Washington University in St. Louis

Environmental Health & Safety **Radiation Safety Office**

September 1, 2010

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, STE 210
Lisle, Illinois 60532-4352

Attn: Kevin G. Null

RE: Clarification of additional information to C/N 318581

Subject: Clarification on Certain Responses to Request for Additional Information and Clarification on Washington University in St. Louis Application for New Production License Using an Accelerator

The purpose of this letter is to clarify certain responses made in our April 9, 2010 response letter which presented additional information in support of the Washington University in St. Louis (WU) application for new production license using an accelerator (C/N 318581). The clarifications being provided below are in response to Mr. Kevin Null's telephone request for clarifying information on Requests 2 through 5, and his discussions with me on August 27 and 30, 2010.

Request 2: ***Regarding the maintenance of cyclotrons, describe systems in place for checking and safely replacing delivery lines that become worn or brittle due to repeated exposure to radiation. Submit procedures that will be followed to measure radiation levels during the work, and measure occupational exposure to workers. Describe training that will be provided to individuals who perform these duties and confirm that these functions will be performed under the supervision of an authorized user.***

In addition to the license application changes submitted for Request 2 in the April 9, 2010 WU Response letter, I have modified Sections ACC 10.7 and ACC 10.8 of our production license application to address the commitments asked for in this Request, and included those sections in Attachment A.

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***Request 3:* Describe and submit diagrams of ventilation systems for each cyclotron. Include a description of effluent filtration systems and the means to detect and evaluate concentrations of radioactive materials released to the environment. Include procedures used to determine change-out of filters due to, e.g., saturation, and provisions for safe storage and disposal of filters.**

Ventilation lines that exit a cyclotron vault are covered under the WU Broad Scope License No. 24-00167-11. Therefore, the information asked for in Request 3 is not applicable to the WU application for new production license using an accelerator.

***Request 4:* Describe practices that will be followed to minimize potential skin dose and methods that will be used to evaluate dose to skin in the event a worker is exposed to, e.g., F-18 skin contamination.**

This response replaces the response to Request 4 provided in the April 9, 2010 WU Response letter. To address the commitments asked for in this Request, I have modified Section ACC 10.4 of our production license application, and included that section in Attachment A.

***Request 5:* Describe methods used to evaluate concentrations of radioactive material in worker breathing zones due to effluents from cyclotron operations. Also submit a bioassay program to evaluate worker intake of effluents in the event of release of effluents in worker breathing zones.**

This response replaces the response to Request 5 provided in the April 9, 2010 WU Response letter. To address the commitments asked for in this Request, I have modified Section ACC 10.4 of our production license application, and included that section in Attachment A.

For the requests requiring additional information which directly relates to commitments made in the WU new production license application, we request the following changes be made to our new license application as part of our clarification of responses made in the April 9, 2010 WU Response letter. See Attachment A for the updated pages containing the new license commitments to substitute for pages in our original September 30, 2009 production license application document, as modified by the April 9, 2010 WU Response letter. The updated pages are described as follows.

Pages ACC-26 through 27 – Section ACC 10.4 is modified to add Subsection ACC 10.4-1 to address Request 4.

Pages ACC-27 through 27a – Section ACC 10.4 is modified to add Subsections ACC 10.4-2 and ACC 10.4-3 to address Request 5.

Pages ACC-27a through 27c – Sections ACC 10.7 and ACC 10.8 are modified to address Request 2.

Please contact me at (314) 362-2988 or at langhors@wustl.edu if you have any further questions concerning these clarifications of our responses to your request for additional information on the WU application for new production license using an accelerator.

Sincerely,

Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

Cc w/att: Barry A. Siegel, M.D., Radiation Safety Committee Chairman
Bruce D. Backus, P.E., Environmental Health & Safety
Christopher W. Goddard, Assistant General Counsel

Attachment A

Updated Pages to be Substituted in
Washington University in St. Louis New Production License Application
as Described in Clarifications to Responses for Requests 2, 4 and 5

Pages ACC-26 through 27c

ACC 10.2-3 Instrument Calibration

Instruments used to quantitatively measure the radioactivity in the radioactive material products and process, and the procedures followed to ensure accuracy of those measurements are discussed in the University's broad scope license application.

ACC 10.3 Material Accountability

No additional response is required.

ACC 10.4 Occupational Dose

Occupational doses will be monitored and controlled under the same dosimetry program established for the Washington University in St. Louis Broad Scope License No. 24-00167-11. The following subsections provide additional information on the specific parts of the dosimetry program involving positron-emitting radioactive materials (PET isotopes).

ACC 10.4-1 Minimizing and Evaluating Skin Dose Incidents

Individuals are instructed in the practices to be followed to minimize the potential for skin dose when handling any radioactive material. Due to the high contact dose rates of PET isotopes, individuals who are PET radiation workers are provided additional training specific to preventing skin and other personal contamination. Radiation safety review of specific authorized work performed under the University's production license may establish work-specific requirements and training for radiation workers to ensure proper dose controls.

Radiation workers are specifically trained in, and inspected on, safe handling techniques, contamination control, proper use of personal protective equipment (PPE) and their frequency of surveying for radioactive contamination. Radiation workers must demonstrate their use of techniques and procedures established for their specific handling of PET isotopes using applicable shielding and remote handling equipment.

PET radiation workers are instructed to immediately notify Radiation Safety for all personal contamination events, including skin contaminations. This notification allows Radiation Safety staff to quickly be involved in the discussion of occupational dose potentials and corrective actions being taken. Radiation Safety staff evaluate shallow or extremity dose for each skin contamination event. Initial skin contamination is measured with a nearby radiation survey meter, if practical, or is estimated based on source activity, later skin contamination measurements and/or other available data. Skin contaminations are measured to determine location, radionuclide if not known, and activity levels. If the skin contamination cannot be totally washed off of the skin, a thin window Geiger survey meter is used to periodically measure activity levels in order to determine the effective half-life of the PET

isotope on the skin. Radiation Safety staff estimate the shallow dose (SDE), or extremity dose, using the available contamination data and the Varskin computer code.

The contaminated radiation worker and others involved in the contamination incident or clean up are requested to help write an incident report whenever an individual becomes contaminated with radioactivity which cannot be immediately removed by washing. The incident report includes the who, what, when, where, and how for the contamination incident, and is reviewed by the Authorized User and by Radiation Safety staff to evaluate the corrective actions taken to date, lessons learned, need to take further corrective actions and plan to ensure effective implementation of corrective actions. Personal contamination incidents and follow up are presented and discussed with the RSO and with the Radiation Safety Committee, or one of its subcommittees.

ACC 10.4-2 Evaluating Radioactive Material Concentrations in Worker Breathing Zone

The cyclotron vaults are ventilated directly to the main cyclotron facility exhaust at a rate of 10 or more air exchanges per hour. Access to each of the BCF vaults is limited for some time after the last shut down, depending on what radioactive material was being produced and the dose rate measured at the cyclotron vault door when entering. This limitation allows for the decay of very short-lived radionuclides, as well as for the exhaust of any potential airborne radioactivity that was created due to cyclotron operation. These engineering and administrative controls prevent an individual from receiving an intake by inhalation due to the operation of the cyclotron.

For most of the PET isotopes produced under this production license, the submersion dose rate can be easily measured by a survey meter, and when found to be fairly unidirectional quickly identified as airborne activity. The submersion dose generally exceeds the internal dose to a radiation worker exposed to PET airborne activity. Assuming a radiation worker works in a semi-infinite cloud[1] of F-18 airborne activity at the derived air concentration (DAC), the photon submersion dose (D_s) would be:

$$D_s = 0.25\ (\text{rad-dis-m}^3/\text{sec-MeV-Ci}) * \text{Ave E}\ (\text{MeV/dis}) * \text{DAC}\ (\text{Ci/m}^3)$$

$$= 0.25 * 0.986 * 3e\text{-}5 * 3600 * 1000\ \text{mrem/h}$$

$$= 27\ \text{mrem/h}$$

The radiation worker's internal dose per hour worked (D_i) would be:

$$D_i = \text{DAC}\ (\mu\text{Ci/ml}) * 2e4\ (\text{ml/min}) * 5\ \text{rem} * 1/\text{ALI}\ (\mu\text{Ci})$$

$$= 3e\text{-}5 * 2e4 * 5 * 1/7e4 * 60 * 1000\ \text{mrem/h}$$

$$= 2.6\ \text{mrem/h}$$

[1] Shleien, B., The Health Physics and Radiological Health Handbook, Revised Edition (1992)

Part of the radiation safety review for approving production and use of new PET isotopes includes an evaluation of potential airborne releases into radiation worker breathing zones. Airborne and potentially volatile PET isotopes are transferred through transfer lines to the University's broad scope license.

ACC 10.4-3 Bioassay Program

A single accidental release of airborne radioactivity into the worker's breathing zone that is capable of resulting in an intake in excess of 10% of the applicable annual level on intake (ALI) would be easily detected by area monitors and available Geiger survey meters. The ALARA actions taken by radiation workers to minimize their external whole body dose would also minimize their intake dose. The bioassay program established under the University's broad scope license will be applied to this production license. The existing urine and thyroid bioassay protocols will be modified, and other internal dose assessment protocols developed, as necessary, to detect cyclotron-produced radioactive material. The bioassay protocols will be used as necessary to assess suspected intakes of these radioactive materials for determining internal occupational dose as required by 10 CFR 20.1502(b).

ACC 10.5 Public Dose

No response is required.

ACC 10.6 Safe Handling of Radionuclides and Emergency Procedures

The safe handling procedures established under the University's broad scope license application will also be applied to this production license (see Washington University in St. Louis Broad Scope License No. 24-00167-11 Application, Section RES 10.6). In addition, cyclotron production procedures will be developed and maintained for the safe handling of radionuclides covered by this production license and for associated emergency responses. These procedures and revisions will require review and approval by the Primary Cyclotron Authorized User and the RSO. Review will assure that the procedure provides continued compliance with NRC regulations and this license and does not degrade the effectiveness of the radiation safety program. Staff will be trained in revised procedures prior to implementation.

ACC 10.7 Surveys {clarification for Request 2}

The survey program established under the University's broad scope license application will also be applied to this production license (see Washington University in St. Louis Broad Scope License No. 24-00167-11, Section RES 9.1 and Section RES 10.7). In addition, specific survey program requirements of cyclotron vault surveys for personnel entry are presented in ACC 9.2, and other specific requirements are described below.

Maintenance work performed on external parts of the cyclotron, or loading/unloading targets are done when the ambient radiation exposure rates in the vault are ALARA. When working on internal cyclotron components (i.e., ion source), the time individuals spend working in the maximum dose area is limited. An individual who handles or manipulates activated targets and/or cyclotron components will, in addition to their personal dosimeters, wear an electronic dosimeter with audible or vibration alarms set to alarm at dose rates or cumulative doses chosen to ensure occupational dose for that maintenance procedure is not likely to exceed 10% of the dose limit. If an electronic dosimeter is not available, the individual will continuously monitor the work area using a survey meter which has either an audible alarm or is continuously observed by a second individual. Historically, personnel are able to limit their accumulated dose to less than 20 mrem per maintenance procedure.

Radioactive materials removed from a cyclotron vault are surveyed to determine the approximate activity unless the radioactive material is from a known target and irradiation protocol. Evaluation for irradiation of new types of target materials is required. Prior to irradiation, the following information should be provided:

- Chemical and physical form of the target material
- Enrichment of target material
- Excitation function for the production of the intended radionuclide to be produced
- Properties of the intended radionuclide to be produced with regard to radiation types and energies emitted
- Anticipated radionuclide purity
- Irradiation conditions (beam type, current and irradiation time)
- Anticipated production yield per irradiation
- Anticipated incidental activation of other radioactive materials

Low level test irradiations may be used to determine and/or confirm this information.

Radiation surveys are made of public access areas surrounding the cyclotron vaults to ensure compliance with public dose limits as required by 10 CFR 20.1302. These surveys are repeated as necessary when there is significant change in cyclotron operation, irradiation protocols or shielding.

ACC 10.8 Maintenance {clarification for Request 2}

ACC 10.8-1 General Maintenance Procedures

All individuals who perform cyclotron maintenance will either be named as a cyclotron authorized user under the University's production license, will work under the supervision of a cyclotron authorized user named under the University's production license, or be named on an NRC service provider license or equivalent Agreement State license to perform maintenance and/or repair activities that involve the handling of radioactive materials (e.g., activated targets or components) during the accelerator maintenance and repair activities.

ACC 10.8-2 Delivery Lines

The delivery lines exiting a cyclotron vault automatically transfer their radioactive material to the University's broad scope license. Therefore, the majority of these delivery lines are maintained under the University's broad scope license.

For O-15 gas delivery lines coming directly from a cyclotron, the integrity of the delivery line is tested by pulling a vacuum on the line prior to each set of O-15 gas deliveries to determine if there is any leakage along the line. All other radioactive material delivery lines coming directly from a cyclotron are inspected on a quarterly basis. These lines are replaced if the inspection indicates replacement is needed, and they are cleaned or replaced if less than optimal isotope production yields are observed.

ACC 10.9 Transportation

No response is required.

ACC 10.10 Minimization of Contamination

No response is required.

Washington University in St. Louis

SCHOOL OF MEDICINE — RADIATION SAFETY OFFICE

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Date 9/1/10 Time

Total Number of Pages Including Cover 10

Message

Clarification letter on WU new accelerator production license (C/N 318581).

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If you did not receive all the pages as indicated above, call (314) 362-3476.

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