



MERCY HOSPITAL • 2200 JEFFERSON AVENUE • TOLEDO • OHIO • 43624-1181 • 419/259-1500

October 22, 1996

30-02641

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington D.C. 20555

RE: Reply to a Notice of Violation
RIA Laboratory, Mercy Hospital, Toledo, OH
Lic.# 34-00305-03

10 CFR 35.315 (a) (8) requires that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after administration of the dose.

Mercy Hospital RIA Laboratory has a written policy to comply with this regulation; however, we failed to measure thyroid burden after three different doses - greater than 30 millicuries - of I-131 inpatient treatments because of an oversight.

The bioassay procedure has been in place since 1991. Logs to document compliance are in use. An addendum has been added to indicate that the bioassay documentation will also be recorded on the I-131 NRC inpatient form (see attached), will be part of the audit review process and a line item on a newly developed I-131 inpatient treatment checklist (see attached).

All forms are in place as of October 28, 1996. No inpatient treatments have been scheduled since September 18, 1996.

Ron O'Neal
Vice President of Service Centers

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

October 11, 1996

Ron O'Neal
V.P. of Service Centers
Mercy Hospital
2200 Jefferson Avenue
Toledo, OH 43624

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Mr. O'Neal:

This refers to the inspection conducted on September 23, 1996 at Mercy Hospital. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you members of your staff.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements and observation of activities in progress.

Based on the results of this inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice). A written response is required.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

License No.: 34-00305-03
Docket No.: 030-02641

Enclosure: Notice of Violation

461016 0009

NOTICE OF VIOLATION

Mercy Hospital
Toledo, Ohio

License No. 34-00305-03
Docket No. 030-02641

During an NRC inspection conducted on September 23, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on February 29, 1996, March 27, 1996, (2 administrations), and September 17, 1996 (2 administrations), the licensee administered to patients 151-251 millicuries of iodine-131, dosages which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the authorized physician users who helped prepare and administer these dosages.

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

Pursuant to the provisions of 10 CFR 2.201, Mercy Hospital 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 III, 801 Warrenville Road, Lisle, Illinois 60532-4351 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 11th day of October 1996

96/014 UDL31P

MERCY HOSPITAL RIA LABORATORY
October 1991

BIOASSAY PROCEDURE

A bioassay will be performed on all technicians and physicians that are involved in providing I-131 treatment to a patient in doses greater than 30 millicuries which require hospitalization. A post dose count will be done 24-72 hours after the treatment.

Results of the bioassay are recorded. Action limits are noted on the bioassay log. Counts are recorded in CPM, DPM and MicroCi.

Action Limits are: 333.3 CPM, 2000 DPM, and 2.6×10 microCi.

If the action limits are exceeded, the radiation safety officer is notified immediately.

10/96 Addendum : To assure compliance, the bioassay results will be part of the I-131 inpatient NRC record form, reviewed as part of the audit process and on a newly developed checklist for all inpatient I-131 treatments.

**I-131 INPATIENT TREATMENT
CHECKLIST**

PATIENT: _____

DATE OF ADMISSION: _____

	<u>Initial</u>	<u>Date</u>
1. Room Scheduled	_____	_____
2. Room Prepared	_____	_____
3. Dose Given	_____	_____
4. Daily Room Readings Taken	_____	_____
5. Physician Post Dose Bioassay (24-72 hrs. post)	_____	_____
6. Room Released	_____	_____

THYROID BIO-ASSAY

[illegible]

THE ACTION LIMITS SHOULD BE: 2000 DPM

$$2.6 \times 10^{-2} \text{ uCi}$$

BIOASSAY

I-131 INPATIENT NRC RECORD FORM
Mercy Hospital, Toledo, OH

PATIENT: _____ DATE: _____

PHYSICIAN: _____ ROOM: _____

RX DOSE: _____ ACTIVITY DELIVERED: _____ mCi

ASSAYED ACTIVITY: _____ mCi CHECKED BY: _____

RESIDUAL ACTIVITY: _____ mCi CHECKED BY: _____

IF DOSE IS GREATER THAN 100 mCi, A SURVEY MUST BE DONE.

OUTER PKG. _____ pm INNER PKG. _____ cpm DOSE VIAL _____ cpm BKG _____ cpm

READINGS IMMEDIATELY POST TREATMENT

DOSE ADMINISTERED AT _____ A.M./P.M. ROOM TYPE _____

1 METER _____ mR/hr 2 METERS _____ mR/hr OUTSIDE DOOR _____ mR/hr

ADJACENT ROOM # _____ READING _____ mR/hr (AT WALL)

ADJACENT ROOM # _____ READING _____ mR/hr (AT WALL)

ROOM ABOVE # _____ READING _____ mR/hr

ROOM BELOW # _____ READING _____ mR/hr TECH _____

24 HOURS POST TREATMENT

TIME: _____ DATE: _____

1 METER _____ mR/hr 2 METERS _____ mR/hr OUTSIDE DOOR _____ mR/hr

ADJACENT ROOM # _____ READING _____ mR/hr (AT WALL)

ADJACENT ROOM # _____ READING _____ mR/hr (AT WALL) TECH _____

48 HOURS POST TREATMENT

TIME: _____ DATE: _____ TECH _____

1 METER _____ mR/hr 2 METERS _____ mR/hr OUTSIDE DOOR _____ mR/hr

72 HOURS POST TREATMENT

TIME: _____ DATE: _____ TECH _____

1 METER _____ mR/hr 2 METERS _____ mR/hr OUTSIDE DOOR _____ mR/hr

PATIENT WAS DISCHARGED ON: _____ WITH I-131 ACTIVITY OF: _____ mCi.

ROOM SURVEYED AND DECONTAMINATED ON: _____ BY _____
AND RADIATION PRACTICES DISCONTINUED. ROOM WAS RELEASED TO NURSING SERVICE.
THE LEVEL OF RADIOACTIVITY WAS AT BACKGROUND I.E. <0.01 mR/hr.

THYROID BIO-ASSAY

POST DOSE

NAME	CPM	DPM	uCi

THYROID BIO-ASSAY

DATE	DOSE	NAME	PRE DOSE			POST DOSE		
			CPM	DPM	uCI	CPM	DPM	uCI
1/4/96	14.45mCi	R. Beham MD	76	456	98×10^{-2}	82	492	1.6×10^{-2}
" "	" "	S. Goulet	79	474	1.0×10^{-2}	98	588	1.27×10^{-2}
1/11/96	11.4mCi	J.F. Brunner	88	528	1.14×10^{-2}	106	636	1.4×10^{-2}
" "	" "	D. Davis	88	528	1.14×10^{-2}	106	636	1.4×10^{-2}
1/22/96	24.7mCi	J. Chakravarty MD	79	474	1.0×10^{-2}	98	588	1.27×10^{-2}
" "	" "	S. Goulet	73	438	$.9 \times 10^{-2}$	89	534	1.2×10^{-2}
1/26/96	18mCi	J.E. Brunner	86	516	1.1×10^{-2}	102	612	1.3×10^{-2}
" "	" "	S. Goulet	93	558	1.2×10^{-2}	110	660	1.4×10^{-2}
2/9	8.0mCi	J.F. Brunner	82	492	1.1×10^{-2}	96	540	1.2×10^{-2}
2/9	" "	S. Goulet	85	510	1.1×10^{-2}	102	612	1.3×10^{-2}
2/26	13.59mCi	R. Beham	96	576	1.2×10^{-2}	111	666	1.4×10^{-2}
2/26	" "	S. Goulet	98	588	1.3×10^{-2}	115	690	1.5×10^{-2}
2/29	29mCi	J.E. Brunner	98	588	1.3×10^{-2}	115	690	1.5×10^{-2}
" "	" "	S. Goulet	79	474	1.0×10^{-2}	93	558	1.2×10^{-2}
3/4	151.8mCi	R. Beham	65	390	$.84 \times 10^{-2}$	78	468	1.0×10^{-2}
" "	" "	S. Goulet	77	462	1.0×10^{-2}	89	534	1.2×10^{-2}
3/4	17.98mCi	J.E. Brunner	83	498	1.1×10^{-2}	97	582	1.3×10^{-2}
3/4	" "	S. Goulet	73	438	$.9 \times 10^{-2}$	82	492	1.0×10^{-2}
3/12	26.0mCi	R. Beham	85	510	1.1×10^{-2}	98	588	1.27×10^{-2}
" "	" "	S. Goulet	98	588	1.3×10^{-2}	102	612	1.3×10^{-2}
3/15	29.4mCi	J. Chakravarty	98	588	1.3×10^{-2}	102	612	1.3×10^{-2}
" "	" "	S. Goulet	79	474	1.0×10^{-2}	89	534	1.2×10^{-2}
3/25	13.95mCi	J.E. Brunner	76	456	$.98 \times 10^{-2}$	84	504	1.09×10^{-2}
" "	" "	S. Goulet	86	516	1.1×10^{-2}	105	630	1.36×10^{-2}

THE ACTION LIMITS SHOULD BE: 2000 DPM

-2
2.6 X 10⁻² uCi

BIOASSAY

THYROID BIO-ASSAY

[illegible]

THE ACTION LIMITS SHOULD BE: 2000 DPM

$$2.6 \times 10^{-2} \text{ uCi}$$

BIOASSAY