

MAY 16 1994

Docket No. 030-19354

License No. 29-20513-01

Deborah Research Institute
ATTN: Joseph R. Manni
Administrator
Trenton Road
Browns Mills, NJ 08015-1799

Dear Mr. Manni:

SUBJECT: ROUTINE INSPECTION NO. 030-19354/94-001

This letter refers to your April 18, 1994 correspondence, in response to our March 23, 1994 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

No reply to this letter is required. Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

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RETURN ORIGINAL TO
REGION I

1507

bcc:
Region I Docket Room (w/concurrences)

DRSS:RI
Dolce/cmm

4/28/94

DRSS:RI
Mann

4/28/94

DRSS:RI
Shanbaky

5/16/94

Deborah
Research Institute



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Joseph R. Manni
Administrator

April 18, 1994

Mohamed M. Shanbaky, Chief Research and Development Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Routine Inspection No. 030-19354/94-001
License No. 29-20513-01
Docket No. 030-19354

Dear Mr. Shanbaky:

Thank you very much for your letter of March 23, 1994, concerning the routine inspection of the Deborah Research Institute conducted on February 22, 1994, by David Mann and Kathleen Dolce.

As required, please accept this as the "Reply to a Notice of Violation" as indicated in Appendix A of the above mentioned letter. These issues are addressed specifically to note the reason for the violation, corrective steps taken or to be taken, and dates of compliance.

1) **VIOLATION:** "Item 7 of the application dated November 28, 1986, indicates that John Bianchi, Ph.D. will be the Chief Radiation Protection Officer (RPO). Contrary to the above, between May 1990 and February 1991, John Bianchi, Ph.D. was not the Chief RPO. Specifically, John Bianchi was not employed by the licensee during this time period."

REASON: Oversight on the part of Deborah Research Institute in the time frame of May 1990, not to amend the license to delete John Bianchi, Ph.D. as RPO and add Jiang Gu, M.D., Ph.D., as the Chief RPO.

CORRECTIVE ACTION: Jiang Gu, M.D., Ph.D., is listed on the current license for Deborah Research Institute as the Chief RPO. Additionally, internally three other individuals have been identified and trained to act as RPO in the absence of Dr. Gu; Dr. Xenachis, Dr. Smith, and Dr. Locke. The administration of the Institute is fully aware of the obligation to immediately inform the NRC and amend its license in the event that Dr. Gu no longer fulfills the role of Chief RPO.

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APR 22 1994

COMPLIANCE DATE: On or about February, 1991.

- II) VIOLATION: "Item 10.1 (Section B, No. 12) of the application dated April 27, 1992, requires the Radiation Protection Officer (RPO) to maintain an inventory of all radioisotopes at the institution and limit the quantities of radionuclides at the institution to the amounts authorized by the license. Contrary to the above, as of February 22, 1994, the RPO did not maintain an inventory of all radioisotopes at the institution. Specifically, the RPO did not provide a total of radioactive material at the institution."

REASON: Oversight on the part of Deborah Research Institute to not adequately maintain inventory records for all radioisotopes during the time period March 1989 to October 1991.

CORRECTIVE ACTION: An inventory of all radioisotopes and the total quantity in the Institute has been maintained jointly by the RPO and the Purchasing Department of the Institute since October 1991 (Attachment 1). This manual record keeping system can be validated against actual purchase orders, receiving documents, and paid invoices. Additionally, inventories are provided by each lab that use radioisotopes to the RPO, including amounts in decay, and are maintained in the RPO'S office. Since the previous routine inspection by the NRC in March 1989, only ³⁵S, ³²P, trace amounts of ¹⁴C and ¹²⁵I, have been used. Close attention is given to the total amounts of radioisotopes possessed by the Institute to assure that at all times we remain below the maximum allowed limit. Documentation of inventories and quantities shall continue, improving whenever and however necessary, and shall remain on file at all times.

COMPLIANCE DATE: On or about October 1991.

- III) VIOLATION: "Item 10.2 (Sections A and B) of the application dated April 27, 1992 and Item 10.2 (Sections A and B) of the letter dated May 5, 1993, requires individuals to be informed on the basic knowledge about radioactive materials, working around radioactive materials, the meaning of signs and labels, restricted areas, safety precautions, radiation physics, basic principles in radiation protection, measurement of radioactivity, radiation biology and comparative risk of low level radiation, radiopharmaceutical chemistry, procedure manual for handling radioactive materials and where and how to obtain assistance before starting to work with radioactive materials. Contrary to the above, as of February 22, 1994, individuals were not informed on the basic knowledge about radioactive materials, working around radioactive materials, the meaning of signs and labels, restricted areas, safety

precautions, radiation physics, basic principles in radiation protection, measurement of radioactivity, radiation biology and comparative risk of low level radiation, radiopharmaceutical chemistry, procedure manual for handling radioactive materials and where and how to obtain assistance before starting to work with radioactive materials. Specifically, a researcher working in the Molecular Biology Laboratory stated, that she never received radiation safety training prior to working with radioactive materials at the licensee's facility."

REASON: Oversight on the part of the Deborah Research Institute to adequately document radiation safety training for new employees, and on-going radiation safety training for existing employees, eventhough radiation safety training programs were routinely conducted.

CORRECTIVE ACTION: Annual radiation safety training for all employees is routinely conducted at the Institute and documentation of such, including an attendance sheet, will be better maintained. These training programs are presented by a qualified individual and cover all required issues as mentioned in the violation. Employees not in attendance at the regular training session will be required to make-up the program at their earliest possible convenience or within thirty days. New employees, within their first two days of employment, and before working in any laboratory, undergo a complete radiation safety training orientation given by the RPO. The researcher referred to above that works in the Molecular Biology Laboratory was given a formal radiation training session on February 23, 1994 (Attachment 2), and the entire staff was presented with a program on March 23, 1994 (Attachment 3). All documentation will be on file in the office of the RPO.

COMPLIANCE DATE: Formal and complete compliance with radiation safety training documentation effective February 23, 1994, for all existing and new employees.

- IV) **VIOLATION:** "Item 10.5 (Section entitled: Surveys of Laboratories Using Radioactive Materials) of applications dated April 27, 1992, November 28, 1986, and letters dated May 5, 1993 and December 8, 1992, require that a radiation survey be performed and recorded at least once a month in areas where radioactive materials are used. The RPO requires a weekly survey in laboratories using radioactive materials daily and a survey at the end of each procedure involving millicurie amounts of radionuclides. Contrary to the above, prior to November 11, 1991, the licensee did not perform nor record radiation surveys at least once a month in areas where radioactive materials are used. Specifically, between March 1989 and November 1991, surveys of laboratories where RAM was used were not performed on a monthly basis as required."

REASON: Oversight on the part of the Deborah Research Institute to adequately perform wipe tests and complete monthly surveys in laboratories where radioactive materials were used between March 1989 and November 1991.

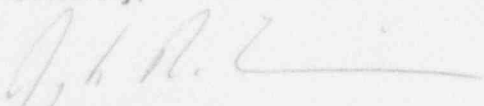
CORRECTIVE ACTION: Laboratory surveys, including wipe tests, are performed on a monthly or weekly basis as indicated by radioactive materials usage. This program is enforced and maintained by the RPO and on file in his office and in each individual laboratory.

COMPLIANCE DATE: On or about January 1992.

We hope that our actions and responses satisfy and abate the violations noted by your inspection. We greatly appreciate the time and information Mr. Mann and Ms. Dolce afforded us. Their comments and concerns have made it possible for us to better our radioisotope program and ensure the safety of our employees and our community. We take our involvement with radioactive materials and our responsibility of holding an NRC license very seriously. A Radiation Consultant, Diana Stockdale, M.S., is on an annual retainer with our facility to help guide us through the requirements and regulations.

Once again, thank you. If there are any questions regarding the above please do not hesitate to contact me.

Sincerely,



Joseph R. Manni
Administrator

cc: Jiang Gu, M.D., Ph.D., Radiation Protection Officer
Deborah Research Institute

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Enclosures

P6669	12/10	S35 DATP	250 uCi
P6635	1/21	S35 DATP	250 uCi
P6556	10/22	S35 DATP	250 uCi
P6689	12/24	RIK-9103	
P6677	12/11	RIK-9103	
P6655	11/27	^{new} RIK-9103	

1491

No radioisotope was purchased between March 1989 to October 1991 except trace amount (1.5 μ Ci) of 125 I comes with the RIA kit and trace amount of 14 C.

1992

P.D.	Date	Item	Vendor	Qty.	Dept.
6744	V10	DATP S35	Amersham	250 uci	400
6744	V10	ATP P32	"	"	"
6824	2/24	DATP S35	"	"	"
6864	2/25	DATP S35	"	"	"
6796	V29	RIK 9103 I125		2x1.5 uci	300
6748	V13	RIK 9103 I125		1x1.5 uci	300
6917	3/17	DATP S35	Amersham	250 uci	400
6974	4/8	DATP S35	"	"	"
6974	4/8	ATP P32	"	"	"
7101	5/14	ATP P32	"	250 uci	"
7101	5/14	RPA.509 I125	"	} .003 mei	200 Tan
7101	5/14	RPA.525 I125	"		200 Tan
7120	5/27	DATP S35	"	250 uci	400
7235	7/15	DATP S35	"	250 uci	"
7344	8/27	ATP P32	"	250 uci	"
7463	10/8	DATP S35	"	250 uci	"
7463	10/8	ATP P32	"	250 uci	"
7485	10/15	ATP P32	"	250 uci	"
7514	10/21	ATP P32	"	500 uci	"
7533	1/4	Carbon 14 L-Proline	"	250 uci	300
7663	12/11	YATP P32	"	250 uci	400
7687	12/14	DATP S-35	"	250 uci	400
7945	2/19/93	DATP S-35	"	250 uci	400
7991	3/4/93	DCTP P-32	"	250 uci	400
8072	3/25/93	NEK-CO1 S-35	NEU	5 mei	200 marinus
8135	4/6/93	PB10218 P-32	Amersham	250 uci	400
8191	4/20/93	SJ1304 S-35	"	250 uci	400
8166	4/23/93	PB10207 P32	"	250 uci	Goldenthal
8099	4/5/93	PB10218 P32	"	250 uci	400
8099	4/5/93	SJ1304 S35	"	250 uci	400

P.O.	Date	Item	Vendor	Qty	Dept.
7654	12/11/93	P32	Amersham	250 uci	400
7817	1/25/93	P32 ATP	"	250 uci	400
8051	3/22/93	RPA.525 GMP Assay	"	1,100 nci	200 Tan
8284	5/24/93	S35	"	250 uci	400
8298	5/26/93	S35	Promega Biotec	10 uci	No Isotope in Kit
8390	6/21/93	P32 DCTP	Amersham	250 uci	400
8468	7/19/93	S35 DATP	Amersham	250 uci	400
8474	7/20/93	P32 ATP _g	"	205 uci	500 marine
8553	8/10/93	S35 DATP	"	250 uci	400
"	"	P32 DCTP	"	250 uci	400
8586	8/16/93	P32 DCTP	"	250 uci	400
8672	9/10/93	P32 DCTP	"	250 uci	400
8728	9/24/93	P32 DCTP	"	250 uci	400
8756	10/1/93	P32 ATP	"	250 uci	500 marine
8792	10/8/93	P32 DCTP	"	250 uci	400
8792	10/8/93	S35 DATP	"	250 uci	400
8850	10/25/93	P32 DCTP	"	250 uci	400
P8904	11/5/93	P32 DCTP	"	250 uci	500
8929	11/11/93	S35 DATP	"	250 uci	400
8989	12/1/93	P32 ATP	"	250 uci	500
9008	12/8/93	S35 DATP	"	250 uci	400
9015	12/10/93	32P DCTP	"	250 uci	400
9077	12/28/93	S35 DATP	"	250 uci	400
9091	12/29/93	P32 ATP	"	250 uci	400
9151	1/11/94	P32 ATP	"	250 uci	500 marine
9186	1/19/94	CHK Chloramphenicol	"	50 uci	400
9200	1/20/94	P32 ATP	"	250 uci	500 marine
9220	1/27/94	P32 ATP	"	250 uci	500 marine
9280	1/14/94	P32 ATP	"	250 uci	500 marine

1994

PO.	Date	Item	Vendor	Qty	Dept.
9327	2/24	P32	Amersham	250uci	500 marine
9360	3/4	P32	"	250uci	500 "
9442	3/23	P32	"	250uci	400 Party
9448	3/24	P32	"	250uci	400 "
9454	3/25	P32 ATP	"	250uci	500 marine
"	"	P32 DTP	"	250uci	500 "
9512	4/8	P32 ATP	"	250uci	500 "

Deborah Research Center
Inventory of Radioactive Waste Freezer

Date: September 14, 1993

Container Number	Radionuclide	Activity	Date Placed in Storage	Total Activity In Container
A	Urinal Acetate	5%		Unknown
B	H-3	25 uCi 10 uCi		35 uCi
C	C-14	10 uCi 12 uCi 10 uCi 10 uCi 10 uCi 10 uCi 20 uCi	7/29/93 10/18/92 11/18/92 11/13/92 6/15/92 7/27/92 9/14/92	82 uCi
D	S-35	500 uCi 500 uCi	2/18/92 11/21/91	1000 uCi
E	S-35	1 uCi 10 uCi 350 uCi 500 uCi	10/5/92 7/12/90 4/24/92 9/14/92	861 uCi
F	C-14	50 uCi	4/26/93	50 uCi
G	P-32	300 uCi 150 uCi 250 uCi 300 uCi 300 uCi	6/30/93 11/21/92 4/24/92 9/14/93	1300 uCi
H	I-125	35 uCi	4/24/93	35 uCi

DEBORAH RESEARCH INSTITUTE
Browns Mills, N.J. 08015-1799

MEMORANDUM

TO: Candyce I. Smith, Ph.D., Research Associate

FROM: Jiang Gu, M.D., Ph.D., Chairman, Scientific Affairs *J.G.*

DATE: February 23, 1994

SUBJECT: One on One Radiation Safety Inservice

This is to summarize the one on one radiation safety inservice that we had this morning. During the inservice, we went through our radiation safety protocol and discussed different steps to carry out the program relevant to Molecular Biology. We had a question and answer session and a number of points have been clarified.

I sent you a memo on January 26, 1994, indicating that the GM counter in your lab needed to be repaired or replaced immediately. You changed the battery of the counter but this meter was still not working properly. This was pointed out as a concern by the NRC inspectors during their inspection. I have removed the geiger counter from your lab and am making arrangements to buy a new one. Meanwhile, you may borrow the one in Biochemistry but they will have priority in using it. The plastic container that you used to collect the liquid waste from your gel apparatus was not secured. This was another concern of the NRC inspectors. You should change that to a carboy or something that is much more stable and secure so that there is no chance it will be knocked over accidentally.

We also went over waste disposal procedures, record keeping, wearing of ring badge, estimation of radioactivity in waste, etc. You indicated that all the procedures described in our radiation safety protocol were clear to you and you had no further questions. You have been stopped from using radioisotopes until the requirement for securing the collecting container is met. Because you missed the Radiation Safety Inservice given by Ms. Diana Stockdale in 1993, this morning's session will be regarded as a makeup session for that safety inservice. I would be happy to discuss any questions or concerns that you may have in the future concerning radiation safety at DRI. Your signature on this memo will indicate that you attended this radiation safety inservice and agree with the content of this memo. Thank you for your cooperation.

Candyce I. Smith

Candyce I. Smith, Ph.D.

2.24-94

Date

DEBORAH RESEARCH INSTITUTE
GENERAL LAB MEETING
Attendance List

March 23, 1994: Radiation Safety Inservice, Diana Stockdale, M.S. (Mandatory for all Staff) and Richard E. Klabunde, Ph.D., Associate Director, Meeting Report - IBC's 3rd Symposium on Nitric Oxide. Advances in Therapeutic Application & Commercial Development

Present: (please sign)

Michael M. Fort

Robert G. Carter
Richard E. Klabunde

Jacob Bell
David England
G. Pochini

Gene Kanga
Cindy Smith
Neena Agrawal

Tom Kates
Glenn Stewart
D. G. G.

Steph. Dupont

Harold Cannon
Lizid. Danyze
Maggie Field
Cristina Xenari

Dolly Ford
Carmel Malais
Samuel A. Straeter
Theodore Jackson
ROEMAN, TORAZONA

Romy Vance
Marius Lock