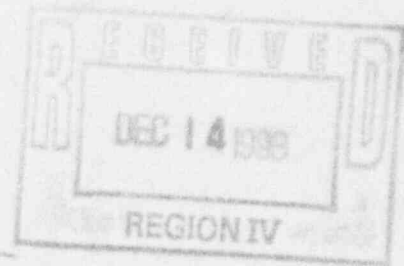


BROKEN ARROW MEDICAL CENTER

AFFILIATED WITH SAINT FRANCIS HOSPITAL

December 7, 1993

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011



RE: NRC Inspection Report No. 030-12713/93-01
(Notice of violation)

File: 35-17414-01
Ref: 030-12713

Gentlemen:

This letter is in response to your letter of November 17, 1993.

Attached is our response to each violation with appropriate documentation.

Should you have any questions regarding the enclosed documentation, please contact me or Karen McCann, RSO.

Sincerely,

Bruce Switzer
Administrator

BS:gld
Enclosures

01007A

94-0306

9312270033 931207
PDR ADOCK 03012713
C PDR

DMB CIE-02

111

ITEM A

Reasons for Violation:

When developing our QM program, it was our feeling that with concurrent and quarterly review of all studies we exceeded the minimum requirements of 10 CFR 35.32.

Corrective Steps:

The QM program is now included in our annual radiation safety committee review process.

Steps to assure future compliance:

We have developed a Nuclear Planning Schedule that will be posted by January 1 of each year to insure timely and ongoing compliance.

Date of Compliance:

QM review included in July 1994 annual review process.

NUCLEAR MEDICINE
PLANNING SCHEDULE
1994

JANUARY	INITIAL	DATE	JULY	INITIAL	DATE
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
Radiation Safety Committee - 14th	_____	_____	Radiation Safety Committee - 8th	_____	_____
QA Review	_____	_____	QA Review	_____	_____
Dosimetry	_____	_____	Dosimetry	_____	_____
Physicist Report	_____	_____	Physicist Report	_____	_____
NRC Mail	_____	_____	NRC Mail	_____	_____
Linearity D.C.	_____	_____	I 131 QM Review	_____	_____
Source Inventory	_____	_____	Review NM Service Policies and Procedures	_____	_____
Records Review	_____	_____	Linearity D.C.	_____	_____
			Source Inventory	_____	_____
			Records Review	_____	_____
			Inservice	_____	_____
			Maintenance	_____	_____
			Inservice	_____	_____
			Housekeepers	_____	_____
			Geometric Test DC	_____	_____
FEBRUARY			AUGUST		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
MARCH			SEPTEMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
APRIL			OCTOBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
Radiation Safety Committee - 8th	_____	_____	Radiation Safety Committee - 14th	_____	_____
QA Review	_____	_____	QA Review	_____	_____
Dosimetry	_____	_____	Dosimetry	_____	_____
Physicist Report	_____	_____	Physicist Reports	_____	_____
NRC Mail	_____	_____	NRC Mail	_____	_____
Linearity D.C.	_____	_____	Linearity D.C.	_____	_____
Source Inventory	_____	_____	Source Inventory	_____	_____
Records Review	_____	_____	Records Review	_____	_____
Survey Meter	_____	_____	Survey Meter	_____	_____
Calibration	_____	_____	Calibration	_____	_____
Room Air Ventilation	_____	_____	Room Air Ventilation	_____	_____
Review of Continuing	_____	_____	Check	_____	_____
Education	_____	_____	Review of Continuing	_____	_____
			Education	_____	_____
MAY			NOVEMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
JUNE			DECEMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____

ITEM B

Reasons for Violation:

History of dose calibrators for 1993

Broken Arrow Medical Center Dose Calibrator - 33518

Out of house for repair January 29 - March 1, 1993

Linearity check dated 03/04/93 (attached)

No longer in service effective June 3, 1993

Loaner Dose Calibrator - 51379

In use January 29 - April 21, 1993

Linearity check dated January 29, 1993 (attached)

Loaner returned May, 1993

Numed Dose Calibrator - 51423

Delivered to nuclear medicine in May, 1993. Not used while dose calibrator 33518 in place.

Utilization began June 3, 1993

Linearity check dated 10/12/93

Attached is the dose calibrator calibration data for dose calibrator - 51423 for June 2, 1993. It was the intent for a linearity check to be done at this time, however, documentation of this is unavailable.

It is our conclusion that the only missing linearity check is the third quarter (June) for dose calibrator - 51423.

Corrective Steps:

Procedure will be strictly adhered to that linearity checks will be performed quarterly.

Item B (continued)

Steps to assure future compliance:

The linearity checks have been included on the nuclear medicine planning schedule.

Date of compliance:

October 25, 1993

Dose Calibrator Activity Linearity Check

Facility: Broken Arrow Medical Center Date: 03-04-93
 Dose Calibrator & Model: Searle Calicheck Serial No.: 34-210
 Dose Calibrator Serial No.: 33518 Performed by: Kent McCann
 Source Configuration: 4cc in 6cc syringe Reviewed by: Kevin McClain RSO

All readings must be taken at the lowest range setting available and converted to mCi units.

A Tube Color	B** Displayed Activity	x	C*** Calibration Factor	=	D Product of B x C
Black Only	281 mCi	x	1.0	=	281
Black & Red	93.7 mCi	x	2.99	=	280
Black & Orange	31.2 mCi	x	8.97	=	280
Black & Yellow	9.65 mCi	x	29.1	=	281
Black & Green	2.35 mCi	x	119	=	280
Black & Blue	0.892 mCi	x	314	=	280
Black & Purple	0.285 mCi	x	900	=	279
<hr/>					
Black & Purple/Red	0.0901 mCi	x	3116	=	281
Black & Purple/Orange	0.0325 mCi	x	8735	=	284
Black & Purple/Yellow	0.0108 mCi	x	27,000	=	292
Black & Purple/Green	mCi	x		=	
Black & Purple/Blue	mCi	x		=	
			SUM		2818
SUM (From Column D)		X	1.05	=	296
	<u>2818</u>			=	<u>2818</u>
No. Entries (Column B)	10	X	0.95	=	268
				=	LOWER LIMIT

Compare Column D data to upper and lower limits to confirm linearity.

*The source configuration to be used must be that which was used when the calibration factors in Column C were determined.
 **Continue testing in sequence shown until the display is reduced to your minimum patient dose, 1 uCi or less, or as your regulatory agency requires. Use the number of entries in Column B in calculating the upper and lower limits.
 ***The calibration factors for this column are specific to your dose calibrator and the source geometry used when determined. They can be found on data sheet #1 in your Calicheck Kit instruction manual.

KSM

Dose Calibrator Activity Linearity Check

Facility: Broken Arrow Date: 29 JAN 93
 Dose Calibrator & Model: Capintec CRC5 Calcheck Serial No: 2264
 Dose Calibrator Serial No: 51379 Performed by: KE Douglas
 Source Configuration: Syringe 40ul/obc Reviewed by: _____ (HSC)

All readings must be taken at the lowest range setting available and converted to mCi units.

A Tube Color	B** Displayed Activity	C*** Calibration Factor	D Product of B x C
Black Only	291 mCi	1.00	291
Black & Red	95.8 mCi	3.04	291.23
Black & Orange	31.9 mCi	9.17	292.52
Black & Yellow	9.53 mCi	27.73	292.25
Black & Green	2.59 mCi	124.82	255.76
Black & Blue	0.911 mCi	317.80	259.30
Black & Purple	0.291 mCi	996.62	290.02
Black & Purple/Red	0.091 mCi	3172.04	288.66
Black & Purple/Orange	0.032 mCi	8909.09	285.09
Black & Purple/Yellow	0.011 mCi	26727.27	294.00
Black & Purple/Green	0.005 mCi	9800.00	294.00
Black & Purple/Blue		29300.00	
		SUM	3196.86
SUM (From Column D)	3196.86	X 1.05 =	3351.5 = UPPER LIMIT
No. Entries (Column B)	11	X 0.95 =	276.09 = LOWER LIMIT

Compare Column D data to upper and lower limits to confirm linearity.

*The source configuration to be used must be that which was used when the calibration factors in Column C were determined
 **Continue testing in sequence shown until the display is reduced to your minimum patient dose, 10 uCi or less, or as your regulatory agency requires. Use the number of entries in Column B in calculating the upper and lower limits.
 ***The calibration factors for this column are specific to your dose calibrator and the source geometry used when determined. They can be found on data sheet #1 in your Calcheck Kit instruction manual.

Dose Calibrator Activity Linearity Check

Facility Broken Arrow Date 10/12/93
 Dose Calibrator & Model Cypratec CCR Calicheck Serial No. 34-210
 Dose Calibrator Serial No. 51423 Performed by B Maxey
 Source Configuration 4cc in 6cc Syringe Reviewed by _____ RSO

All readings must be taken at the lowest range setting available and converted to mCi units.

A** Tube Color	B** Displayed Activity	C*** Calibration Factor	D Product of B x C
Black Only	<u>106.3 mCi</u>	<u>x 1.0</u>	<u>= 106.3</u>
Black & Red	<u>34.8 mCi</u>	<u>x 3.05</u>	<u>= 106.1</u>
Black & Orange	<u>11.6 mCi</u>	<u>x 9.16</u>	<u>= 106.3</u>
Black & Yellow	<u>3.57 mCi</u>	<u>x 29.8</u>	<u>= 106.4</u>
Black & Green	<u>0.982 mCi</u>	<u>x 120.5</u>	<u>= 106.3</u>
Black & Blue	<u>0.335 mCi</u>	<u>x 314.5</u>	<u>= 106.3</u>
Black & Purple	<u>0.110 mCi</u>	<u>x 966.4</u>	<u>= 106.3</u>
Black & Purple/Red	<u>0.0370 mCi</u>	<u>x 2873.0</u>	<u>= 106.3</u>
Black & Purple/Orange	<u>0.015 mCi</u>	<u>x 7086.7</u>	<u>= 106.3</u>
Black & Purple/Yellow	<u>0.007 mCi</u>	<u>x 15185.7</u>	<u>= 106.3</u>
Black & Purple/Green	<u>_____ mCi</u>	<u>x _____</u>	<u>= _____</u>
Black & Purple/Blue	<u>_____ mCi</u>	<u>x _____</u>	<u>= _____</u>
		SUM	<u>1062.9</u>
SUM (From Column D)		<u>x 1.05 = 111.6</u>	= UPPER LIMIT
	<u>1062.9</u>		<u>= 106.29</u>
	<u>10</u>		
No. Entries (Column B)		<u>x 0.95 = 100.97</u>	= LOWER LIMIT

Compare Column D data to upper and lower limits to confirm linearity.

*The source configuration to be used must be that which was used when the calibration factors in Column C were determined.

**Continue testing in sequence shown until the display is reduced to your minimum patient dose, 10 uCi or less, or as your regulatory agency requires. Use the number of entries in Column B in calculating the upper and lower limits.

***The calibration factors for this column are specific to your dose calibrator and the source geometry used when determined. They can be found on data sheet #1 in your Calicheck Kit instruction manual.

DOSE CALIBRATOR CALIBRATION
CALIBRATOR VISUAL INSPECTION
SEALED SOURCE LEAK TEST
SEALED SOURCE INVENTORY

Broken Arrow Medical Center
Broken Arrow, Oklahoma

6/2/93

02-Jun-93

Dose Calibrator Description: Capintec CRC-5 S.N. 51423

NUMED Device

****Co-57:**

Source description: CIS
Activity: 5.7 mCi 07-Feb-92
Expected reading: 1.671 mCi
Actual reading: 1.750 mCi
Variation: 5%
Multiplication factor: 0.96

Scintillation det. Lower window: 50 keV
Upper window: 950 keV
Standard: 0.003 microCuries Cs-137 equivalent
Standard Reading: 2249 counts/min.
B.G. Reading: 128 counts/min.
Wipe Reading: <150 counts/min.
Wipe Activity: 0.0003 microCuries Cs-137 equivalent

Comments: Co-57 scale (setting: 112)

****Ba-133**

Source description: Amersham 2199MA
Activity: 0.266 mCi 01-Mar-83
Expected reading: 0.135 mCi
Actual reading: 0.142 mCi
Variation: 5%
Multiplication factor: 0.95

Lower Window: 50 keV
Upper window: 950 keV
Standard: 0.003 microCuries Cs-137 equivalent
Standard Reading: 2249 counts/min.
B.G. Reading: 128 counts/min.
Wipe Reading: <150 counts/min.
Wipe Activity: 0.0003 microCuries Cs-137 equivalent

Comments: (setting: 591)

****Cs-137:**
Source description: Amersham 3360MA
Activity: 0.276 mCi 01-Mar-83
Expected reading: 0.218 mCi
Actual reading: 0.225 mCi
Variation: 3% high
Multiplication factor: 0.97

Lower Window: 50 keV
Upper window: 950 keV
Standard: 0.003 microCuries Cs-137 equivalent
Standard Reading: 2249 counts/min.
B.G. Reading: 128 counts/min.
Wipe Reading: <150 counts/min.
Wipe Activity: 0.0003 microCuries Cs-137 equivalent

Comments: Cs-137 scale (setting:220)

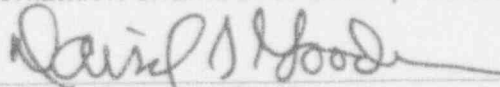
****Other Sources:**

Co-57 5.04 mCi 10/16/87
Co-57 5.3 mCi 11/17/88

Lower Window: 50 keV
Upper window: 950 keV
Standard: 0.003 microCuries Cs-137 equivalent
Standard Reading: 2249 counts/min.
B.G. Reading: 128 counts/min.
Wipe Reading: <150 counts/min.
Wipe Activity: 0.0003 microCuries Cs-137 equivalent

**The sources described in this report were also inventoried and found to be properly labeled and housed.

A visual inspection showed no shift in the ionization chamber or other problem.



David S. Gooden, Ph.D.
Radiological Physicist

(BADOSCAL)

KSM

NUCLFAR MEDICINE
PLANNING SCHEDULE
1994

JANUARY	INITIAL	DATE	JULY	INITIAL	DATE
Xenon Trap Check			Xenon Trap Check		
Radiation Safety Committee		14th	Radiation Safety Committee		8th
QA Review			QA Review		
Dosimetry			Dosimetry		
Physicist Report			Physicist Report		
NRC Mail			NRC Mail		
Linearity D.C.			I 131 QM Review		
Source Inventory			Review NM Service Policies and Procedures		
Records Review			Linearity D.C.		
			Source Inventory		
			Records Review		
			Inservice		
			Maintenance		
			Inservice		
			Housekeepers		
			Geometric Test DC		
FEBRUARY			AUGUST		
Xenon Trap Check			Xenon Trap Check		
MARCH			SEPTEMBER		
Xenon Trap Check			Xenon Trap Check		
APRIL			OCTOBER		
Xenon Trap Check			Xenon Trap Check		
Radiation Safety Committee		8th	Radiation Safety Committee		14th
QA Review			QA Review		
Dosimetry			Dosimetry		
Physicist Report			Physicist Reports		
NRC Mail			NRC Mail		
Linearity D.C.			Linearity D.C.		
Source Inventory			Source Inventory		
Records Review			Records Review		
Survey Meter			Survey Meter		
Calibration			Calibration		
Room Air Ventilation			Room Air Ventilation		
Review of Continuing			Check		
Education			Review of Continuing		
			Education		
MAY			NOVEMBER		
Xenon Trap Check			Xenon Trap Check		
JUNE			DECEMBER		
Xenon Trap Check			Xenon Trap Check		

ITEM C

Reasons for Violation:

The removable contamination in each area was expressed in counts per minute. It was our understanding that this practice was acceptable.

Corrective Steps:

Removable contamination is currently being recorded in disintegration's per minute.

Steps to assure future compliance:

Technologists have been instructed to count removable contamination in disintegration's per minute. Reporting form has been revised to reflect the change. See attached.

Date of Compliance:

October 22, 1993

BROKEN ARROW MEDICAL CENTER NUCLEAR MEDICINE DAILY WORKSHEET

DATE: _____ TIME: _____

TRANSPORT CONTAINER

Dose Calibrator: # _____

External Condition: _____

Daily Checks

Constancy: _____ uCi Co57 _____

Survey at 3': _____ mr/hr

Constancy: _____ uCi Cs137 _____

Survey at Surface: _____ mr/hr

Constancy: _____ uCi Ba 133 _____

Wipe Test: _____ DPM

Survey Calibrator: _____

Bulk Activity Received: _____ mCi / _____ ml _____ Time

Unit Doses Received (See Slips)

Checks Performed

Daily Flood: _____

Dose Calibrator: _____

Receipt & Disposal: _____

Xenon Unit: (if used) _____

Wipe Tests: _____

Reagent & Manufacturer: _____
 Lot# _____ Exp: _____
 _____ ml Tc99m _____ ml Saline
 Assay _____ mCi/ml _____ Time
 Total _____ mCi _____ ml

Room Survey and Wipe Test Results

Reagent & Manufacturer: _____
 Lot# _____ Exp: _____
 _____ ml Tc99m _____ ml Saline
 Assay _____ mCi/ml _____ Time
 Total _____ mCi _____ ml

- A. _____ mr/hr _____ DPM Background
- B. _____ mr/hr _____ DPM Shield (work area)
- C. _____ mr/hr _____ DPM Dose Calibrator
- D. _____ mr/hr _____ DPM Floor Injection Area
- E. _____ mr/hr _____ DPM Patient Table
- F. _____ mr/hr _____ DPM Camera
- G. _____ mr/hr _____ DPM Hands

Reagent & Manufacturer: _____
 Lot# _____ Exp: _____
 _____ ml Tc99m _____ ml Saline
 Assay _____ mCi/ml _____ Time
 Total _____ mCi _____ ml

Waste Disposal

Container Returned: _____

Biohazard/Radioactive Waste

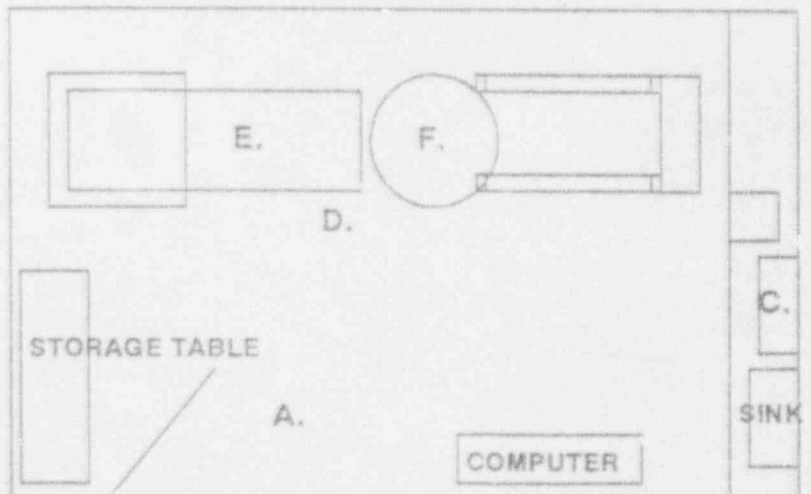
To: Pharmacy _____ To: Hot Storage _____

Date: _____ Tech: _____

On Site Disposal Date: _____

Nuclide: _____ / _____ mr/hr

Disposed To: _____ Tech: _____



ITEM D

Reasons for Violation:

Our nuclear medicine department has been using the aerosol delivery system exclusively which does not utilize the reusable collection system. Recently the reusable collection system has been used occasionally. Due to oversight, the monthly test for radioactive gases was not performed each month.

Corrective Steps:

The reusable collection system will be checked for radioactive gases each month irrespective of utilization. Form attached.

Steps to assure future compliance:

This test has been included on the nuclear medicine planning schedule.

Date of Compliance:

November 2, 1993.

133 XENON TRAP TEST

DATE: _____ SIGNATURE _____

1 minute background counts _____

1 minute 133 Xenon Effluents Bag _____

1.2 x background counts is acceptable limits

133 XENON TRAP TEST

DATE: _____ SIGNATURE _____

1 minute background counts _____

1 minute 133 Xenon Effluents Bag _____

1.2 x background counts is acceptable limits

NUCLEAR MEDICINE
PLANNING SCHEDULE
1994

JANUARY	INITIAL	DATE	JULY	INITIAL	DATE
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
Radiation Safety Committee - 14th	_____	_____	Radiation Safety Committee - 8th	_____	_____
QA Review	_____	_____	QA Review	_____	_____
Dosimetry	_____	_____	Dosimetry	_____	_____
Physicist Report	_____	_____	Physicist Report	_____	_____
NRC Mail	_____	_____	NRC Mail	_____	_____
Linearity D.C.	_____	_____	I 131 QM Review	_____	_____
Source Inventory	_____	_____	Review NM Service Policies and Procedures	_____	_____
Records Review	_____	_____	Linearity D.C.	_____	_____
			Source Inventory	_____	_____
			Records Review	_____	_____
			Inservice	_____	_____
			Maintenance	_____	_____
			Inservice	_____	_____
			Housekeepers	_____	_____
			Geometric Test DC	_____	_____
FEBRUARY			AUGUST		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
MARCH			SEPTMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
APRIL			OCTOBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
Radiation Safety Committee - 8th	_____	_____	Radiation Safety Committee - 14th	_____	_____
QA Review	_____	_____	QA Review	_____	_____
Dosimetry	_____	_____	Dosimetry	_____	_____
Physicist Report	_____	_____	Physicist Reports	_____	_____
NRC Mail	_____	_____	NRC Mail	_____	_____
Linearity D.C.	_____	_____	Linearity D.C.	_____	_____
Source Inventory	_____	_____	Source Inventory	_____	_____
Records Review	_____	_____	Records Review	_____	_____
Survey Meter	_____	_____	Survey Meter	_____	_____
Calibration	_____	_____	Calibration	_____	_____
Room Air Ventilation	_____	_____	Room Air Ventilation	_____	_____
Review of Continuing	_____	_____	Check	_____	_____
Education	_____	_____	Review of Continuing	_____	_____
			Education	_____	_____
MAY			NOVEMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____
JUNE			DECEMBER		
Xenon Trap Check	_____	_____	Xenon Trap Check	_____	_____