

August 25, 2006

Mr. John Nicholson
Health Physicist
Nuclear Regulatory Commission / Region I
Commercial and R&D Branch
Division of Nuclear Materials Safety
475 Allendale Rd.
King of Prussia, Pennsylvania 19406-1415

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REGION 1

**Ref: Amendment request / Additional information / License No. 45-03253-02.
Docket No. 03006551 / Control No. 139057**

Dear Mr. Nicholson:

Thank you for both the written and verbal information you provided regarding our effort to amend and up-date our materials license. In accordance with directives (by item number) provided in your letter of July 6, 2006 and the Covance amendment request letter of June 21, 2006 the following is provided:

- I have signed and acknowledged the amendment request letter of June 21, 2006 submitted by our RSO.
- Covance agrees with the intent to end the "hybrid" provisions of the current license regarding authorized user approval by the Covance RSO. In this regard authorized user approval is requested for Messrs. Borneo and Weaver (H-3) and Ms. Satyanarayan (H-3 and I-125). Their respective isotope training and materials usage experience is attached.
- In reference to the remaining Nickel-63 generally licensed sources noted in our inventory (5 ea. as noted during the inspection of August 19, 2002) the following occurred:

In September of 2002, 3 of 5 remaining sources were transferred to the following vendor as part of an ECD exchange program (Hewlett-Packard Company, Little Falls Site, 2850 Centreville Rd., Wilmington, DE 19808-1610). These retired sources (ID Nos. S-11483, S-11169 and S-10747) were then removed from our inventory.

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Note: The GC instruments formerly housing these particular ECDs were subsequently sold to a scientific equipment vendor (Research Instrument Services, 1197 Baltimore/Annapolis Blvd., Arnold, Md. 21012) as they no longer served a business need.

The remaining Nickle-63 sources (2 ea - ID Nos. F-4575 & F-5083) contained within gas chromatographic instruments were transferred to our sister company (Covance – East side Lab, located at 3301 Kinsman Blvd. in Madison, Wisconsin 53704. The materials license number (State of Wisconsin) for this facility is 025-1076-01. These instruments and accompanying sources were transferred to this licensee in November of 2003.

None of the previously described Nickle-63 sources had any history of leakage. Sources were contained within seam welded steel capsules located within the ECD permanently assembled device. Historically, leak tests on these five sources, conducted at six month intervals, were always negative for leakage or contamination (i.e. less than 0.005 microcuries).

- Covance (in consideration of the 10CFR 30.35 financial assurance requirements regarding exceeding the “unity rule” for a combination of isotopes with half lives >120 days) requests a reduction in the possession limit for the following:

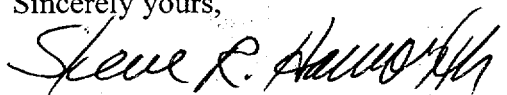
H-3 Reduction from 800 to 300 millicuries.
C-14 Reduction from 100 to 10 millicuries.

Note: These isotope possession limit reductions are in addition to those requested in our amendment letter of June 21, 2006

Please contact Mr. Blauvelt, our Radiation Safety Officer, at (703) 245-2200 ext. 5294 if you have additional questions or concerns regarding any information provided.

Thanks for your timely assistance in helping us to update our license.

Sincerely yours,


Dr. Steve Haworth / General Manager

Mr. Brian Parker
License Reviewer / Inspector
US Nuclear Regulatory Commission / Region I
475 Allendale Road
King of Prussia, PA 19406-1415

June 21, 2006

Re: License # 45-03253-02 /Request for Amendment/Notification of program changes.

Dear Mr. Parker:

The usage of by-product materials here at Covance is much reduced. This trend, as you may observe in our license/amendment file, has undergone further reductions in scope beginning in early July of 2003. Unfortunately this has caused a fairly large need to update both the license and for that matter the representations made in the original license application. Ordinarily, with 5 five year term licenses, we would have already been through a mandatory renewal by now although, as you are well aware, we are still 4 years away from our 10 year license term. It also appears the Virginia has finally elected primacy and funded the conversion to agreement state oversight for the USNRC although that is probably a couple of years away at best and perhaps a bit too long to await license up-dating.

Listed below are a series of requests/changes that would, if approved, at least bring the major program elements/representations reasonably up to date.

Table 1. Amendment requests to Materials License # 45-03253-02.

Materials License Item No.	Actual Title of Section on Current License.	Last amend. Date Requested Action	Requested action justification
6	By-product, Source and /or special nuclear material	Aug. 18, 2003 Terminate possession for all indicated nuclides and related statements.	B - I ¹³¹ Never Ordered - Studies utilizing this nuclide never materialized E - Cr ⁵¹ Never Ordered - Studies utilizing this nuclide never materialized F - P ³² Last Ordered - 4/1/03 - Work with his nuclide has ceased H - Ni ⁶³ 2 Sources (ECDs in GCs) were Leak tested, certificated and transferred to State of Wisconsin License No 025-1076-01 in Nov. 2003.

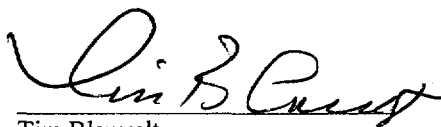
Table 2. Changes/Requested actions bearing on representations made in July 2000 on renewal application for license # 45-03253-02.

License Application Item No.	Conditions	Section	Section Title and Requested Action	Requested action justification
9	Facilities and Equipment	9.0	Radiation and Detection Monitoring Equipment Add detection equipment	For detection of low level removable beta nuclides Covance purchased a Perkin Elmer Beta-Scout model 2007 Liquid Scintillation counter. EGG Wallac equipment was transferred to the Chantilly Va. Lab noted in (Item 9A - June 18, 2002).

10	The Radiation Safety Program	2.1	Procedures for Control of Procurement and Use.	RSO approves all requests for radioactive materials which are purchased through the Sourcing/Supply Dept.
		4.0	Procedure Change Program Administration Name change	Mr. David Lumby has been replaced by Mr. Todd Meyer who is the current Sr. Manager of the EH&S Dept.
		5.0	Radiation Safety Committee	Radiation Safety Committee – Reduced program. Covance requests committee charter/required meeting with an annual program audit copied to all authorized individuals and Sr. Mgmt
		8.0	Bioassays Delete / All related references.	Bio-assay for thyroid up-takes is no longer necessary as the labeling business terminated several years ago. Currently only “kit” type assays are conducted with 0.25 millicurie or less of “bound” versus the “free” I-125 previously ordered and used.
		10.0	Radiation Surveys Altered procedure	Wipes for the presence of low energy beta emitters will be placed in a 20 mL liquid scintillation vial to which 10 mL of counting cock-tail is then added.
		11.1	Airborne Surveys Delete / All related references	Quarterly monitoring of effluent air from charcoal filter no longer applicable as iodination/labeling business is at end.
		12.0	Sealed Source Surveys Delete /All related references	All Ni 63 sources were transferred to sister company with approved Wisconsin agreement state license. Six month inventory and leak testing requirements no longer apply.
		15.0	Personal Monitoring Devices Discontinued issuance	Personal dosimeters are currently issued to all radiation workers and authorized users working with radioactive material or who are likely to receive a whole body dose in excess of 100 mRem/yr. A review of personnel dosimetry reports collected over the past 3 years, dating from the inception of program reductions, have not exceed this limit. Note: In concert with 10 CFR 20.1502 Covance has discontinued use of personal dosimeters. Area specific dosimeters are however placed in radiographic/isotope handling areas.

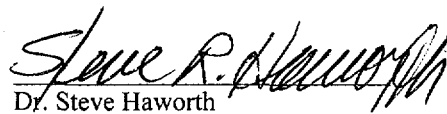
Please call me at (703) 245-2200 ext. 5294 (new licensee contact number) or contact me via e-mail at tim.blauvelt@covance.com should you have questions or concerns regarding these requests/notifications.

Sincerely,



Tim Blauvelt
Radiation Safety Officer

Acknowledged
Date: August 25, 2006



Dr. Steve Haworth
General Manager

Joanne Satyanarayan, B.A.

Position: Assay Labs Manager

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4
(Use supplemental sheets if necessary)

TYPE OF TRAINING	WHERE TRAINED	LENGTH OF TRAINING	ON THE JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
Principles and practice of radiation protection.	Covance Laboratories, Vienna, VA	1.0	<u>YES</u> NO	<u>YES</u> NO
Radioactivity measurement standardization and monitoring technique and instrument	Covance Laboratories, Vienna, VA	2.5	<u>YES</u> NO	<u>YES</u> NO
Mathematics and Calculation basic to use and measurement of radioactivity.	Covance Laboratories, Vienna VA	0.5	<u>YES</u> NO	<u>YES</u> NO
Biological effects of radiation	Covance Laboratories, Vienna VA	1.0	<u>YES</u> NO	<u>YES</u> NO
Study and review safety manual, and exam.	Covance Laboratories, Vienna VA	3.0	<u>YES</u> NO	<u>YES</u> NO

EXPERIENCE WITH RADIATION. (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAX AMOUNT	WHERE EXPERINCE WAS GAINED	DURATION OF EXPERINCE	TYPE OF USE
I ¹²⁵	15 m Ci	Covance Laboratories, Vienna VA	21 YEARS	SUPERVISE ASSAY
H ³	15 m Ci	Covance Laboratories, Vienna VA	21 YEARS	SUPERVISE ASSAY

Gerasimo Borneo, M.S.

Position: Supervisor Genetic Toxicology

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4
(Use supplemental sheets if necessary)

TYPE OF TRAINING	WHERE TRAINED	LENGTH OF TRAINING	ON THE JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
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Mathematics and Calculation basic to use and measurement of radioactivity.	Covance Laboratories, Vienna VA	0.5	<u>YES</u> NO	<u>YES</u> NO
Biological effects of radiation	Covance Laboratories, Vienna VA	1.0	<u>YES</u> NO	<u>YES</u> NO
Study and review safety manual, and exam.	Covance Laboratories, Vienna VA	3.0	<u>YES</u> NO	<u>YES</u> NO

EXPERINCE WITH RADIATION. (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAX AMOUNT	WHERE EXPERINCE WAS GAINED	DURATION OF EXPERINCE	TYPE OF USE
H ³ Thymidine	40 mCi	Covance Laboratories, Vienna , VA	3 YEARS	SUPERVISE ASSAY

William J. Weaver, B.S.

Position: Senior Research Associate & Supervisor – Method Development

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4
(Use supplemental sheets if necessary)

TYPE OF TRAINING	WHERE TRAINED	LENGTH OF TRAINING	ON THE JOB (Circle Answer)	FORMAL COURSE (Circle Answer)
Principles and practice of radiation protection.	Covance Laboratories, Vienna , VA	1.0	<u>YES</u> NO	<u>YES</u> NO
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Mathematics and Calculation basic to use and measurement of radioactivity.	Covance Laboratories, Vienna VA	0.5	<u>YES</u> NO	<u>YES</u> NO
Biological effects of radiation	Covance Laboratories, Vienna VA	1.0	<u>YES</u> NO	<u>YES</u> NO
Study and review safety manual, and exam.	Covance Laboratories, Vienna VA	3.0	<u>YES</u> NO	<u>YES</u> NO

EXPERINCE WITH RADIATION. (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAX AMOUNT	WHERE EXPERINCE WAS GAINED	DURATION OF EXPERINCE	TYPE OF USE
I ¹²⁵	15 m Ci	Covance Laboratories, Vienna VA	21 YEARS	SUPERVISE ASSAY
H ³	5 m Ci	Covance Laboratories, Vienna VA	21 YEARS	SUPERVISE ASSAY