MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9892 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? YES. 04/28/2010

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Cari Dzanbazoff, consultant	Children's Hospital of Michigan	O: 734-662-3197 x320 F: 734-662-9224

SUBJECT
License No.: 21-03298-05 Control No.: 318806

SUMMARY
We have reviewed your letter dated January 27, 2010, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. The submitted Agreement State license provided for Dr. Majid Zaydan Khalaf's preceptor, Dr. Hani H. Abdel-Nabi, is beyond the seven-years recentness of training requirement in 10 CFR 35.59. Please provide documentation that Dr. Abedel-Nabi meets the requirements as a preceptor authorized user for byproduct material permitted by 10 CFR 35.100 and 35.200.

2. For your new use areas utilizing PET radionuclides, please provide documentation that the limits specified in 10 CFR 20.1301 will not be exceeded, i.e. shielding calculations, survey measurements, etc.

We will be unable to continue processing your request until we receive this information. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this correspondence will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

ACTION REQUIRED

Please **facsimile a signed written response** by April 30, 2010, or contact me to arrange an alternate response date. **Facsimile number is (630) 515-1078.** Be sure to reference control number 318806 to facilitate correct processing of your response.

If we do not receive a written response by April 30, 2010, please note that we may void this request in order to enable you to prepare a quality response without time constraints. This would be done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

Upon receipt of your response we will resume our review.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9892

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Jose Macatangay	Jose Macatangay	04/28/2010

TRANSMISSION VERIFICATION REPORT

TIME : 04/28/2010 11:08
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE,TIME	04/28 11:08
FAX NO./NAME	87346629224
DURATION	00:00:46
PAGE(S)	02
RESULT	OK
MODE	STANDARD ECM

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 04/28/2010

NUMBER OF PAGES: 2
(including this page)

SEND TO: Cari Dzanbazoff, consultant

LOCATION: Children's Hospital of Michigan

FAX NUMBER: 734-662-9224 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) Jose Macatangay

TELEPHONE NUMBER: 630-829-9892 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Ms. Dzanbazoff,

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 04/28/2010

NUMBER OF PAGES: 2
(including this page)

SEND TO: Cari Dzanbazoff, consultant

LOCATION: Children's Hospital of Michigan

FAX NUMBER: 734-662-9224 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) Jose Macatangay

TELEPHONE NUMBER: 630-829-9892 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Ms. Dzanbazoff,

Per our conversation on 04/27/2010.
Additional information is requested as attached.

Thank you.
Jose Macatangay

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address , by U.S. Mail. Thank you.

MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9892 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? NOT FAXED

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Patricia Woodcroft, Director PET Services	Children's Hospital of Michigan	O: 313-745-0657

SUBJECT
License No.: 21-03298-05 Control No.: 318806

SUMMARY
Background
Licensee is adding PET use areas to their NRC license. These areas were previously under State of Michigan jurisdiction. Waiver termination was August 7, 2009. Initial submittal date was January 27, 2010 (within 6-months for license amendment).

Licensee facsimiled shielding calculations for the PET use areas on 04/29/2010. In these calculations, I had a question on the exposure rate (1.88 mR/mCi at 1m) used in calculating the integrated doses for the PET scanner room north of the control room and south of the radiochemistry lab.

05/05/2010 conversation w/Patricia Woodcroft, Director PET Services
I had asked Ms. Woodcroft where the 1.88 mR/mCi was derived from. Ms. Woodcroft indicated it was the hospital physicist who calculated the shielding and provided me the reference that was used for the 1.88 mR/mCi. See attached.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Jose Macatangay	Jose Macatangay	05/06/2010

ing of both radioactive gas and exhaust are provided automatically by electrical solenoid valves, and gas supply to various areas may be monitored through a set of ball-type flowmeters mounted on the distribution board. Communication among the cyclotron, hot chemistry area, and clinical imaging suite is provided via voice-activated intercom and television surveillance. Also, flow values at both ends of the line are monitored, a difference in these values indicating a leak.

III. SYSTEM PERFORMANCE AND RADIATION SAFETY

A. Batch lot system

The transit time of capsules loaded with two 10-cm³ vials of fluid has been measured as a function of line driving pressure and the results are illustrated in Fig. 3. At pressures above 3.4 atm, the delivery of driving air becomes erratic due to the limited capacity of the reservoir and transfer valve. As a safety factor, it is desirable to keep enough reserve air to send several high pressure (5.4 atm) pulses along the line in the event of a capsule being jammed. At pressures below 0.8 atm, a loaded capsule is unable to negotiate the vertical portion of the route (two floors) after just emerging from several 90° bends. This phenomenon is strongly dependent upon the exact configuration of a given system and the lower limit of driving pressure will therefore vary from system to system. It is extremely difficult to model the transit of a capsule within such a system because the frictional forces on the capsule vary with position, gravitational effects vary along the line, and there is a significant slipstream of air traveling by the capsule. The optimum operating point for our system was chosen to be 1.5 atm which results in a transit time of 6 s but still allows for two successive transits to be made while maintaining enough reserve pressure to pulse the line to high pressure. Because the transit of a capsule is so fast, the radiation exposure to personnel along the route is negligible in normal operation. In the event of a jammed capsule, however, significant exposure to nonradiation workers could accrue. Table I lists the accumulated exposure doses for several situations of a jammed capsule.

TABLE I. Exposure doses at 1-m distance from jammed capsule.

Length of time (min) capsule stuck	Exposure dose mR/mC: ^{13}N	^{11}C	^{18}F
1	0.010	0.012	0.012
5	0.050	0.055	0.058
10	0.090	0.100	0.116
60	0.170	0.305	0.597
∞	0.173	0.350	1.887

It is extremely unlikely in practice that the source would remain trapped long enough to cause significant exposure to an individual, since it may be removed by pulsing the transport line to 5 atm pressure. This has been effective in all cases to date.

B. Gas lines

The operating characteristics of the gas line are illustrated in Fig. 4. The line is operated in the laminar flow range[3] (i.e., Reynolds numbers below ~2000) and can be described by a simple model based on a computation of transfer through the pipeline.

A general pipeline system may be described by its transfer function $h(t)$. This transfer function gives the probability that a given element of fluid when introduced into the pipeline at $t = 0$ will emerge from the other end at time t. For this general case, the fraction of input activity arriving at the distal end of the pipeline would be given by

$$F = \frac{\int_0^\infty e^{-\lambda t} h(t)\,dt}{\int_0^\infty h(t)\,dt},$$

where λ is the radioactive decay constant of the gas and the $e^{-\lambda t}$ factor accounts for radioactive decay in transit for an element taking time t to negotiate the pipeline. If one assumes that the amount of dispersion of a bolus in transmitting the line is small, this assumption being supported by experimental observation of several pipelines in our laboratory, then

$$h(t) \simeq \delta(T),$$

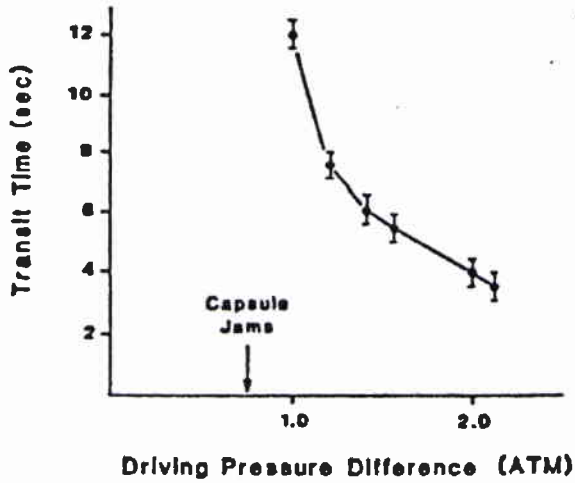

FIG. 3. Experimentally measured capsule transit time as a function of driving pressure difference for 300-m transport system.

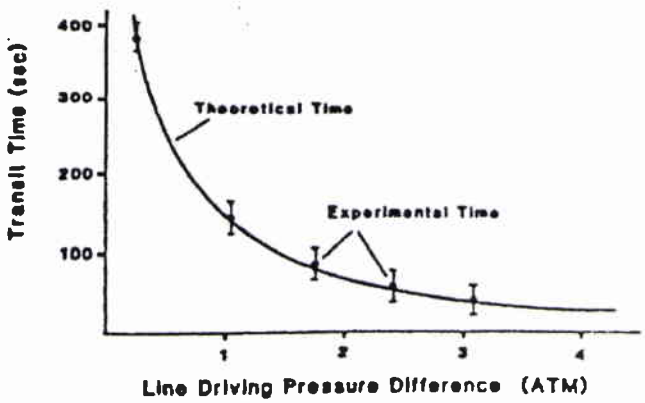

FIG. 4. Experimental and theoretical values (simple model) for radioactive gas transit time in 1.6-mm-diam polyethylene tube 300 m in length. Data were measured using 15-oxygen.

MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9892 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? N/OT FAXED. 04/01/2010

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Cari Dzanbazoff, consultant	Children's Hospital of Michigan	O: 734-662-3197 x320 F: 734-662-9224

SUBJECT
License No.: 21-03298-05 Control No.: 318806

SUMMARY

Background

After initial review of letter dated January 27, 2010, and review of current license, the threshold requirements for DFA in 10 CFR 30.35(d) were reached but no DFA was submitted for this license. Therefore, I contacted the licensee's consultant.

04/01/2010 conversation w/Cari Dzanbazoff, consultant

I spoke Ms. Dzanbazoff and informed her that the licensee's possession limits for C-14 (200mCi) and Zn-65 (20mCi) had triggered DFA requirements under 10 CFR 30.35(d) for the licensee and therefore would require either a DFA or a decrease in the possession limits.

Ms. Dzanbazoff indicated she will verify with licensee that the possession limits are to be lowered. I also informed her to ensure that the possession limits for the C-14, Zn-65, and H-3 do not trigger the DFA via 'unity rule'. Ms. Dzanbazoff agreed and indicated the response will be sent no later than 04/15/2010. → response rec'd 04/07/2010.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Jose Macatangay	Jose Macatangay	05/05/2010