

March 2, 1992

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: LICENSE NO. 06-01060-1
DOCKET NO. 030-01247
INSPECTION NO. 030-01247/92-001

Dear Sir/Madam:

This letter is in response to violations noted in your correspondence of February 12, 1992, as a result of the inspection conducted on January 9, 1992.

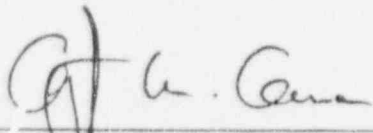
Our responses follow your Appendix A outline:

NOTICE OF VIOLATION

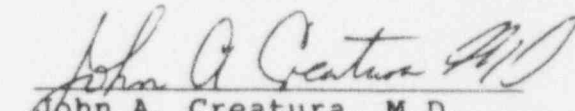
- A. 10 CFR 35.406(C)
This violation has been previously reviewed by the Hospital Radiation Safety Committee as evidenced by minutes of the January 8, 1991 meeting. Corrective action as well as discussion/training of procedures to be followed without exception in accordance with 10 CFR 35.406(C), have taken place with the clinician involved effective January 9, 1991.
- B. 10 CFR 35.415 (a)(4)
This violation has been previously reviewed by the Hospital Radiation Safety Committee as evidenced by minutes of the January 8, 1991 meeting. Corrective action as well as discussion/training of procedures to be followed in accordance with 10 CFR 35.415 (a)(4), without exception have taken place with the clinician involved effective January 9, 1991.
- C. 10 CFR 20.205 (b)(1)(IV)
Survey of isotope shipments in accordance with 10 CFR 20.205 (b)(1)(IV) are being made and documented. In-service conducted by the physicist with the Nuclear Medicine staff to review/reinforce these procedures. Routine in-service sessions are conducted with Nuclear Medicine staff on a quarterly basis for the review of such procedures as well as others which had been covered in the previous meeting of November 1991. Compliance date, January 10, 1992.

- D. 10 CFR 35.50 (e)
The Radiation Safety Officer in accordance with 10 CFR 35.50 (e) will sign records of linearity tests and geometry dependence tests effective January 9, 1992 as reflected on attached copies.
- E. 10 CFR 35.205 (d)
In accordance with 10 CFR 35.205 (d) clearance times relating to the use of XE-133 have been posted, effective February 28, 1992. Immediately following your inspection, The Air Balance Service, Co., checked the intake/exhaust levels of the rooms in question and a report delivered on January 20, 1992 following which time clearance times were posted.

If we can further clarify or provide additional information, please contact Mr. Cannon.



Christopher M. Cannon
Assistant Vice President
for Operations



John A. Creatura, M.D.
Radiation Safety Officer

UNIT DOSAGE RECEIPT AND USE LOG

Instructions:

1. Put on gloves.
2. Visually inspect package for sign of damage. If present notify RSO.
3. Measure exposure at 1 meter and surface.
4. Open package
5. If contamination is suspected, obtain wipe.
6. Verify contents with packing slip.
7. Monitor packing material and empty packages for contamination. If not contaminated, obliterate radiation labels and disclose

WIPE ON RECEIPT
 ✓
 R

Date	Packing Slip #	Transport Index	mCi	Iso.	Chem.	Supplier	pkd OK?	mR/hr @ 1 meter	mR/hr @ surface	Agree w Wipe Pkg slip?	Req'd?	Comment	Init
3-29	—	WI	338	Tc ^{99m}	—	SYNOR	YES	0.02	0.12	YES	YES	92.65pm	RC
	288467		5		MAA								
	288470		30		MDD							R	
	288471		30		MDD								
	288472		30		MDD								
	288478		30		Tc ^{99m}								
	288479		25		Tc ^{99m}							R	
	288480		25		Tc ^{99m}								
3-30	—	WI	2203	Tc ^{99m}	—	SYNOR	YES	0.05	0.10	YES	YES	71.35pm	RC
	288473		30	Tc ^{99m}	Tc ^{99m}								
	288474		30										
	288475		30									R	
	288476		30										
	288476		1		I ¹³¹								
	288474		5		Chem								
	288475		5		MAA								
3/3/92	—	WI	179	at 4m	—	SYNOR	yes	0.03	0.10	yes	yes	101.20pm	RC
	288468		5		MAA								
	288469		5		MAA								
	288471		25		oy							R	
	288481		25									R	
	288482		25									R	

Acceptable Exposure Rates:

Type	mR/hr @ 1m	mR/hr @ surface
White I	bkgd	.50
Yellow II	Trans. Index	200
Yellow III	Trans. Index	200

BRIDGEPORT

EXHIBIT 8



EXH-14 Hours

Wa. Calibrator Linearity

Manufacturer: CRC-7

Model: SN: 71235

date	time	mCi	hours assay elapsed
11/18	8AM	105.6	0
	2PM	52.0	6
11/19	8AM	6.5	24
	2PM	3.3	30
11/20	8AM	0.415	48
	2PM	0.197	54
11/21	8AM	0.025	72
	2M	0.0133	78

worst point deviation: 4.83%
 54 hr reading by *Dis. Moly*

FACILITY: BRIDGEPORT HOSPITAL
 DATE OF TEST: Start: 11/18/91
 TYPE OF TEST: LINEARITY OF ISOTOPE CALIBRATOR
 CALIBRATOR: CRC-7, SERIAL 71235

DATE	TIME	ELAPSED TIME	READING mCi.	CORRECTED mCi.	DIFFERENCE mCi.	PERCENT DIFFERENCE	CORRECTION FACTORS
11/18	0800	0	103.6	104.4*	0.8	0.77	1.0077
	2pm	6	52.0	52.31*	0.31	0.59	1.0060
11/19	0800	24	6.5	6.58*	0.08	1.22	1.0123
	2pm	30	3.3	3.3*	0.00	0.00	1.0000
1/20	0800	48	0.415	0.4158*	0.0008	0.19	1.0019
	2pm	54	0.197	0.207 +	0.01	4.83	1.0508
11/21	0800	72	0.025	0.0255 +	0.0005	1.96	1.0200
	2pm	78	0.0123	0.01276 †	0.00046	3.67	1.0374

Unit is operating within \pm 5.0%.

Stanley J. Malsky
 Stanley J. Malsky, Ph.D.
 Radiological Physicist
 SJM/geg

* USING NRC CORR values based
 ON 30hr. Reading
 + By Computation

P.S.O.
Jr

FEB 92

Month
Date 2/13/92

Feb 92

R.S.O 2/2/92

JR

Daily

	57Co (112)	57Co on 99MTC	CS 137 (220)	CS 137 123 I
1.				
2.	<u>WEEKEND</u>			
3.	360	429	171	142
4.	360	428	170	142
5.	361	428	171	141
6.	359	426	170	142
7.	358	425	171	142
8.				
9.				
10.	354	420	170	142
11.	353	420	170	141
12.	353	419	171	142
13.	352	418	170	142
14.	351	417	170	141
15.				
16.				
17.				
18.	350	416	169	142
19.	349	414	170	141
21.	342	412	171	142
22.	345	409		
23.				
24.	345	410	170	142
25.	344	410	170	141
26.	344	409	171	142
27.	343	408	169	141
28.	342	407	169	141
29.				
30.				

Daily

R.S.O.
2/13/92
JR

San 1992 Month Date	57Co (112)	57Cs on 99MTC	CS 137 (220)	CS 137 123 I
1.	WEEKEND	467		141
2.	393	467	170	141
3.	391	465	171	140
4.				
5.				
6.	388	462	170	141
7.	387	461	171	142
8.	384	460	170	141
9.	387	461	170	142
10.	385	459	171	142
11.				
12.				
13.	389	453	171	141
14.	380	454	170	141
15.	379	454	171	142
16.	379	454	171	142
17.	378	453	170	141
18.	377	452	170	141
19.				
20.	373	448	171	141
21.	372	448	170	141
22.	371	443	171	142
23.	370	443	170	142
24.				
25.				
26.				
27.	367	440	170	142
28.	346	438	171	142
29.	365	436	171	141
30.	364	434	171	142
31.	362	433	171	141

Bridgeport Hospital
Bridgeport, Connecticut

RADIATION SAFETY COMMITTEE MINUTES

DATE: January 8, 1991
Time: 12:00 hours

PRESENT: David S. Wishko, Ph.D., Radiation Safety Officer/Chairman
Jay Meizlich, M.D., Cardiology
Mark Kovalsky, R.T.R., Radiation Medicine, Dosimetrist
Stanley Malsky, Ph.D., Radiology
✓ Michael Tatta, Radiology Administrator
Joyce Arena, R.N., C.N.S. Oncology. Nursing Representative
Paul S. Berger, M.D., Chief, Radiation Medicine

ABSENT: Christopher Cannon, V.P., Administration

VISITORS: Ann Lane, Chief Technologist, X-Ray
Andy Poniros, Radiology Engineer

OLD BUSINESS:

1. I-125 Implant Incident

(See enclosed report) On October 25, 1990, the patient died. All appropriate precautions were taken with the body to ensure no procedure was performed without the prior approval of the RSO. The body was followed to the mortuary and the body was placed in a closed coffin. All areas were monitored and the mortuary personnel were given film badges. No doses were recorded. The NRC were informed of all steps taken and a confirmatory note was received from the NRC.

To prevent a reoccurrence of a radioactive implant being admitted without notification, Ms. Arena shall add a question to the Oncology admitting information questionnaire covering this area.

2. I-131 Consent Form

A I-131 consent form has been developed to meet the criteria as outlined in the NRC information notice, 90-59.

NEW BUSINESS:

1. 3rd quarter review of Film Badge Reports

An analysis of the film badge reports for the period 7/1/90 - 9/30/90 was performed. (see Report) A total of 3 badges, two whole body and one collar badge, exceeded the ALARA 1 limits. The badges were from the following sections: 1 whole body - X-Ray, 1

whole body - Nuclear Medicine and 1 collar - Cardiology. Notifications were sent to these individuals and their supervisors were notified. The number of individuals in Cardiology who would exceed the Hospital ALARA 1 limits but not ALARA 2 limits were 3. 4 individuals exceeded the ALARA 2 limits.

2. Diagnostic Misadministration Report

A misadministration occurred on 11/7/90 involving a dose of 28.4 mCi of Tc99m given to the wrong patient. The appropriate individuals and the NRC were notified of the incident. The nurse who caused the misadministration was counselled by her head nurse. Discussion then followed. Ms. Arena asked if further verification would be appropriate, i.e. examining the patient's chart prior to injection. Dr. Creatura and Dr. Meizlich both stated that this would cause further slowdown of the study process and was unnecessary because the order is direct from the physician.

3. Misadministration Report

A misadministration occurred on 11/6/90 involving a dose of 21 mCi of Tc99m - MDP. The material received from the radiopharmacy was defective and the study had to be repeated. The proper individuals were notified and the corrective action taken was to notify the pharmacy.

4. Failure to measure exposure rate during Cs-137 implant procedure.

On 11/23/90, Dr. Berger performed a Cs-137 implant procedure and failed to measure the required exposure rates around the patient. Dr. Berger stated he could not operate the survey meter given to him by the Radiation Safety staff. It is recommended that a GM survey meter be given to Dr. Berger with the appropriate instructions. If the measurements cannot be taken by him the appropriate personnel be contacted to come in and take the measurements.

5. NRC information notice 90-71.

Dr. Wishko read to the Committee the information notice 90-71 outlining the duties and responsibilities of the Radiation Safety Committee.

6. Interim RSO duties

Mr. Tatta brought to the Committee the interim plan for radiation safety coverage due to Dr. Wishko vacating that position. Among the changes was that Dr. Creatura would be in interim Radiation Safety Officer. During discussion, Dr. Creatura stated that due to the demands and changes in radiation safety, he would be Radiation Safety Officer but that he could not provide the necessary coverage required and he will not be responsible for any incident that may occur that would be a violation of NRC regulations. Dr. Malsky tried to reassure Dr. Creatura that he shall provide all the necessary technical support necessary and Mr. Tatta also stated that the Hospital was committed to obtaining a new physicist as fast as possible but Dr. Creatura stood by his statement. Dr. Berger asked if Mr. Kovalsky could be RSO but Dr. Wishko stated that Mr. Kovalsky did not have the necessary credentials for this position.

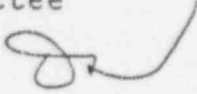
The Radiation Safety Committee adjourned at:

End: 1:00 P.M.

David S. Wishko, Ph.D.
Radiation Safety Officer

Bridgeport Hospital

MEMO

To: Radiation Safety Committee
From: David S. Wishko, Ph.D. 
Subject: Appendum to January 8, 1991 Minutes
Date: 1/10/91

Discussion of the duties of Radiation Safety Officer were conducted among Drs. Bravo, Creatura and Mr. Tatta. An action plan was developed in which Dr. Creatura shall assume the duties of the Radiation Safety Officer with close support being provided by Dr. Stanley Malsky, Ph.D. It is acknowledged that Dr. Creatura shall oversee the Radiation Safety program.