS - "AEOD CASE STUDY REPORT ON THE RUPTURE OF AN IODINE-125 BRACHYTHERAPY SOURCE AT THE UNIVERSITY OF CINCINNATI MEDICAL CENTER"

This replies to your September 26, 1986 memo (COMFB-86-7), in which you asked three questions about the subject requirements:

Question 1:

Explain whether Region III correctly applied the misadministration reporting requirements in 10 CFR 35.42(a) and (b). If it did, does the General Counsel agree with that application of the regulation?

Answer:

Review by OGC has indicated that the event should have been reported as a misadministration. While the staff agrees that the event was reportable as a misadministration, Region III's action, which was based in part on discussion among regional and headquarters staff, in not classifying it as such at the time is understandable, as described below.

This was an unusual case where one of eight sealed sources containing radioactive iodine (iodine-125) had been inadvertently and unknowingly punctured while being prepared for implantation into a patient's brain tumor. Although the sources were left in the tumor to deliver the critical treatment dose as prescribed by the physicians, the one leaking source caused a concurrent dose to the patient's thyroid via redistribution of unsealed iodine-125. This entire problem might have been prevented if the licensee had been more careful in handling the sealed sources and had conducted adequate radiation surveys in the area where the sources were prepared for implantation.

The University of Cincinnati Medical Center adopted the use of a procedure in 1984 which involved cutting open containers used to implant iodine-125 sources in a patient so that the sources could be recovered for reuse. During the time period August 10 through August 27, 1984, Medical Center staff performed this protocol two times prior to placing eight iodine-125 sources in the brain tumor of a terminal patient on August 27, 1984. Enclosure 1 provides a brief account of the incident that followed and actions taken by Medical Center staff.

H/9

8612040363XA 5pp.

Licensees are required to report misadministrations involving therapy procedures within 24 hours after discovery. All leaking sources are required to be reported within 5 days regardless of whether a misadministration is involved. As indicated in Enclosure 1, the Medical Center first determined on September 1, 1984 substantial, though not quantified, thyroid uptake had occurred. Based on a November 2, 1984 letter from and a November 24, 1986 telephone conversation with the Director, Division of Radiation Oncology, the doctors involved suspected leaking iodine-125 sources on August 28 or 29, 1984. In spite of the suspected leaking sources they "... felt that because of the significant medical problem, recurrent malignant brain tumor, that the patient's implant should be continued to achieve full dose. This was felt medically to be of primary importance, far overshadowing the effects of iodine-125 irradiation of the thyroid gland." The staff believes that the Medical Center should have reported this to the NRC within 24 hours after September 1, 1984, when the leaking sources were confirmed. The Medical Center discharged the patient temporarily on September 1 and upon return on September 4, confirmation of the radioiodine uptake was made through urine sample bioassay. The NRC was first notified on September 4, 1984, when the Medical Center thoroughly described the incident and chronology.

Members of the technical staff who deal with misadministrations on a regular basis had, at the time and currently, mixed opinions as to whether the incident was technically a misadministration. The Region III decision was made after careful review of the information understood at the time and interpretation of NRC documentation on the subject. The decision was made after discussions among regional and headquarters staff and recognizing that the licensee made a decision to continue the treatment of the tumor believing that the leaking source(s) would result in an exposure of the patient's thyroid.

After further staff and OGC review, we now believe this event would be more appropriately classified as a misadministration. We think that the definitions of misadministrations are clear enough and that the one in paragraph (c) of 10 CFR 35.41 covers the incident in question: the radiation's route of administration was unintended and, therefore, a misadministration should have been reported. The prescribing physicians intended to irradiate the patient's brain tumor but did not originally intend to also irradiate the thyroid; a leaking source irradiated both. The idea behind paragraph (c) is that a misadministration occurs if radiation is intended to go from one point to another and somehow (for whatever reason) does not reach the intended point or reaches it in some way that was not intended. In this case, the radiation reached the intended point and an originally, unintended point.

Region III should have used 10 CFR 35.41(c) to classify the incident as a misadministration. It did not, accepting the licensee's decision on the issue as a reasonable one. In retrospect, the decision should have gone the other way. The case was unusual, however. Though the licensee mishandled a source, it does not appear that the licensee was "trying to pull a fast one" on the staff. The licensee did report the incident. The staff was aware of the situation and it did take enforcement and other actions.

Question 2:

Address whether IE, NMSS, and other Regions are applying this regulation and 10 CFR 35.43 (pertaining to reporting diagnostic misadministrations) consistently with the appropriate legal interpretation of "misadministration" under the regulations.

Answer:

We believe that for the most part, the misadministration reporting regulations are fairly straightforward and are being applied consistently. The staff has used this case as an instructional opportunity during a recent meeting among regions and headquarters, to discuss the issues in the misadministration area. The discussion should help it make better decisions in the future.

Questions 3:

Address whether the enforcement action by the Region was appropriate with respect to other license requirements implicated in the incident in view of the existing evidence and the Commission's enforcement policy.

Answer:

IE has reviewed the enforcement action by Region III with respect to the incident. The Region's action was taken with regional management review following normal regional practice including the holding of an enforcement board which is done for the more significant cases in the Region. Based on the Region's determination that there was not a therapeutic misadministration, the Severity Level IV categorization of the two violations identified by the Region, i.e., unauthorized opening of a sealed source containing licensed material and failure to perform an adequate survey to detect low level contamination, was not unreasonable under Supplements IV and V of the Enforcement Policy. Recognizing that the categorizing of a violation requires the exercise of judgement, it would also not have been unreasonable to conclude that these violations amounted to a significant regulatory concern because the exposures to the number of individuals which occurred, though small in magnitude, were clearly unnecessary and preventable if the Commission's survey regulations were followed. Under that view, the violations could have been categorized at a Severity Level III and a civil penalty considered. The small magnitude of dose to hospital personnel was one basis for the Region's Severity Level IV assignments.

In retrospect, this matter involved a therapeutic misadministration and, therefore, the violations associated with the misadministration under Supplement VI could have been categorized as a Severity Level III violation and a civil penalty considered. However, the staff is satisfied that given the time that has passed, the enforcement action taken, the licensee's corrective action, followup inspections, and the publicity given to this event, further enforcement action at this time for the failure to make a more timely report to the NRC or the issuance of a civil penalty is neither necessary nor appropriate.

As to the issue of an investigation, the staff does not believe one is necessary or appropriate under the Commission's threshold for investigations. While the staff does not rule out the possibility that there might have been wrongdoing, given the Region's understanding of the incident, there is neither a reasonable basis to believe that there was wrongdoing in not notifying the Region on September 2 instead of September 5, 1984, nor is there an identified regulatory need for an investigation. Likewise, based on the facts of this case, neither I nor the staff see any basis for an OIA investigation into the manner in which the staff handled this incident. Given the interest in this matter, the staff will be pleased to brief the Commission on this incident if the Commission so desires.

Victor Stello, Jr.
Executive Director
for Operations

Enclosure:
Summary of Incident

cc w/enclosures:
Commissioner Roberts
Commissioner Asselstine
Commissioner Bernthal
Commissioner Carr
SECY
OGC

Enclosure 1

Summary of Incident

August 28, 1984 - Iodine-125 contamination discovered and determined to have originated from the area where implanted sources were prepared.

August 29, 1984 - It was suspected that the implanted seeds were the source of the Iodine-125 contamination. A medical decision was made to continue the implant. Wipe tests performed on shielding and bandages covering the patient's head and implant did not detect contamination.

August 30 thru August 31, 1984 - Performed thyroid counting on all personnel who may have been exposed to sources.

August 31, 1984 - Urine and blood samples were obtained from the patient and technicians who prepared sources.

September 1, 1984 - The Medical Center removed the sources from the patient and measured direct radiation level of about 1.5 mrem/hr outside the patient's neck near the thyroid. This showed that a substantial, though not quantified, amount of radioactivity was deposited in the thyroid. The patient was discharged but instructed to return to the hospital for further bioassays via whole body counting.

September 4, 1984 - Results of the patient's urine bioassay revealed iodine-125 activity in the urine. The Medical Center notified the NRC via telephone.

September 5, 1984 - Performed additional whole body thyroid counting of the patient and quantified the iodine-125 activity present at 557 microcuries, corresponding to 7087 rads to the thyroid.