

JAN 16 1991

In Reply Refer To:
License: 40-15697-01
Docket: 030-09603/90-01

Huron Regional Medical Center
ATTN: R. Sommer, Administrator
172 Fourth Street, S.E.
Huron, South Dakota 57350

Gentlemen:

Thank you for your letter of December 31, 1990, in response to our letter and attached Notice of Violation both dated December 4, 1990. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Original Signed By:
LAWRENCE A. YANDELL *for*
A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
South Dakota Radiation Control Program Director

bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (MS 4503)
CLCain
WLFisher
RABrown
NMSIS
MIS System
RIV Files (2)
RSTS Operator

RIV:NMSIS *RAB*
RABrown:nh
1/15/91

C:NMSIS *CLC*
CLCain
1/15/91

D:DRSS
ABBeach *for*
1/16/91

IE-07
||



RECEIVED
JAN - 7 1991

December 31, 1990

Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

RE: License: 40-15697-01
Docket: 030-09603190-01

Dear sirs:

The following response and related attachments are submitted in response to the Notice of Violation issued following the November 7, 1990 inspection of the Huron Regional Medical Center Nuclear Medicine Department by Mr. R. Brown.

- A. In regard to the violation cited under 10 CFR 35.27(a) it was our understanding that individuals whose names appeared on the Nuclear Regulatory License could supervise physicians which were not listed as authorized users on our list. Inasmuch as Dr. Huet was on the license still the appointed radiation safety officer, as well as having responsibility for overseeing the operation of the license, it was felt that his presence would be sufficient to supervise said users as pointed out in your document.

Appropriate steps have been taken so that all locum tenens physicians in the future will be in compliance with 10 CFR 35.27.

- B. The radiation safety office has now established, collected and implemented in one binder all of the written policies as pointed out in 10 CFR 35.21(b)(2).
- C. The minutes of each radiation safety committee meeting have now been implemented such that we are in compliance with 10 CFR 35.22(a)(4). These have previously been kept in administration's control and henceforth will be stored as in compliance with 10 CFR 35.22(a)(4).
- D. As pointed out in 10 CFR 35.220, our portable radiation detector instrument was being calibrated by the physicist at the time of inspection. In the future we will be certain that a suitable instrument is retained by us whenever any of the equipment is being calibrated.

As pointed out, suitable surveys and logging per 35.70(a), (h) and (e) are now being duly recorded. During the point of violation it should

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GPP

72 FOURTH STREET SE

HURON, SOUTH DAKOTA 57350

(605) 352-6431

IC 91-004

December 31, 1990

be noted that a new camera was being installed and that basically only p.m. maintenance was performed and no scanning was performed during that time.

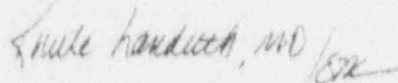
- E. Per 10 CFR 35.60(b) from the point of inspection and, henceforth,
- F. all labeling of syringes to comply with 10 CFR 35.60(b) are being undertaken.

As pointed out in violation for 10 CFR 35.59(g), attached you will find monthly calibration and inventory of sealed sources. We have changed our reporting form from a monthly to a quarterly physical inventory to remain in compliance with 10 CFR 35.59(g).

We hope that the above explanations as well as the suitable documentation for corrective measures falls in compliance with provisions 10 CFR 2.201.

If you have further questions regarding the corrective steps which we have undertaken, please inform us. All of the corrective measures have been undertaken since speaking with Robert A. Brown, Senior Radiation Specialist, on site visit November 7, 1990.

Respectfully,



Knute Landreth, MD
Chief of Radiology
Huron Regional Medical Center

KL/jb

Sealed source inventory and measurement

Date	Cs ¹³⁷ 220	Co ⁶⁰ 9901	Co ⁵⁷ 112	Ba ¹³³ 591
1-15-90	146.8 uCi	11.1 uCi	1.29 mCi	124.5 uCi SH
2-16-90	147.9 uCi	11.0 uCi	1.20 mCi	123.0 uCi SH
3-15-90	147.0 uCi	10.8 uCi	1.12 mCi	122.5 uCi SH
4-10-90	146.4 uCi	10.7 uCi	1.04 mCi	121.9 uCi SH
5-2-90	146.4 uCi	10.6 uCi	989 uCi	121.4 uCi SH
6-8-90	146.9 uCi	10.5 uCi	901 uCi	121.0 uCi SH
6-28-90	146.6 uCi	10.5 uCi	855 uCi	120.0 uCi SH
7-26-90	146.6 uCi	10.5 uCi	799 uCi	119.0 uCi SH
8-9-90	145.8 uCi	10.4 uCi	768 uCi	118.8 uCi SH
8-21-90	146.1 uCi	10.4 uCi	744 uCi	118.4 uCi SH
9-20-90	145.4 uCi	10.3 uCi	688 uCi	118.1 uCi SH
10-29-90	144.8 uCi	10.0 uCi	624 uCi	117.2 uCi SH
1-23-90	144.8 uCi	9.9 uCi	586 uCi	117.8 uCi SH

DATE	C ¹⁵ ₁₃₇ 220	C ¹⁴ ₉₀ 990	C ¹⁴ ₉₇ 112	DATE 591
9-19-88	152.4 uCi	13.3 uCi	4.63 mCi	135.9 uCi R
10-11-88	152 uCi	13.1 uCi	4.26 mCi	135.3 uCi R
11-15-88	150.7 uCi	12.9 uCi	3.89 mCi	134.7 uCi R
12-19-88	151.2 uCi	12.9 uCi	3.54 mCi	133.6 uCi R
1-23-89	152.0 uCi	12.9 uCi	3.24 mCi	133.4 uCi R
2/27/89	150.2 uCi	12.6 uCi	2.95 mCi	132.2 uCi R
3/30/89	150.0 uCi	12.5 uCi	2.72 mCi	131.0 uCi R
4/24/89	150.0 uCi	12.2 uCi	2.57 mCi	130.7 uCi R
5/22/89	150.2 uCi	12.1 uCi	2.45 mCi	130.6 uCi R
6/23/89	150.8 uCi	12.0 uCi	2.20 mCi	129.0 uCi R
7/19/89	149.9 uCi	11.7 uCi	2.05 mCi	127.6 uCi R
8/17/89	149.0 uCi	11.7 uCi	1.90 mCi	127.8 uCi R
9/20/89	148.2 uCi	11.3 uCi	1.82 mCi	127.4 uCi R
10/23/89	148.4 uCi	11.4 uCi	1.61 mCi	126.2 uCi R
11/25/89	148.4 uCi	11.5 uCi	1.47 mCi	125.4 uCi R
12/26/89	148.3 uCi	11.2 uCi	1.35 mCi	124.8 uCi R
1/15/90	146.8 uCi	11.1 uCi	1.29 mCi	124.5 uCi R

DATE: 1/2 304 Cr¹³⁷ 220 Co⁶⁰ 5.271yr 990 Co⁵⁷ 270.9 days 112 Ba¹³³ 12-10.74yrs 591

-25-86	160.0	17.0 uCi	2.36	154.4
0-6-86	159.2 uCi	17.2 uCi	2.31 mCi	154.2 uCi DR
2-24-86	159.2 uCi	17.1 uCi	2.25 mCi	154.2 uCi DR
4-4-86	159 uCi	16.9 uCi	2.15 mCi	153.8 uCi DR
2-8-86	158 uCi	16.8 uCi	1.97 mCi	152.2 uCi DR (DR)
1-15-87	162.3 uCi	16.6 uCi	1.786 mCi	152 uCi
1-26-87	158.8 uCi	16.4 uCi	1.74 mCi	151.2 uCi DR
2-6-87	157.9 uCi	16.0 uCi	1.72 mCi	151.0 uCi SH
2-23-87	157.0 uCi	16.2 uCi	1.62 mCi	150.4 uCi SH
3-26-87	158.0 uCi	16.2 uCi	1.495 mCi	149.0 uCi SH
3-31-87	157.0 uCi	16.3 uCi	1.48 mCi	149.8 uCi SH
4-13-87	158.3 uCi	16.1 uCi	1.43 mCi	148.2 uCi SH
5-13-87	157.5 uCi	15.8 uCi	1.32 mCi	148.0 uCi DR
6-15-87	158.0 uCi	15.6 uCi	1.22 mCi	146.4 uCi SH
7-15-87	156. uCi	15.3 uCi	1.130 mCi	146.6 uCi DR
8-11-87	157.8 uCi	15.3 uCi	1.069 mCi	146.2 uCi SH
9-8-87	156.9 uCi	15.0 uCi	982 uCi	145.6 uCi DR
0-15-87	156.0 uCi	14.8 uCi	891 uCi	144.2 uCi SH
11-17-87	155.0 uCi	14.7 uCi	818 uCi	143.3 uCi DR
12-15-87	155.0 uCi	14.5 uCi	748 uCi	142.2 uCi DR
1-18-88	155.0 uCi	14.5 uCi	699 uCi	141.0 uCi DR
2-11-88	154.5 uCi	14.4 uCi	604 uCi	141.0 uCi DR
3-10-88	154.0 uCi	14.2 uCi	616 uCi	140.0 uCi SH
4-21-88	154.8 uCi	13.8 uCi	550 uCi	139.6 uCi SH
5-11-88	154.0 uCi	13.8 uCi	524 uCi	139.1 uCi DR
6-14-88	153.3 uCi	13.7 uCi	480 uCi	137.3 uCi DR
7-15-88	153.4 uCi	13.4 uCi	443 uCi	137.9 DR
8-19-88	153.2 uCi	13.3 uCi	41.91 mCi	136.4 uCi DR

DATE	Ca ¹³⁷ 220	Co ⁶⁰ 990 2-5-2641	Co ⁵⁷ 112 2-270 day	Ba ¹³³ 591
-3-84	169.7 uCi	24.6 uCi	1.96 mCi	185.3 uCi DR
-30-84	171.0 uCi	24.6 uCi	1.834 mCi	194.5 uCi - 18
7-5-84	170.0 uCi	24.1 uCi	1.679 mCi	184.0 uCi - 18
3-30-84	169.0 uCi	23.9 uCi	1.575 mCi	183.4 uCi - 18
1-22-84	168.8 uCi	23.3 uCi	1.480 mCi	182.1 uCi DR
7-14-84	169.0 uCi	23.6 uCi	1.404 mCi	181 uCi - 18
-1-84	168.7 uCi	23.6 uCi	1.35 mCi	180.7 uCi - 18
5-18-84	168.9 uCi	23.3 uCi	1.29 mCi	180.2 uCi
2-17-84	167.8 uCi	22.7 uCi	1.103 mCi	179.3 uCi
-17-84	167.4 uCi	22.4 uCi	1.10 mCi	179.1 uCi
0-10-84	167.4 uCi	22.3 uCi	.961 mCi	177.4 uCi
2-3-84	166.6 uCi	21.7 uCi	.835 mCi	174.4 uCi
-9-85	165.6 uCi	21.6 uCi	759 uCi	173.5 uCi
2-21-85	165.0 uCi	21.2 uCi	682 uCi	172.0 uCi
-28-85	165.4 uCi	20.9 uCi	626 uCi	171.0 uCi
1-29-85	164.6 uCi	20.8 uCi	574 uCi	170.2 uCi
5-29-85	164.3 uCi	20.5 uCi	525 uCi	169 uCi
-25-85	165.2 uCi	20.5 uCi	498 uCi	168 uCi
2-85	164.2 uCi	20.0 uCi	456 uCi	167.5 uCi
-10-85	163.8 uCi	19.6 uCi	409 uCi	166.1 uCi
0-22-85	163.0 uCi	19.4 uCi	366 uCi	164 uCi
2-5-85	162.5 uCi	19.2 uCi	New source 5.05 mCi	163.6 uCi
1-6-86	162.8 uCi	19.0 uCi	4.65 mCi	162.5 uCi
2-10-86	162.0 uCi	17.8 uCi	4.25 mCi	161.0 uCi
3-20-86	162.0 uCi	18.4 uCi	3.84 mCi	159.7 uCi
4-17-86	164.0 uCi	18.3 uCi	3.57 mCi	159.4 uCi
5-29-86	161.0 uCi	17.9 uCi	3.23 mCi	159.0 uCi
6-26-86	164.0 uCi	17.6 uCi	2.94 mCi	154 uCi
7-22-86	160.0 uCi	17.5 uCi	2.80 mCi	156.6 uCi
8-4-86	159.6 uCi	17.5 uCi	2.76 mCi	156.0 uCi
8-21-86	160.2 uCi	17.4 uCi	2.60 mCi	155.4 uCi

DEC 4 1990

In Reply Refer To:
License: 40-15697-01
Docket: 05J-09603/90-01

Huron Regional Medical Center
Attn: R. Sommer, Administrator
172 Fourth Street S.E.
Huron, South Dakota 57350

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Mr. R. Brown of this office on November 7, 1990, of the activities authorized by NRC Byproduct Material License No. 40-15697-01, and to the discussion of our findings held by the inspector with members of your staff at the conclusion of the inspection.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observations by the inspector.

During this inspection, certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter.

We are concerned about the implementation of your program in the area of management control that permitted these violations to occur. Consequently, in your reply to this letter, you should describe those specific actions planned or taken to improve the effectiveness of the management control of your licensed operations, with particular emphasis on measures currently being taken to prevent further violations. In particular, we suggest that you consider reviewing the effectiveness of your radiation safety committee.

The inspector also reviewed the actions you had taken with respect to the violations observed during our previous inspection conducted on February 23, 1988. He verified that the corrective actions had been implemented.

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RABrown:st CLCain
/ /90 / /90
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In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,

Original Signed

A. B. BEACH

A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

Enclosures:
Appendix - Notice of Violation

cc:
South Dakota Radiation Control Program Director

bcc:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (4503)
*WLFisher
*CLCain
*RABrown
*NPISIS
*MIS System
*RIV Files (2)
*RSTS Operator
*REHall, URFO

*W/766

APPENDIX

NOTICE OF VIOLATION

Huron Regional Medical Center
Huron, South Dakota 57350

Docket No. 030-09603/90-01
License No. 40-15697-01

During an NRC inspection conducted on November 7, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

- A. 10 CFR 35.27(a) states, in part, that a licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if the licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, and if that copy identifies the visiting authorized user by name as an authorized user for medical use.

Contrary to the above, on at least four occasions in 1989 and 1990, visiting authorized users used licensed material for medical use without the licensee first obtaining a copy of the license that identified the visiting authorized user by name.

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

- B. 10 CFR 35.21(b)(2) requires the radiation safety officer to establish, collect in one binder or file, and implement specified written policy and procedures.

Contrary to the above, the radiation safety officer had neither established, collected in one binder or file, nor implemented the required written policies and procedures.

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

- C. 10 CFR 35.22(a)(4) requires, in part, that the minutes of each radiation safety committee meeting include certain specified information. This includes members absent, summary of deliberations and discussions, recommended actions, and the numerical results of all ballots.

Contrary to the above, minutes of the licensee's radiation safety committee meetings for 1988, 1989, and 1990 did not contain the information required above.

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

- D.1. 10 CFR 35.270 requires that a licensee authorized to use byproduct material for imaging and localization studies have in its possession a

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portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

Contrary to the above, from October 31, 1990, to November 7, 1990, the licensee did not possess a portable radiation detection survey meter.

2. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, the licensee did not perform the required daily surveys between October 31, 1990, and November 6, 1990.

3. 10 CFR 35.70(h) requires that records of surveys for contamination and ambient radiation exposure rate contain specified information.

Contrary to the above, the records of surveys performed by the licensee in accordance with 35.70(a) and (e) did not contain the required specified information.

This is a Severity Level IV problem (Supplement VI).

- E. 10 CFR 35.60(b) requires the licensee to conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Contrary to the above, syringes containing radiopharmaceuticals were not labeled during 1989 and 1990.

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

- F. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, no quarterly inventories of sealed sources used to test the dose calibrator were performed from February 23, 1988, to November 7, 1990.

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

Pursuant to the provisions of 10 CFR 2.201, Huron Regional Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, and if

applicable, a copy to the NRC Resident Inspector, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 4th day of December 1990