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US Nuclear Regulatory Commission
Attention: Penny Lansizera
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pa. 19406-1415

January 6, 2006

Licensee: Geisinger Health System, Danville, Pa. 17822
License: #37-01421-01, Amendment #36
Subject: Response to NRC Inspection Conducted November 30, 2005

03002984 / 2005001

Penny,

This letter is written to document our actions in response to two potential violations of NRC regulations pointed out by you and your inspection team following our routine inspection in November. The actions were executed immediately and completed as a priority. We have also put into place a number of measures to prevent future occurrences of these events and related events to assure compliance. Please see the attached document for the details of our response.

Very sincerely,

Cathy Anderko

Catherine Anderko, M.S., CHP, DABR
Director, System, Medical Health Physics
Radiation Safety Officer, Geisinger System Services

Robert W. Davies

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Vice President, Support Services
Geisinger Health System

NMSS/RGNI MATERIALS-004

The following information is provided to NRC to document changes in our radiation safety program relative to two program areas, (1) the calibration of portable survey meters (2) the HDR quality assurance program. We recently became aware of issues in each of the above areas, and have taken the following steps to correct the issues and ensure that they do not resurface in the future.

Portable survey meter calibration:

1. Our standard operating procedure "Calibration of Portable Survey Instruments" was reviewed and found to be accurate in terms of acceptable standard of practice. The procedure clearly indicates that instruments used for exposure rate measurement be calibrated on each scale for exposure rate using a NIST-traceable source. The procedure also indicates a process to follow when a meter, or a scale on a meter, is not able to be calibrated for whatever reason. That process involves either an outsourced calibration, or a lock-out/tag-out of the un-calibrated scales / meter. Although the procedure was determined to be accurate as written, one section was changed which contained wording that could be misinterpreted. A copy of the revised procedure is attached.

2. The Health Physicist who is assigned the job of meter calibration did not follow the procedure, and allowed the lower meter scales to go un-calibrated due to the background radiation level. While it is recognized that there are simple techniques to overcome the background problem, the HP showed poor judgment in not considering them. He did not obtain permission for his actions or notify anyone that the lower scales were not calibrated. The calibration reports are not typically reviewed by a senior Health Physicist, as the procedure is straightforward and relatively simple, and the HP was well experienced and trained in the job. Therefore, the problem was not immediately identified. The responsible HP was counseled and a disciplinary action administered by Human Resources.

3. Immediately upon recognition of the problem, the lower scales on all portable GM survey meters were re-calibrated for exposure rate with our NIST-traceable ^{137}Cs calibration source. To overcome the background radiation level for the lower scales, the distance between the source and the meters was increased. None of the lower scales on the 34 meters re-calibrated required adjustment. A copy of the current inventory is attached. It shows the annual calibration dates and the lower scales on each meter that were re-calibrated.

4. The inventory of portable survey meters was augmented to include, for each portable survey meter, an indication of whether it is mandatory to calibrate for exposure rate. A copy of the current inventory, showing annual calibration dates, also shows the indication of mandatory exposure rate calibration per meter.

5. Effective immediately, a Senior Health Physicist will review and sign off on all instrument calibration reports.

6. The calibration report forms were changed to add a section that identifies all of the possible scales to be calibrated, so that a reviewer can tell if the calibration was complete. The form also adds a space for a Senior Health Physicist reviewer signature, and a section for the user to identify any deviations from standard operating procedure (actions or omissions) and the rationale for each deviation. A checkbox for "follow-up action required" was added, with a prompt for a date that confirms "follow-up action completed".

HDR Quality Assurance:

10 CFR 35.633 requires, in part, that the length of source transfer tubes and applicators be measured as part of full calibration measurements before 1st medical use, following source exchange, and following re-installation of the unit to a new location outside the facility. This should be done quarterly at a minimum. The record of the calibration is to be maintained for 3 years and show the date of calibration, manufacturer, model and serial number of the HDR device, the instruments or measurement tools used to perform the calibration, the resulting data and its' analysis, and the signature of the AMP.

Quarterly full calibrations of the HDR are performed after source exchange by AMP's, according to 10 CFR.633, however, the measurement of length of the source transfer tubes and applicators was not done quarterly. The length of the source transfer tubes is not variable, and they have connectors at both ends which further prevents any change in length. The applicators are also a fixed length that cannot be changed by virtue of the fact that they are made of hard metal or carbon fiber. They are sterilized between uses, and the wrapping which ensures sterility precludes accurate measurement of length. The actual patient treatments are planned using dummy sources and the source dwell location is according to that plan, and not based on any measured distance of the applicators.

On December 1, 2005, immediately following the NRC inspection, the AMP measured the length of all 15 applicators and all 18 source transfer tubes to the best of his ability. The calibration report is electronic and available for review on Radiation Oncology computers. The AMP compared the measurements to those made in the past and no change in length was noted for any of the applicators or tubes. The form used for "HDR Full Calibration Measurements" was revised to include space to record the results of the measurements each quarter. The form prompts the user for the results, to ensure that it is completed each time. The Chief Therapy Physicist communicated this requirement to the oncology physics team at a staff meeting and reviewed the regulation, the method to make the measurements, the revised form for recording results, and how to interpret the results. The QMP was reviewed and will be revised to clearly incorporate procedural language for conducting these quarterly checks.

During routine audits of the QMP program in Radiation Oncology conducted by Health Physics, the quality assurance information required by regulation for HDR and LDR will be reviewed and documented on the QMP or Annual Audit form. This will be done annually at a minimum.

Attachments:

(1) "Radiation Survey Instrument Calibration" Form
(2) "Calibration of Portable Survey Instruments" Procedure
(3) "Inventory of Portable Survey Meters" Database

Calibration of Portable Survey Instruments

I. Applicability:

A. Applies to Medical Health Physics staff specifically trained to calibrate survey meters and authorized to use the instrument calibration source.

B. Applies to portable survey meters, required by regulation to be calibrated before first use, annually[1] and following repair (not including battery or cable replacement).

II. Materials:

A. HV Voltmeter
B. Cs-137 Calibrator
C. Electronic Pulser
D. Range table
E. Flathead Screwdriver
F. Probe Jig
G. Calculator
H. Calibration worksheet
I. Calibration stickers
J. Calibration report forms
K. Tweaker

III. General Guidelines:

A. The electronic pulser, used for count rate instrument calibration, shall be calibrated at the frequency recommended by the manufacturer.

B. The radiation source used to calibrate for exposure rate shall be NIST-traceable.

C. All portable instruments will be calibrated using a standard, reproducible geometry, in the designated instrument calibration facility.

D. Calibrate survey meters considering the radiation types in use in the end-user lab.

E. A real-time meter inventory will be maintained. New equipment will be added and defunct equipment deleted to/from the inventory within 7 days of the action. Meters removed from inventory shall be listed as inactive with the reason for inactivation noted.

F. Instruments sent to Health Physics for calibration shall be calibrated and returned to the owner with a new calibration label and certificate within 7 days, unless previous arrangements have been made with the end-user.

G. Never attempt to service a meter or detach a meter's cable with the instrument's power ON. Doing so can result in electric shock, and may damage the meter's electronics.

H. All new instruments entering the Geisinger system shall be subject to a "new meter check-in procedure", where the instrument is evaluated for appropriateness of use, entered into the inventory, calibrated[2], and tested for proper function.

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[1] Annually means that the meter shall be calibrated at intervals not exceeding 365 days. When 365 days has elapsed and no recalibration has occurred, the instrument shall be considered in a state of non-compliance, and taken out of service.

[2] A valid calibration sticker and certificate from an authorized calibration facility may be acceptable if the calibration methodology was appropriate for the types of use and radioisotopes being surveyed.

I. Each instrument scale shall be calibrated up to 1000 mR/hr using two separate points with a radiation source and/or pulser. A point shall be considered calibrated if the indicated and calculated exposure rates differ by ≤ 20%.

J. The exposure rate from a known dedicated check source will be assessed and noted on the calibration sticker for use in operability checks.

IV. **Procedure**:

A. Prepare the instrument calibration facility to ensure safety according to HP procedure.

B. If a meter is new, or has not been calibrated in the past 3 years or longer, record general characteristics and any special calibration guidelines for the instrument by reviewing the manufacturer's instruction manual.

C. Survey the instrument for contamination. Decontaminate as needed.

D. Verify that the unit is in good working order by performing an ***instrument check***. Assess the general condition of the unit; make sure the display window is not broken. Confirm that the toggle, selector switches, and reset button work properly. Visually inspect the probe; if GM, the GM tube window coating should be dark gray. If the window is clear, suggest replacing it soon. Inspect the batteries (if applicable) to rule out rupture or corrosion on the battery terminal contacts.

E. ***Assess battery condition***. Turn the scale switch to the 'Battery Check' position. Verify that the needle indicator enters the "battery OK" region, which indicates sufficient power for instrument operation. If the reading is low, replace the batteries before continuing the calibration, and re-check battery status. AC-powered instruments with battery backup, such as the Ludlum Model 177 and Eberline Model RM-2, must be unplugged before pushing the "battery test" button. If the battery is dead, attach a note to the instrument stating, "AC power only, internal battery dead", and note in the calibration report. Complete the calibration with the meter running on AC power.

F. ***Check the cable(s)*** for visible or internal damage. Broken insulation or loose fittings may indicate cable problems. To check for internal damage, set the scale switch to any "ON" position, and with the probe connected, stretch the cable to its full length and joggle it around a bit, noting any erratic audio or visual response. Replace the cable before continuing with the calibration if an abnormal response is observed.

G. Perform an ***operability test*** by placing the probe flush against the dedicated check source, and recording the exposure rate. Compare it to the previous year's exposure rate on the calibration sticker, to be sure it is within 20%. If not, repeat the test, and attempt to find the source of the problem and correct it. If the instrument does not have a dedicated check source, attach a depleted uranium foil from the Health Physics inventory. If the instrument does not have a separate probe (an ion chamber), note the identity and storage location of the check source used on the calibration sticker.

H. Perform a ***high voltage check*** as follows:

1. "Zero" the instrument. With the meter lying on a flat surface and turned off, assess whether the needle lines up with the demarcation for "0" on the meter face. To adjust, turn the set screw near the meter's face until the needle lines up with the "0" demarcation.

2. Connect the meter's cable to a calibrated voltmeter. Turn both the voltmeter and the survey meter on. Verify that the high voltage is set according to the manufacturer's specifications for the type(s) of probe in use. This step may be omitted for certain instruments, such as Mini-Monitors, due to either a non-removable cable or internal probe.
3. To change the high voltage setting, adjust the potentiometer (pot) labeled "H.V.", usually located under a small cover on the top of the meter near the handle, or inside the meter on the printed circuit board, usually near other pots for adjusting the scales, marked X 0.1, X 1, X 10 and X 100.
4. Determine whether the meter needs to be calibrated for count rate (cpm), exposure rate (mR/hr), or both:
   a) Meters having only a "cpm" or "cps" scale, or if used only for contamination monitoring, will be calibrated only for count rate (see "Count Rate Calibration" section).
   b) Calibrate meters for "exposure rate" if they will be used for exposure rate measurements. For these meters, use the "Exposure Rate Calibration" section.
   c) If the meter can be calibrated for both count rate and exposure rate (this would only be the case if the meter responds 1:1 on both the mR/hr and cpm scales), first follow the "Count Rate Calibration" procedure, then proceed to the "Exposure Rate Calibration" section.

I. **Count Rate Calibration**:

1. This calibration method verifies that the instrument's electronics and meter readout are accurate. The electronic pulser provides a known count rate signal to the meter in place of the signal to a detector probe from an actual radiation field. Determine the meter sensitivity by providing an input signal from the pulser, and decreasing the amplitude until no signal is counted by the meter.
2. Slowly increase the amplitude until the meter records the signal. Use the pulser to check the meter's response as close as possible to the 20% and 80% points of each scale or decade (check logarithmic scales at the midpoint of the scale). Mark the pulser input and the meter response on the calibration report.
3. If the meter fails to respond to the pulser, increase the amplitude of the incoming signal. Adjustments to the scale are made with a *tweaker*, or a small flat-head screwdriver, by turning the adjustment pot marked for each scale. If one of the readings on a given scale needs adjustment, check other points on the same scale to determine if further adjustments are needed.
4. If the meter continues to improperly respond to the pulser, increase the high voltage to within the manufacturer's recommendations for the probe.

J. **Exposure Rate Calibration**:

1. Calibrate for exposure rate (mR/hr) at a minimum of two points (as close as possible to 20% and 80% of full scale) on each scale or decade.

2. Obtain the sheet of calculated exposure rates, by entering the current date into the spreadsheet located at h:\saf\instruments\metercal\calwks.xls. The spreadsheet calculates exposure rates at various distances, for each possible combination of attenuators. A chart of commonly used exposure rates and their corresponding settings is provided.
3. Place the detector at a known distance from the ^{137}Cs calibrator, and compare the meter reading to the calculated exposure rate at that distance. (Readings above 1000 mR/hr need not be calibrated).
4. Adjust the potentiometers for each scale to obtain a 1:1 relationship between known and observed exposure rates for both points on each scale. Alternately, a correction factor must be applied to the scales. The correction factor is determined by dividing the known exposure rate by the observed, taken as an average for each scale.
5. The exposure rate must not vary by more than 20% per point on each scale. If a correction factor (other than 1.0) is required, apply this average correction factor before determining if the meter's scales meet these limits.
6. Record the instrument's correction factor on the calibration report and on the calibration sticker, unless it is 1.0 (+/- 10%).
7. Certain instruments, such as Mini-Monitors, cannot be pulsed due to a non-removable cable or internal probe. For these instruments, a modification of the procedure is necessary.

K. **Failed Calibration**:

1. If, after necessary adjustments are made, an instrument fails to respond within ± 20% of the known exposure rates (or the indicated readings on the pulser) at two points on any scale, the calibration is considered to have failed for that scale. If the scale is one that is not likely to be used, the other scales may be calibrated and the meter returned to service if the uncalibrated scale(s) is removed from service according to a lock-out/tag-out procedure.
2. Instruments that fail calibration or cannot be calibrated at GHS will be sent out for service and/or calibration. The instrument will be removed from service through the lock-out / tag-out procedure until it is calibrated.
   a) Types of Malfunction and Action Plan:
      (1) Failed calibration or unable to calibrate: outsource the calibration
      (2) Minor malfunction: Repair in-house and re-calibrate
      (3) Significant malfunction: Return to manufacturer for repair
      (4) Not repairable: Disassemble instrument for spare parts, or remove check source and dispose of instrument.

V. **Determination of Detector Probe Efficiency (as applicable)**:

A. Determine the efficiency for the radionuclide(s) of interest. Use a source of known activity and of similar characteristics to the nuclides of interest.

B. Place the probe at a fixed, known distance from the source. Record the observed count rate (cpm). Determine the counting efficiency by dividing the observed count rate (cpm) by the known activity of the source (dpm) and multiply by 100%.

C. Record the nuclide and efficiency on the calibration sticker and report sheet.

VI. Records:

A. Send a copy of the calibration report to the end user. File the original report in the "Instrument Calibration" file. Files are sorted by: department, instrument, and date. Calibration reports must be maintained for 3 years.

B. Calibration certificates will be maintained in MHP for each meter for 3 years, and will also accompany each calibrated meter upon return to the end user.

C. The calibration sticker affixed to each instrument will contain: date calibrated, date due, HP initials, calibration source used, check source reading, instrument ID (serial number), and any special or limited use conditions.

VII. Document Information:

Devised	Revised	Reviewed
6/7/02	4/30/03 10/6/05 CMA 1/6/06 CMA	4/13/04 4/21/05 RD

Geisinger Health System

Medical Health Physics Radiation Survey Instrument Calibration

Area / Location	Calibration Type
Authorized User	New Instrument ☐ Annual Routine ☐ Following Repair ☐

If instrument has more than one probe: Probe _____ of _____

Date	Due	Make	Model	Serial #	Base Connector
					C BNC MHV None _____

Probe Type	Probe Model	Probe Serial #	Probe Connector	Source Data	
			C BNC MHV None _____		
Calibration Source ☐ Cs-137 ☐ Pulser	Geometry (circle one)	Range	Check Source	Source Type	Cs-137
				Initial Activity Date	February 24, 1994
				Initial Activity, mCi	163.10
Calibrated For ☐ Count Rate ☐ Exposure Rate	List all available scales		☐ Shield Open ☐ Shield Closed ☐ No Probe Shield	Initial mR/hr @ 1m	52.30
				Pulser Mode 500-2	Serial No 177078
				Calibration Date	31-May-2005

Scale Multiplier	Actual	Observed		Correction Factor	Average C.F.	Units
						Radionuclide
						Efficiency
						High Voltage
						Sensitivity
		As Found	As Left	Instrument Correction Factor		

Adjustments, Repairs, Comments (note all deviations from standard operating procedure): _____

Performed by: _____ Date _____

Reviewed by: _____ Date _____

☐ Follow up required
☐ Follow up action completed

Date completed: _____

Geisinger Health System

Portable Radiation Detection Instruments

Medical Health Physics
Phone: 17015
Fax: 49248

Serial Number	Type	Make	Model	Last Calibration	Comment
01F3/506 *	MCA	target	fieldSPEC	11/3/2005	Digital - one scale
04F3/2269 *	MCA	Thermo	identiFIND	11/7/2005	Digital - one scale
100592 *	GM	Ludlum	3	7/13/2005	Lower scales checked 12/2/05
1007-009 *	GM	Dosimeter	3007A	3/25/2005	Lower scales checked 12/2/05
100737	NaI(Tl)	Ludlum	3	9/30/2005	Count rate only
104456 *	GM	Ludlum	3	1/21/2005	Lower scales checked 12/8/05
105666	NaI(Tl)	Ludlum	3	5/5/2005	Count rate only
11161 *	GM	Eberline	E-120	1/21/2005	Lower scales checked 12/2/05
11546 *	Ion Chamber	Keithley	36100	9/30/2005	All scales checked
116906 *	GM	Ludlum	3	9/30/2005	Lower scales checked 12/2/05
1222	NaI(Tl)	RPI	Rad monit	7/13/2005	Count rate only
1248 *	Ion Chamber	Victoreen	451P	4/27/2005	Digital - one scale
12505 *	GM	Eberline	E-120	1/21/2005	Lower scales checked 12/2/05
128742 *	GM	Ludlum	2241-2	12/5/2005	Lower levels checked 12/2/05 (digital)
130289 *	GM	Ludlum	3	1/21/2005	Lower scales checked 12/2/05
133464 *	GM	Ludlum	3	9/30/2005	Lower scales checked 12/2/05
136715 *	GM	Ludlum	3	1/21/2005	Lower scales checked 12/2/05
144634 *	GM	Ludlum	3	5/5/2005	Lower scales checked 12/15/05
150285 *	GM	Ludlum	3	5/5/2005	Lower scales checked 12/2/05
153421 *	GM	Ludlum	3	6/30/2005	Lower scales checked 12/2/05
159253 *	GM	Ludlum	3	9/30/2005	Lower scales checked 12/2/05
161465 *	GM	Ludlum	3	7/13/2005	Lower scales checked 12/5/05
171969 *	GM	Ludlum	3	1/7/2005	Lower scales checked 12/2/05
182434 *	GM	Ludlum	3	3/28/2005	Lower scales checked 12/8/05
207363 *	GM	Ludlum	3	12/7/2005	Lower scales checked 12/2/05
2083 *	GM	Victoreen	491	10/21/2005	Lower scales checked 12/2/05
23577 *	GM	Ludlum	3	2/4/2005	Lower scales checked 12/2/05
2766 *	GM	Victoreen	491	1/21/2005	Lower scales checked 12/2/05
2795 *	GM	Johnson	GSM-505DP	1/26/2005	Lower scales checked 12/2/05
300 *	GM	Picker	655-188	1/7/2005	Lower scales checked 12/2/05
3064 *	GM	Victoreen	491	2/4/2005	Lower scales checked 12/2/05
31882	GM	Ludlum	177	2/3/2005	Count rate only
3323 *	GM	Victoreen	489-35	10/20/2005	Lower scales checked 12/2/05

** Exposure Rate (mR/hr) calibration required*

Serial Number	Type	Make	Model	Last Calibration	Comment
39090 *	GM	Lionel	CDVB-700 6b	11/16/2005	Lower scale checked 12/5/05
39226 *	GM	Ludlum	3	10/17/2005	Lower scales checked 12/8/05
40999 *	GM	Lionel	CDV-700 6b	11/16/2005	Lower scale checked 12/5/05
412	GM	Eberline	RM21-1	6/30/2005	Count rate only
42428	GM	Mini-Monitor	900	9/30/2005	Count rate only
4791 *	Ion Chamber	chnical Associat	TBM-IC	12/9/2005	Do not use 0.1 scale
48843	GM	Mini-Monitor	900	6/30/2005	Count rate only
49885	Beta Scintillator	Ludlum	3	1/7/2005	Count rate only
51894 *	Ion Chamber	Keithley	36100	9/30/2005	All scales checked
5741 *	GM	Radiation Alert	Inspector	2/4/2005	Lower level checked 12/15/05 (digital)
6477 *	Ion Chamber	Inovision	451P	7/13/2005	Digital - one scale
66801 *	GM	Ludlum	3	5/5/2005	Lower scales checked 12/2/05
71085 *	GM	Ludlum	3	12/15/2005	Lower scales checked 12/2/05
8712-1401	GM	Nucleus	500	10/18/2005	Count rate only
88342 *	GM	Ludlum	3	1/21/2005	Lower scales checked 12/2/05
C517 *	GM	Victoreen	5-571	7/13/2005	All scales checked
C569 *	GM	Victoreen	05-571	7/13/2005	All scales checked
C582 *	GM	Victoreen	05-571	1/7/2005	All scales checked
I585C *	GM	Bicron	Surveyor 2000	11/21/2005	Lower scales checked 12/5/05
L0002478 *	Ion Chamber	Mini-Monitor	Smartion	9/30/2005	Digital - one scale

** Exposure Rate (mR/hr) calibration required*