

SB
SmithKline Beecham
Clinical Laboratories

November 7, 1996

Mr. James M. Bondick
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Bondick:

I am writing to follow up on the questions which remained after your recent inspection of our facility. Kathleen Sellon, the Facilitator of the Serology/Immunology Department, and Ted Freedman, our Radiation Safety Officer, were both back in the laboratory on November 4, and I was able to review the findings with them at that time.

1. Survey Meter Calibrations from 1991-present

Certifications from the vendor we use are enclosed for 1990 through 1995. (See attachments A-1 through A-6.) Mr. Freedman advised me that he has not yet sent the meter out for calibration this year and he will do so shortly.

2. Radiation Safety Training Records for 1993-1995

The former Department Supervisor, Eugenia Lenz, conducted radiation safety training during her regular staff meetings. I have attached a signature sheet showing those who attended a session in 1993 and meeting minutes from 1994 and 1995 documenting the items discussed. (See attachments B-1 through B-3.)

3. Missing Wipe Test Records for Certain Periods in 1992 & 1993

The record book is the only place these wipe tests would be recorded; therefore, we conclude that tests were probably not performed for the dates involved.

4. Wipe-Testing of Incoming Packages Containing more than 250 μ Ci

The shipments we receive now contain 12 kits with 16 μ Ci of Iodine-125 per kit for a total of 192 μ Ci. Therefore, the requirement to perform a wipe test would not apply. The

**RETURN ORIGINAL TO
REGION I**

9611260040 961118
PDR ADOCK 03004721
C PDR

NOV 12 1996

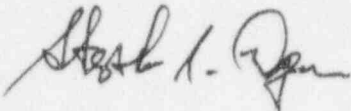
last time we received a shipment with more than 250 μ Ci was 4/25/96.

Other items:

- I reviewed the calculations in our log book regarding the disposal of isotope into the sanitary sewer system, and the units were incorrect. I revised the instructions and the calculations going back to 1993, and copies of this information are also enclosed. (See attachments C & D.)
- As you recommended, we have posted the sink where we wash tubes with yellow radiation-warning tape.
- Mr. Freedman confirmed that our wipe testing does routinely include the compactor which you inspected during your visit.
- You indicated that our wipe-test data should be expressed as DPM, not CPM. The efficiency of our counting equipment is 80-85%. Would you recommend that we routinely convert the CPM values to DPM's using the known efficiency of the counters?

Thank you for taking time to perform a very thorough and helpful review of our operation. I look forward to receiving your final report.

Sincerely,



Stephen M. Dungan, Ph.D.
Director of Operations

cc: K. Sellon, SIA Department Facilitator
E. Freedman, Radiation Safety Officer
N. McKendry, General Manager

A-1

NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS

CALIBRATION CERTIFICATE

Customer Smith Kline Bio Sci. Probe Type 44-3 Scint.
Instrument Model Ludlum 3 Serial No. -----
Serial No. 25899 Calibration Date 9-17-90

Calibration Source I-129
Quantity .101 uCi (equiv. to .080 uCi, I-125)
Mfgs. No. NES 9033
NBS Traceable No. SRM-4949
Date 7-22-76
Activity 177,600 DPM.

Calibration:

I-129 on window contact = 45,000 CPM.
Efficiency = 25.34 %

I-129 on even plane with probe end = 40,000 CPM.
Efficiency = 22.5 %

I-129 @ 1cm distance from window = 16,500 CPM.
Efficiency = 9.29 %

Background, unshielded = 300-380 CPM.

High voltage set at 810 Volts.

Electronic pulse calibration X

Instrument Check Source: Reading -----
Range -----

Comments:

Calibrated by Carl F. Bousari U.S.NRC. License No. 20-16972-01

35 Grove Street - P.O.Box 178 - Rockland, MA. 02370 - Tel. Area Code 617 - 878-6878

NUCLEAR / radiation detection products / instrument services / accessories / supplies

A-2

NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS

CALIBRATION CERTIFICATE

Customer Smith Kline Lab.s Probe Type 44-3 Scint.
Instrument Model Ludlum 3 Serial No. -----
Serial No. 25879 Calibration Date 9-24-91

Calibration Source I-129
Quantity .101 uCi (equiv. to .080 uCi, I-125)
Mfgs. No. NES 9033
NBS Traceable No. SRM-4949
Date 7-22-76
Activity 177,600 DPM.

Calibration:

I-129 on window contact = 50,000 CPM.
Efficiency = 28.15 %
I-129 on even plane with probe end = 40,000 CPM.
Efficiency = 22.5 %
I-129 @ 1cm distance from window = 16,000 CPM.
Efficiency = 9.0 %
Background, unshielded = 300-380 CPM.
High voltage set at 810 Volts.
Electronic pulse calibration X
Instrument Check Source: Reading -----
Range -----

Comments:

Calibrated by Carl J. Bouari U.S. NRC. License No. 20-16972-01

65 Grove Street - P.O. Box 178 - Rockland, MA. 02370 - Tel. Area Code 617 - 878-6878

NUCLEAR / radiation detection products / instrument services / accessories / supplies



NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS
U.S.N.R.C. Lic.#20-16972-01

REG. NO. 10995-1

A-3

INSTRUMENT EFFICIENCY CERTIFICATION

Customer SmithKline Beecham Date Performed 10-7-92
Instrument Mfg. Ludlum Detector Mfg. Ludlum
Instrument Model 3 Detector/Type 44-3 / SCINT
Serial No. 25879 Serial No.

Calibration Source	I-129
Quantity	.101 uCi (equiv. to .080 uCi I-125)
Mfgs. No.	NES 9033
NBS Traceable No.	SRM-4949
Date	7-22-76
Activity	176,000 DPM.

Efficiency Factors:

I-129 on window contact = 50,000 CPM.
Efficiency = 28.4 %

I-129 on even plane with probe end = 39,000 CPM.
Efficiency = 22.2 %

I-129 @ 1 cm distance from window = 16,000 CPM.
Efficiency = 9.1 %

Background, unshielded = 320 - 400 CPM.

High Voltage set at 810 Volts.

Electronic pulse check ✓ (All ranges)

Instrument Check Source: Reading
Range

Comments:

Calibrated By Carl F. Bonari

65 Grove Street - P.O. Box 178 - Rockland, MA. 02370 - Tel. Area Code 617 - 878-6878

NUCLEAR / radiation detection products / instrument services / accessories / supplies



NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS

REG. NO. 11594-1

A-4

CALIBRATION CERTIFICATE

Customer Smith Kline Calibration Date 10-27-93
Instrument Mfg. Ludlum Detector Mfg. Ludlum
Instrument Model 3 Detector/Type 44-3/Scint.
Serial No. 25879 Serial No. -----

Calibration Source I-129
Quantity .101 uCi (equiv. to .080 uCi I-125)
Mfgs. No. NES 9033
NBS Traceable No. SRM-4949
Date 7-22-75
Activity 176,000 DPM.

Calibration:

I-129 on window contact = 45,000 CPM.
Efficiency = 25.6 %

I-129 on even plane with probe end = 38,000 CPM.
Efficiency = 21.6 %

I-129 @ 1 cm distance from window = 14,000 CPM.
Efficiency = 7.9 %

Background, unshielded = 360-410 CPM.

High Voltage set at 815 Volts.

Electronic pulse calibration X (All ranges)

Instrument Check Source: Reading -----
Range -----

Comments:

Calibrated By Carl J. Bouari U.S.NRC License No. 20-16972-01

65 Grove Street — P.O. Box 178 — Rockland, MA. 02370 — Tel. Area Code 617 - 878-6878

NUCLEAR / radiation detection products / instrument services / accessories / supplies



NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS
U.S.N.R.C. Lic.#20-16972-01

INSTRUMENT EFFICIENCY CERTIFICATION

REG. NO. 12165-1

Customer Smith Kline Beecham Date Performed 10-20-94
Instrument Mfg. Ludlum Detector Mfg. Ludlum
Instrument Model 3 Detector/Type 44-3/Scint.
Serial No. 25879 Serial No. -----

Calibration Source I-129
Quantity .101 uCi (equiv. to .080 uCi I-125)
Mfgs. No. NES 9033
NBS Traceable No. SRM-4949
Date 7-22-76
Activity 176,000 DPM.

Efficiency Factors:

I-129 on window contact = 45,000 CPM.
Efficiency = 25.0 %

I-129 on even plane with probe end = 39,000 CPM.
Efficiency = 22.2 %

I-129 @ 1 cm distance from window = 14,000 CPM.
Efficiency = 8.0 %

Background, unshielded = 360-420 CPM.

High Voltage set at 820 Volts.

Electronic pulse check X (All ranges)

Instrument Check Source: Reading -----
Range -----

Comments:

Calibrated By Carl J. Borsari U.S.NRC License No. 20-16972-01

65 Grove Street - P.O. Box 178 - Rockland, MA 02370 - Telephone: (617) 878-6878
NUCLEAR / radiation detection products / instrument services / accessories / supplies
-- GEIGER TUBES --



NUCLEAR INSTRUMENT CO.
ROCKLAND, MASSACHUSETTS
U.S.N.R.C. Lic. #20-16972-01

REG. NO. 12542-1

A-6

INSTRUMENT EFFICIENCY CERTIFICATION

Customer Smith Kline Beecham Date Performed 7-7-95
Instrument Mfg. Ludlum Detector Mfg. Ludlum
Instrument Model 3 Detector/Type 44-3/Scint.
Serial No. 25879 Serial No. PR-063842

Calibration Source I-129
Quantity .101 uCi (equiv. to .080 uCi I-125)
Mfgs. No. NES 9033
NBS Traceable No. SRM-4949
Date 7-22-76
Activity 176,000 DPM.

Efficiency Factors:

I-129 on window contact = 48,000 CPM.
Efficiency = 27.3 %

I-129 on even plane with probe end = 39,000 CPM.
Efficiency = 22.2 %

I-129 @ 1 cm distance from window = 16,000 CPM.
Efficiency = 9.1 %

Background, unshielded = 400-450 CPM.

High Voltage set at 760 Volts.

Electronic pulse check ✓ (All ranges)

Instrument Check Source: Reading
Range

Comments:

Calibrated By Carl F. Boriani

65 Grove Street - P.O. Box 178 - Rockland, MA 02370 - Telephone: (617) 878-6878
NUCLEAR / radiation detection products / instrument services / accessories / supplies
— GEIGER TUBES —

Memo

B-2

To: SIA Staff

cc: S. Dungan

From: Genia Lenz *Genia*

Date: July 28, 1994

Re: Minutes of July 22 Department Meeting

- ✓ 1. Radiation Safety - JoAnn discussed this topic which included the following:
 - a. Survey Meter(Geiger Counter) - use to monitor spills, benches and reagent boxes/bottles. Biohazardous waste boxes must be surveyed upon closure. Record that this was done in the Isotope book and put a check mark on the box.
 - b. Spills - wipe up liquid, cover with dry Contrad, allow to absorb, wipe up, wash with water and perform wipe test. Read unused paper in the gamma counter as background. Read paper used to wipe area. Results must be less than three times the background counts to be considered clean. Record spill and cleanup in the Isotope book.
 - c. Isotopes received must be recorded in the log book. Kits must be put in refrigerator labeled radioactive.
 - d. Wipe test must be performed and recorded monthly according to the map in the log book.
 - e. Bench tops must be read with the survey meter weekly and results recorded in the log book.
2. Address changes - I made reference to the attached memo and emphasized the need to ensure that your address is correct. Your benefits packages will be mailed out shortly and it is important that this information is right.
3. HCG's for Hartford Center for Clinical Research - I notified you that we will be receiving specimens from this account which need to be resulted by 6:30 am. The specimens will be coming on Monday and Thursday for the next three weeks and will be ordered as STAT's. There is no need to call the results as long as they are resulted by 6:30.
4. QA Review of Corrective Action Forms - We reviewed recent corrective actions and thought of ways to avoid similar problems in the future.
 - a. Hepatitis C antibody - key steps include wearing clean gloves at all steps, bringing all reagents to room temperature prior to use, priming dispensers just before use (do not leave reagent in tubing for extended period), discarding conjugate daily, discarding controls whenever a new kit is opened.
 - b. AFP - discard diluent whenever a new kit is opened.

Message :85 of 90
From :WMEL01, LENZ,EUGENIA (BOSTON)
Subject :MINUTES OF 8/4/95 DEPT MEETING
Date/Time :08/08/95 10:04 AM
CC. :RI,WMSD02,

B-3a

1. TOPLAB passwords are due to expire on 8/28. Please change your password on or before this date. If you do not change it, you will get an annoying message to change it for 10 days until it expires. As a reminder, you change your password by entering your old password (comma) new password. Password altered will appear on the screen. If for any reason, your new password does not work the next time you sign on, please contact either Karen Field or Mary Fitzpatrick and they will put in a prompt to change your password.

2. TOPLAB 95 version 2 will be loaded into our system on Sunday 8/13. Changes mostly involve labels. I will order a few tests to see what the labels look like and to make sure the instruments can still read them. Due to a lack of time and resources, this is the only testing we will do.

3. Radioactive shipments - please make sure to log all shipments into the isotope log book. This is a regulation for both CLIA and NRC. Even if there is not time to unpack the reagents, please ensure that the radioactivity received is logged in the book. If you have questions about the log book, please see JoAnn or me.

4. ACS:180 - many more tests will be converted with a target date of 10/1. Since this will have a major impact on your next rotation of tests, I will check with Steve to see if I can share the list with you. If I cannot, then training should proceed as if this conversion were not going to happen.

5. CA125 II - we have received the validation package and the correlation specimens from St. Louis. Donna ordered one kit and will make sure the specimens get run. The date for conversion will be 9/5, since the kits we have expire on 9/4.

6. Teams - please consider how you would like to see the structure change, if at all. This may involve team members, test mix, both or neither.

7. IE4 Comprehensive - I will work with Steve and Sales to phase this test out and to provide clients with clear instructions on how to order all immuno tests (including SCAN's and IFIX). Perhaps we can develop a quick reference for them to look at before ordering tests.

8. Prenatal profiles - some accounts (Dr. Roberts in particular) are still ordering Profile 5269, which does not include Rh. I will notify Diane Taluti to remove it from the req and to have the req's replaced by the Account Manager.

9. Qualitative HCG's - the only test code which should be used is the Z code. Please change the SB to Z by doing a change order (3,1,C). However, if the Z code is part of a profile, then the Z code must be added and the SB code must be cancelled by entering TNP/ND* (return) Result to follow.

10. Team I has decided to change the production schedule for AFP to Tues/Thu Sat. This will, hopefully, help make Mondays more manageable.

11. Printers and the early morning crunch - I will submit a capital request to replace P191, which always seems to be breaking.

12. TECAN program for the DNA probes has not arrived yet. I will call St. Louis to find out if there is a problem.

13. STAT light - whenever you see this light flashing, please go down to Tox and pick up the specimens. When you return to the lab, please turn off the

to replace P191, which always seems to be breaking.

B-3b

12. TECAN program for the DNA probes has not arrived yet. I will call St. Louis to find out if there is a problem.

13. STAT light - whenever you see this light flashing, please go down to Tox and pick up the specimens. When you return to the lab, please turn off the light. If the light does not get turned off, we will not know if/when subsequent specimens are sent up.

✓ 14. Radioactive tubes and bottles - make sure to discard these in the red biohazard boxes, not the yellow radioactive barrels. These barrels are for radioactive paper and for those bottles and tubes which still have high counts of radioactivity.

15. Movable bench in immuno area - due to a lab accident which involved Debby last week, we will be replacing the movable bench with the 8-foot bench which was formerly used for filing. This will give more space and it will also eliminate the risk of another accident. We will look into removing the wheels from the movable bench, so that we will be able to use that bench as well.

16. I have asked Donna to order an additional CRT to add to the Hepatitis/Immuno area.

17. Progesterones - the new tracer should arrive with the next shipment. Correlation between the two methods was 99%.

18. Client Service Reminder - please pull and resolve all pending lists for all tests on your bench daily. Worklists beginning with RI appear to fall through the cracks most frequently, so please indicate on the SB worklist summary which other worklists are included in the package. This will alert the releasing tech to look for more worklists to release.

19. Next meeting - Friday 8/12 at 7:00 AM. I will try to get Steve to attend (end)

=====

Message :06 of 90
From :WMMH02, HAFEY, MARY (BOSTON)
Subject :SPECIMEN PROCESSING UPDATE
Date/Time :08/08/95 12:41 AM
CC. :AU, TX, HC, MB, RI,

WE ARE STILL AWAITING THE ARRIVAL OF THE UNISHIP ROUTE.
THERE ARE 2 ON STD, 2 ON VACATION AND 2 OPEN POSITIONS.
WE WILL MAKE AN ANNOUNCEMENT WHEN THIS ROUTE ARRIVES. IF ANYONE HAS
SOME TIME PLEASE COME AND ASSIST US.
THE APPROXIMATE COMPLETION TIME WILL ALSO BE ANNOUNCED WHEN WE SEE
THE VOLUME OF WORK IN THIS ROUTE.
(end)

=====

Message :07 of 90
From :WMEF01, FREEDMAN, EDWARD (BOSTON)
Subject :CRT
Date/Time :08/08/95 6:20 AM
CC. :WMHELP, WMEL01,

WE HAVE A CRT DOWN IN SIA. WE WOULD APPRECIATE REPAIR WHEN YOU HAVE A CHANCE.
. THANK YOU
(end)

=====

Disposal of Iodine 125 via the Sanitary Sewer System

The average percent binding of all tests performed in the SIA Department is 35%. The bound waste is stored on-site for decay to background levels (10 half-lives). The 65% unbound portion is discarded into the sanitary sewer system.

Calculation of Total Isotope Discarded per Day:

There are 21 business days in the average month. Divide the total microcuries discarded by 21 to obtain microcuries discarded per day.

Calculation of Concentration of Isotope Discarded after Dilution:

The average monthly water usage in the lab is 40,000 cubic feet or 1.132688×10^9 mL. Thus the effective concentration of isotope in the sanitary sewer effluent is calculated as follows:

$$\frac{\text{total microcuries discarded per month}}{1.132688 \times 10^9}$$

The result of this calculation will be the effective concentration in microcuries per mL in the sanitary waste stream.

DISPOSAL OF RADIOACTIVE WASTE THROUGH THE SANITARY SEWER SYSTEM

Year	Month	Total microcuries	Microcuries/day	Microcuries/mL
1993	Jan	1214	58	1.07179E-06
	Feb	1335	64	1.17861E-06
	Mar	1996	95	1.76218E-06
	Apr	2180	104	1.92463E-06
	May	691	33	6.10053E-07
	June	1617	77	1.42758E-06
	July	1230	59	1.09298E-06
	Aug	1107	53	9.77321E-07
	Sept	1610	77	1.4214E-06
	Oct	707	34	6.24179E-07
	Nov	726	35	6.40953E-07
	Dec	1275	61	1.12564E-06
1994	Jan	1040	50	9.1817E-07
	Feb	983	47	8.67847E-07
	Mar	732	35	6.4625E-07
	Apr	1235	59	1.09033E-06
	May	1013	48	8.94333E-07
	June	1609	77	1.42051E-06
	July	968	46	8.54604E-07
	Aug	510	24	4.50256E-07
	Sept	1096	52	9.6761E-07
	Oct	421	20	3.71682E-07
	Nov	1030	49	9.09341E-07
	Dec	809	39	7.1423E-07
1995	Jan	1174	56	1.03647E-06
	Feb	625	30	5.51785E-07
	Mar	855	41	7.54842E-07
	Apr	1086	52	9.58781E-07
	May	728	35	6.42719E-07
	June	713	34	6.29476E-07
	July	590	28	5.20885E-07
	Aug	997	47	8.80207E-07
	Sept	652	31	5.75622E-07
	Oct	439	21	3.87574E-07
	Nov	849	40	7.49544E-07
	Dec	814	39	7.18644E-07
1996	Jan	568	27	5.01462E-07
	Feb	785	37	6.93042E-07
	Mar	812	39	7.16879E-07
	Apr	897	43	7.91922E-07
	May	1107	53	9.77321E-07
	June	257	12	2.26894E-07
	July	192	9	1.69508E-07
	Aug	192	9	1.69508E-07
	Sept	240	11	2.11885E-07
	Oct		0	0
	Nov		0	0

FEB 12 1993

1/93

Safety -
Waste Disposal - Radioactive + PPC/CA125 liquid

Edward Freeman

Glenn Savoy
Tam Matyski

John Pham

Mina Barsby

Eva Bugiewicz

BK Chandra Sekhar

Et Clement

Barbara Aisenault

Kathy Sellen

John St.

Valerie Dugley

Celia Perez

Terry Dacey

Andy White

12/93