

DCD

November 19, 1996

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

SUBJECT: NOTICE OF VIOLATION DATED OCTOBER 11, 1996

Dear Mr. O'Neal:

This acknowledges receipt of your letter dated October 22, 1996, in response to our letter dated October 11, 1996, transmitting a Notice of Violation.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original signed by Cynthia D. Pederson

Cynthia D. Pederson, Director  
Division of Nuclear Material Safety

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

bcc w/ltr dtd 10/22/96: PUBLIC  
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DATE	11/15/96	11/15/96	11/18/96					

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

October 22, 1996

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

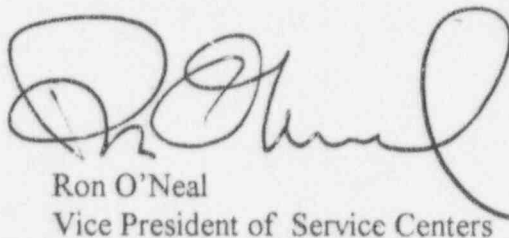
RE: Reply to a Notice of Violation  
RIA Laboratory, Mercy Hospital, Toledo, OH  
Lic.# 34-00305-03

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

pmk

9611140184 tp



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:

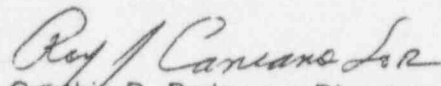
This refers to the inspection conducted on September 23, 1996 at Mercy Hospital. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed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

9610160009 JP

## 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

9610160013

**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  $2.6 \times 10$  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	$98 \times 10^{-2}$	82	492	$1.6 \times 10^{-2}$
"	"	S. Goulet	79	474	$1.0 \times 10^{-2}$	98	588	$1.27 \times 10^{-2}$
1/11/96	11.4mCi	J.F. Brunner, MD	88	528	$1.14 \times 10^{-2}$	106	636	$1.4 \times 10^{-2}$
"	"	D. Davis	88	528	$1.14 \times 10^{-2}$	106	636	$1.4 \times 10^{-2}$
1/22/96	24.7mCi	J. Chakravarty, MD	79	474	$1.0 \times 10^{-2}$	98	588	$1.27 \times 10^{-2}$
"	"	S. Goulet	73	438	$.9 \times 10^{-2}$	89	534	$1.2 \times 10^{-2}$
1/26/96	19mCi	J.E. Brunner	86	516	$1.1 \times 10^{-2}$	102	612	$1.3 \times 10^{-2}$
"	"	S. Goulet	93	558	$1.2 \times 10^{-2}$	110	660	$1.4 \times 10^{-2}$
2/9	8.0mCi	J.F. Brunner	82	492	$1.1 \times 10^{-2}$	96	540	$1.2 \times 10^{-2}$
2/9	"	S. Goulet	85	510	$1.1 \times 10^{-2}$	102	612	$1.3 \times 10^{-2}$
2/26	13.59mCi	R. Beham	96	576	$1.2 \times 10^{-2}$	111	666	$1.4 \times 10^{-2}$
2/26	"	S. Goulet	98	588	$1.3 \times 10^{-2}$	115	690	$1.5 \times 10^{-2}$
2/29	29mCi	J.E. Brunner	98	588	$1.3 \times 10^{-2}$	115	690	$1.5 \times 10^{-2}$
"	"	S. Goulet	79	474	$1.0 \times 10^{-2}$	93	558	$1.2 \times 10^{-2}$
3/4	151.8mCi	R. Beham	65	390	$.84 \times 10^{-2}$	78	468	$1.0 \times 10^{-2}$
"	"	S. Goulet	77	462	$1.0 \times 10^{-2}$	89	534	$1.2 \times 10^{-2}$
3/4	17.98mCi	J.E. Brunner	83	498	$1.1 \times 10^{-2}$	97	582	$1.3 \times 10^{-2}$
3/4	"	S. Goulet	73	438	$.9 \times 10^{-2}$	82	492	$1.0 \times 10^{-2}$
3/12	26.0mCi	R. Beham	85	510	$1.1 \times 10^{-2}$	98	588	$1.27 \times 10^{-2}$
"	"	S. Goulet	98	588	$1.3 \times 10^{-2}$	102	612	$1.3 \times 10^{-2}$
3/15	29.4mCi	J. Chakravarty	98	588	$1.3 \times 10^{-2}$	102	612	$1.3 \times 10^{-2}$
"	"	S. Goulet	79	474	$1.0 \times 10^{-2}$	89	534	$1.2 \times 10^{-2}$
3/25	13.95mCi	J.E. Brunner	76	456	$.98 \times 10^{-2}$	84	504	$1.09 \times 10^{-2}$
"	"	S. Goulet	86	516	$1.1 \times 10^{-2}$	105	630	$1.36 \times 10^{-2}$

THE ACTION LIMITS SHOULD BE: 2000 DPM

-2

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

BIOASSAY

## THYROID BIO-ASSAY

[illegible]

THE ACTION LIMITS SHOULD BE: 2000 DPM

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

BIOASSAY