Washington University in St. Louis

Environmental Health & Safety **Radiation Safety Office**

April 9, 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: Additional information to C/N 318581

Subject: Response 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 provide additional information and clarification in support of Washington University in St. Louis application for new production license using an accelerator (C/N 318581). The requests listed in this letter are from your email sent to me on February 16, 2010.

We have done our best to respond to your requests for additional information on the University's new production license application. However, some of the additional information requested refers to the Washington University in St. Louis Type A Broad Scope Medical Use License (No. 24-00167-11) which has already been approved by NRC (Amendment No. 75) for the license coverage needed to coordinate with the University's new production license application. Also, some of the additional information requested was not required to be submitted in our new production license application, as described in NRC licensing guidance[1]. We provided responses to the requests that fall into these two categories as information only to assist in your review of the University's new production license application.

[1] NUREG-1556, Volume 21 Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Possession Licenses for Production of Radioactive Material using an Accelerator (October 2007).

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Washington University in St. Louis, Campus Box 8053, 660 S. Euclid Avenue, St. Louis, MO 63110-1093
(314) 362-3476, *Fax*: (314) 362-4776, radsafety@wustl.edu, https://radsafety.wustl.edu

For the requests requiring additional information which directly relates to commitments made in the University's new production license application, we requested changes to our new license application as part of our response, and provided updated pages containing the new license commitments to substitute for pages in our original September 30, 2009 production license application document.

***Request 1:** Provide a description of experience in handling targets, and performing maintenance/repair on the cyclotrons for Dr. Robert Mach, or state that he will not perform or supervise these duties.*

Following my discussions with you on NRC's guidance provided in NUREG-1556 Volume 21 Section 8.7.2, we have updated our production license application to indicate that cyclotron authorized users will be reviewed and authorized by the University's Radiation Safety Committee without need to amend the production license. As a result, Dr. Mach's and Mr. Gaehle's curriculum vitae (CVs) were removed from the updated application. As a note of information, Dr. Mach will not be approved to perform or supervise the handling of targets, and the maintenance or repair of cyclotrons at this time.

To request this change, I have modified the following portions of our production license application and included those pages in Attachment A.

Pages ACC-13 through 16a – Page ACC-13 is modified to include description of the Radiation Safety Committee in Section ACC 7.1. This additional wording comes directly from the University's broad scope license application. Pages ACC-14 through 15 are modified to accommodate the new spacing needed for the updated ACC Item 7. Page ACC-16 is modified and Page ACC-16a added to describe the primary responsibilities, review and approval process, and training and experience requirements for authorized users named on the University's production license.

Page ACC-29 – ACC Schedule 1 is updated to include the Radiation Safety Committee (RSC).

Pages ACC-32 through 38 – ACC Schedules 4 and 5 are modified to indicate that the CVs originally submitted have been withdrawn due to NRC's allowance for broad scope programs to review and approve cyclotron authorized users. As a result, Pages ACC-33 through 36 and ACC-38 were deleted.

***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.**

We did not submit specific information concerning cyclotron maintenance in the original new production license application because NRC's guidance in NUREG-1556, Volume 21, Appendix C, Item 10 states, "No response is required in the application process." Therefore, we provide much of this specific response only for NRC's information to represent indicators of how the University's radiation safety program is designed to ensure proper controls have been established for cyclotron maintenance activities. The confirmation you requested is addressed at the end of this response.

Delivery lines – 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. The O-15 gas delivery lines are described in more detail in the University's broad scope license application (see Section RES 9.6-1-1 "Transfer of Gas Targets" on Pages RES-14a through 14b). All other radioactive material delivery lines coming directly from a cyclotron are cleaned and inspected on a quarterly basis, and are replaced if the inspection or less than optimal isotope production yields indicate replacement is needed.

Measuring radiation levels – The procedure requested was given in the original production license application in Section ACC 9.2 on Page ACC-21. The University uses Landauer personal dosimeters to measure occupational exposures.

Training for individuals who perform maintenance - This training was described in the original production license application in Section ACC 8.2 on Page ACC-18. 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.

To request these changes in training requirements, I have modified the following portions of our production license application and included those pages in Attachment B or Attachment D.

Pages ACC-18 through 19 (see Attachment B) – These pages are modified to include the training commitment statement in Section ACC 8.2 and to incorporate changes made in response to Request 1.

Page ACC-26 (see Attachment D) – This page is modified to incorporate changes made in responses to Request 1 and Request 2.

***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.**

In Section ACC 9.5 of the University's new production license application, we stated that the cyclotron ventilation system is described in the University's broad scope license application. A written description of the cyclotron ventilation systems was provided in the University's broad scope license application (see Section RES 9.7 "Cyclotron Ventilation Systems" on Page RES-14f). Diagrams for the University's two cyclotron facility ventilation systems are included for your information in Attachment C.

Please note that there is no system-wide effluent filtration for either of the cyclotron facility ventilation systems. However, hot cells located in the cyclotron facilities are equipped with inlet pre-filter material then HEPA filter, and exhaust pre-filter material then charcoal filters. Or, the hot cells are limited for use with radiochemistry systems that provide their own filtration using a chemical scrubber process and/or are vented to the delay decay loop located in a cyclotron vault, as described in the University's broad scope license application (see Section RES 9.6-2-3 "Examples Delay Loops" on Page RES-14e). Hoods located in the cyclotron facilities are also limited for use with radiochemistry systems that provide their own filtration using a chemical scrubber process and/or are vented to the delay decay loop located in a cyclotron vault.

The hot cell exhaust filters, and their pre-filter materials, are changed out based on the measured pressure drop across the filter housing indicating the filters may be getting clogged. Prior to changing the filters, radiation levels are measured around the exhaust filter housing to ensure radioactivity trapped by the filters has been allowed to decay in place to minimize the dose rates encountered during filter change out. Care is taken when removing filters to place them into plastic bags for contamination control. The filter materials may be stored in the cyclotron facility, or be transferred to Radiation Safety's radioactive waste management program for decay-in-storage. Please see our response to Request 7 for more information on our radioactive waste management program support of the cyclotron facilities. Any prefilter materials and HEPA filters removed from hot cell air intakes are surveyed to confirm radioactivity levels are indistinguishable from background and then are properly disposed.

Each of the cyclotron ventilation systems are equipped with a ROTEM MediSmarts stack monitoring system to measure concentrations of radioactive material released to the environment, as shown on the cyclotron ventilation diagrams. A copy of the brochure describing this stack monitoring system is also included in Attachment C for your information.

Since the information requested here pertains to the University's broad scope license, the information I have submitted is for information only and should not to be included in the University's new production license application. If you decide that any this information needs to be included in our broad scope license application, please let me know so that I can prepare and submit a license amendment request to add the applicable information.

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 worked is exposed to, e.g., F-18 skin contamination.***

We did not submit specific information concerning the University's occupational dose program because NRC's guidance in NUREG-1556, Volume 21, Appendix C, Item 10 only required us to agree to the statement listed under "Occupational Dose." Therefore, we provide this specific response only for NRC's information to represent an indicator of how the University's radiation safety program is designed to meet our license commitment in regard to occupational dose.

Minimize potential skin dose – 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 positron-emitting radioactive materials (PET isotopes), individuals who are PET radiation workers are provided additional training specific to preventing skin and other personal contamination. This additional PET training is the same for the University's broad scope and production licenses. Radiation safety review of specific authorized work performed under the University's broad scope and production licenses 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.

Evaluate skin dose – 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 frequently 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. We currently are using Varskin 3 from the Radiation Shielding Information and Computational Center (RSICC) at www.rsicc.oral.gov.

Evaluation of skin dose events – The contaminated radiation worker and others involved in the contamination incident or clean up write up 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, look at 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 RSC, or one of its subcommittees.

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.

We did not submit specific information concerning the University's occupational dose program because NRC's guidance in NUREG-1556, Volume 21, Appendix C, Item 10 only required us to agree to the statement listed under "Occupational Dose." Therefore, we provide this specific response only for NRC's information to represent an indicator of how the University's radiation safety program is designed to meet our license commitment in regard to occupational dose.

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[2] of F-18 airborne activity at the derived air concentration (DAC), the photon submersion dose (D_s) would be:

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

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

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

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

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

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

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

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 as described in the University's broad scope license application (see Section RES 9.6-1 "Transfer of Cyclotron-Produced Radioactive Materials" on Pages RES-14a through 14c). Criteria for review and procedures for safe handling of PET isotopes under the University's broad scope program are described in the University's broad scope license application (see BSL Item 10 "Radiation Safety Program" on Pages BSL-28 through 35, RES Item 9 "Facilities and Equipment – Research Use" on Pages RES-11 through 14f, and RES Item 10 "Radiation Safety Program – Research Use" on Pages RES-15 through 16).

Bioassay program – With extensive use of ventilated hot cells and fume hoods, we have not observed significant airborne activity in radiation worker breathing zones. A single accidental

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

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 University's broad scope program has an established bioassay program which includes urine bioassays, typically used for determining H-3 intakes, and thyroid bioassays, typically used for determining I-125 and I-131 intakes. The existing urine and thyroid bioassay protocols will be modified, as necessary, to detect cyclotron-produced radioactive material, and used to assess suspected intakes of these radioactive materials for determining internal occupational dose as required by 10 CFR 20.1502(b).

Request 6: ***Provide greater detail on your survey program. Include for example, a description of ambient survey, contamination survey, air sampling in the work place and effluent release survey programs. Model your submittal after Appendix M to Volume 21 of NUREG-1556.***

The vast majority of our survey program related to handling accelerator-produced radioactive materials occurs under the University's broad scope license (see Section RES 9.1: "Criteria for Review and Approval of Facilities and Equipment" on Pages RES-11 through 12, and Section RES 10.7: "Surveys" on Pages RES-15 through 16). We apply the same survey program to work done under the University's production license. Our survey program is based on Appendix S of NUREG-1556, Volume 11, Consolidated Guidance About Materials Licenses - Program-Specific Guidance About Licenses of Broad Scope (April 1999), which is nearly word for word the same as the appendix referenced in this request.

To clarify this information, I have modified the following portions of our production license application and included those pages in Attachment D.

Pages ACC-26 through 27 – In addition to the changes noted in response to Request 2, Page ACC-26 is modified to clarify that the University's broad scope survey program will be used for the production license. Page ACC-27 is modified as the result of adding additional statements on the previous page.

The following examples of surveys made in support of the University's cyclotron facilities are provided for information only in response to your request.

- Hand-held Geiger meters, ion chambers, a neutron rem ball and fixed position Luxel area monitors are used to survey for dose rates in and around the cyclotron vaults and the target delivery lines. The radiation level in these areas are reviewed to ensure that the total effective dose equivalent to an individual member of the public from licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose rate in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

- Area surveys are performed for all existing combinations of beam current, accelerated particle and target formations. Radiation Safety and the cyclotron staff cooperate to ensure that new area surveys are performed when any of these operating parameters significantly change. The area surveys are periodically repeated for the worst case operating parameters; that is, the parameters that cause the higher radiation fields in the surrounding areas.

- Contamination surveys of the cyclotron vaults, target delivery lines and adjacent areas are routinely performed and documented by cyclotron staff. Radiation Safety staff perform confirmatory surveys during routine quarterly inspections. Radioisotope product delivery carts are surveyed for removable contamination prior to each release from a cyclotron facility. A hand and foot monitor is always on at the facility exit. All individuals are required to check their hands and feet for contamination prior to leaving the facility.

- Air sampling is discussed in our response to Request 5.

- The stack monitoring system is observed by cyclotron staff or other trained individuals during cyclotron operation and radioactive material processing in the cyclotron facilities. The Cyclotron Supervisor and Cyclotron Manager are notified if the stack monitor reading exceeds 2 mR/h and assessment of the cause for the increased release is immediately investigated in the processes being conducted in the cyclotron facility. The stack monitor results are reviewed weekly to determine if accumulated peaks, i.e., total area under the peaks for a week, exceed 10 mR. If so, the Cyclotron Manager is notified and assessment of the cause for the increased release is immediately investigated. If there is a release identified from a process unit that exceeds one of these action points on the stack monitoring system, corrective actions must be identified, taken and documented before the process unit can be put back into use. Radiation Safety staff are notified if action points are exceeded and review corrective actions.

***Request 7:* Regarding your Waste Mgmt. program, describe procedures that will be followed for safely collecting waste generated from each cyclotron, and storing and transferring the waste to the broad scope license.**

Additional information in response to this request is included in the University's production license application in Attachment D.

Page ACC-28 – This page is modified to include additional information on the University's radioactive waste management program in Section ACC Item 11.

I appreciate your careful review of our new production license application and your patience in working through the response references to the University's new production license application (C/N 318581) and our broad scope license application (License No. 24-00167-11). Please contact me at (314) 362-2988 or at langhors@wustl.edu if you have any further questions concerning our responses to your request for additional information on the Washington University in St. Louis Application for New Production License Using an Accelerator.

Sincerely,

Susan M. Langhorst

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

Cc w/atts: 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 Response to Request 1

Pages ACC-13 through 16a

Page ACC-29

Pages ACC-32 through 38

ACCELERATOR PRODUCTION LICENSE (ACC) SECTION

ACC Item 7.

Individuals Responsible for Cyclotron Production Radiation Safety Program

ACC 7.1 Executive Management

Executive responsibility and authority for administration of Washington University in St. Louis is assigned to the Chancellor. The Chancellor has delegated the responsibility and authority to oversee the implementation and management of this accelerator production license to the Executive Vice Chancellor for Medical Affairs. This individual appoints the Radiation Safety Committee (RSC) chairman, vice chairman, members and alternates for designated members. The RSC membership shall meet the requirements of 10 CFR 35.24(f). The Executive Vice Chancellor for Medical Affairs ultimately supervises the individuals responsible for the safe production, possession and transfer of radioactive materials from the University's cyclotron facilities to the University's Broad Scope Type A Medical Use License (No. 24-00167-11). The Chancellor appoints the RSO. See the radiation safety program organizational chart in ACC Schedule 1.

ACC 7.2 Radiation Safety Officer (RSO)

The Radiation Safety Officer and Radiation Safety Staff responsible for this production license are also responsible for the University's Broad Scope License. Many of the responsibilities and duties listed below are maintained under the Broad Scope License.

<u>ACC 7.2-1 Radiation Safety Officer Identified</u>

See ACC Schedule 2 for name, training and experience of the Radiation Safety Officer named for this production license.

<u>ACC 7.2-2 Responsibilities and Duties of the Radiation Safety Officer and Staff</u>

a. Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;

b. Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301;

c. Ensure security of radioactive material;

d. Oversee proper transfer of radioactive material to NRC License No. 24-00167-11 (see Section ACC 9.1), including transfer for radwaste disposal (see Section ACC 11.);

e. Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements;

f. Post documents as required by 10 CFR Parts 19.11 and 21.6;

g. Ensure that radiation exposures are ALARA;

h. Oversee all activities (licensed and unlicensed) involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed;

i. Act as liaison with NRC and other regulatory authorities;

j. Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations;

k. Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action;

l. Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, or regulations;

m. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records (see Section 11.);

n. Oversee the storage of radioactive material not in current use, including waste;

o. Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;

p. Maintain an inventory of all radionuclides possessed under the license and limit the quantity to the amounts authorized by the license;

q. Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property;

r. Supervise decontamination and recovery operations;

s. Maintain other records not specifically designated above (e.g., records of production, transfers, and surveys as required by 10 CFR 30.51 and 10 CFR 20, Subpart L, "Records");

t. Hold periodic meetings with, and provide reports to, licensee management;

u. Ensure that all users are properly trained;

v. Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with: all applicable NRC regulations, the terms and conditions of the license (e.g., inventories and possession to trained, approved users), the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 10 CFR 20.1101, and the requirement that all records be properly maintained;

w. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies;

x. Ensure that the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material;

y. Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits; and

z. Maintain an understanding of, and up-to-date copies of, NRC regulations, the license, and revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.

ACC 7.2-3 Radiation Safety Officer Delegation of Authority

See ACC Schedule 3 for the RSO Delegation of Authority signed by the Chancellor of Washington University in St. Louis.

ACC 7.3 Authorized Users Responsible for Cyclotron Production

ACC 7.3-1 Cyclotron Authorized User Responsibilities

Primary responsibilities of a cyclotron authorized user include:

- Handling licensed material safely.
- Maintaining security of, and access to, licensed material.
- Responding appropriately to events or accidents involving licensed material to prevent the spread of contamination.
- And, directing other personnel in performing any of these activities.

ACC 7.3-2 Cyclotron Authorized User Review and Approval

Washington University in St. Louis maintains a Broad Scope Type A Medical Use License (No. 24-00167-11). The Radiation Safety Committee (RSC) established for this broad scope program has the responsibility[1] to, "Review and approve or deny, on the basis of safety and the prior training and/or experience of the applicant, all requests to use radioactive materials within the Institution." In accordance with NRC guidance[2], individuals applying to become cyclotron authorized users will be reviewed and authorized by the Radiation Safety Committee without need to name cyclotron authorized users on this production license.

ACC 7.3-3 Cyclotron Authorized User Training and Experience Requirements

To demonstrate adequate training and experience at an accelerator facility, the individual applying to become a cyclotron authorized user should have: (1) a college degree at the Bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities such as handling of activated targets and activated products associated with cyclotron activities. The individual's training should include the following subjects:

- radiation protection principles,
- characteristics of ionizing radiation,

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[1] Washington University in St. Louis Application for NRC License No. 24-00167-11, Docket No. 030-02271, BSL 7.2-1 g. (page BSL-18, License Renewal, September 30, 2002).

[2] NUREG-1556 Volume 21, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses Production of Radioactive Material Using an Accelerator, *Note* on page 8-18 (October 2007).

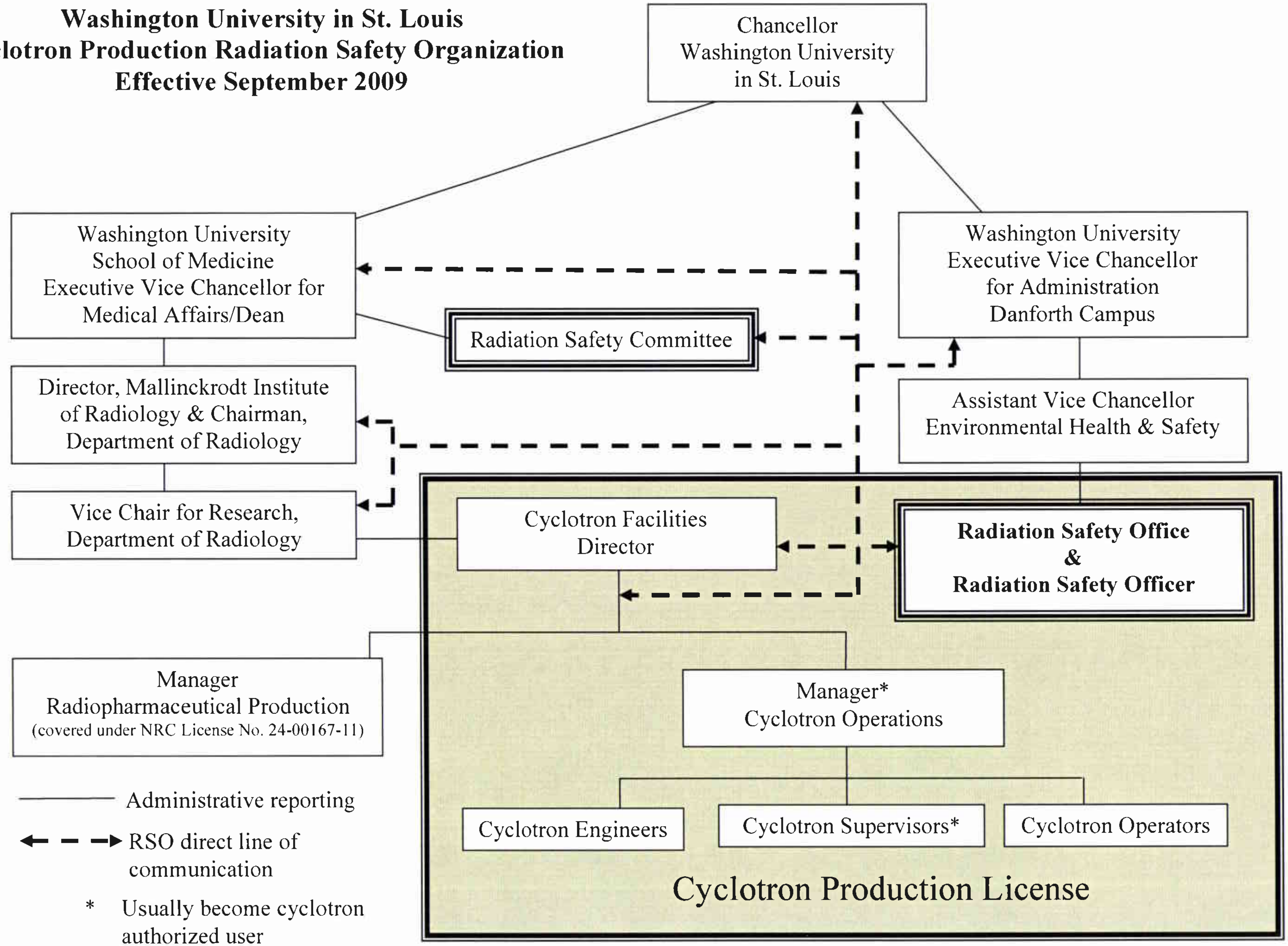
- units of radiation dose and quantities,
- radiation detection instrumentation,
- biological hazards of exposure to radiation (appropriate to the types and forms of byproduct material to be used), and
- handling of radioactive materials relevant to cyclotron activities.

In addition, the individual applying to become a cyclotron authorized user should have at least 40 hours of radiation safety training specific to his or her job duties as well as a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material.

Individuals who are 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 may be allowed to work without supervision of a cyclotron authorized user named under this production license.

ACC Schedule 1

Washington University in St. Louis
Cyclotron Production Radiation Safety Organization
Effective September 2009



ACC Schedule 4

Note

- NRC license reviewer noted that broad scope programs are permitted to name authorized individuals without amending the license. Reference: NUREG-1556, Volume 21 (October 2007)

- The curriculum vita (CV) for cyclotron authorized user originally provided in ACC Schedule 4 was withdrawn with the "Response to Request for Additional Information and Clarification on Washington University in St. Louis Application for New Production License Using an Accelerator" submitted on April 9, 2010.

ACC Schedule 5

Note

- NRC license reviewer noted that broad scope programs are permitted to name authorized individuals without amending the license. Reference: NUREG-1556, Volume 21 (October 2007)

- The curriculum vita (CV) for cyclotron authorized user originally provided in ACC Schedule 5 was withdrawn with the "Response to Request for Additional Information and Clarification on Washington University in St. Louis Application for New Production License Using an Accelerator" submitted on April 9, 2010.

Attachment B

Updated Pages to be Substituted in
Washington University in St. Louis New Production License Application
as Described in Response to Request 2

Pages ACC-18 through 19

potential hazards associated with the licensed materials as approved under the authorization and commensurate with the Radiation Workers' responsibilities.

Radiation Workers are required to follow conditions approved for the authorization under which they use licensed material, written radiation protection procedures established for this license, NRC regulations and license conditions with respect to the research use[1] of licensed material. Authorized Users are responsible for the acts and omissions of Radiation Workers working under their authorization.

Authorized Users and Radiation Workers will be required to complete radiation safety training annually or whenever there is a significant change in duties, regulations, or the terms of the license that are related to their use of licensed materials.

ACC 8.2 Training for Individuals Working in or Frequenting the Cyclotron Vaults

As noted in ACC Schedule 1, the Manager of Cyclotron Operations and the Cyclotron Supervisors usually become cyclotron authorized users, with the Manager usually named as the Primary Cyclotron Authorized User. Cyclotron authorized users are responsible for ensuring only trained individuals are granted unescorted access to the cyclotron vaults. 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.

In addition to the training already described in Section ACC 8.1, individuals granted unescorted access to any or all of the cyclotron vaults will also receive training on the following topics for each applicable cyclotron vault prior to being granted unescorted access.

- Vault and equipment description
- Vault security and safety systems during cyclotron operation
- Vault entry and safety procedures
- Typical radiation exposure rates
- Escorting other individuals into the vault
- Other vault procedures applicable to the individual's duties

An individual's training will be assessed and documented by the trainer through performance-based questioning on the individual's comprehension of the applicable training topics prior to granting the individual unescorted access. Individuals granted unescorted access will review these training topics as part of their annual radiation safety training.

[1] This use would be with respect to production and storage under this license, and the subsequent use for radiochemical or radiopharmaceutical production.

The initial training for cyclotron vault unescorted access will be conducted by a cyclotron authorized user, or by an individual who has had unescorted access for at least one year and who is approved by the Cyclotron Primary User or the Radiation Safety Officer to do this training.

Training needs required to grant unescorted access for licensed service providers will be assessed by a cyclotron authorized user on a case-by-case basis.

ACC 8.3 Training for Ancillary Workers

The term "Ancillary Worker" used in this license is defined to mean those workers who in the course of employment or study enter a cyclotron vault. Ancillary Workers entering a cyclotron vault will be escorted at all times by an individual who has unescorted access to the cyclotron vault. This escorting individual will have the responsibility for maintaining radiation safety for the escorted Ancillary Worker. If an Ancillary Worker's duties require frequent access to a cyclotron vault, the Ancillary Worker will be trained in the topics listed in Section ACC 8.2 and may be granted unescorted access.

Attachment C

<u>Additional Information Described in Response to Request 3</u>

Barnard Cyclotron Facility Ventilation System

East Building Cyclotron Facility Ventilation System

MediSmarts Stack Monitoring System Brochure

Strobic Fan dilutes exhaust air (~ 4,500 to 6,000 CFM) to a height of 30-40 feet above the roof at ~20,000 CFM

Example of ROTEM
MediSmarts Stack Monitor Display

A. PM-11 NaI (Tl) detector – low concentration monitor
B. GM-41 Geiger-Muller detector – high concentration monitor

JSW168 Vault

1

2

CS-15 Vault

CS-15 Vault Exhaust
Vault room exhaust southwest corner

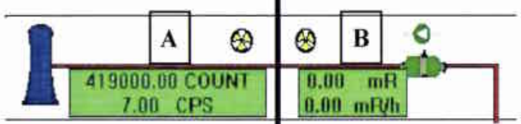
JSW168 Vault Exhaust
1. Vault room exhaust southwest corner
2. Maze exhaust

Barnard Cyclotron
Production Lab hoods and hot cells

Mallinckrodt Radiochemistry
Laboratory hoods and hot cells

Barnard Cyclotron Facility Ventilation System

Strobic Fan dilutes exhaust air (~ 4,500 to 6,000 CFM) to a height of 30-40 feet above the roof at ~20,000 CFM



Example of ROTEM
MediSmarts Stack Monitor Display

A. PM-11 NaI (Tl) detector – low concentration monitor
B. GM-41 Geiger-Muller detector – high concentration monitor

RDS Vault (1, 2)

RDS Vault Exhaust

1. Vault room exhaust northwest corner
2. Heat removal exhaust under the cyclotron

Quality Control Lab hoods

Protective Conduit for O-15 gas lines

Radiopharmaceutical Production Lab hoods and hot cells

East Building Cyclotron Facility Ventilation System

MediSmarts

A Comprehensive Radiation Monitoring System for Cyclotron facilities

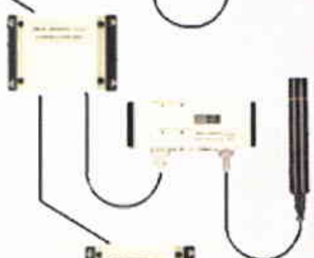
ROTEM's MediSmarts system is a Modular comprehensive real time on-line radiation monitoring system, which provides solutions to regulatory, health physics safety and production monitoring in Cyclotron Facilities

The MediSmarts system is a user friendly, fully automated system, that can be tailored with the following block modules for the specific needs of each site.

Stack monitoring
Area monitoring
Production Monitoring
Comprehensive Radiation analysis software
Site safety control

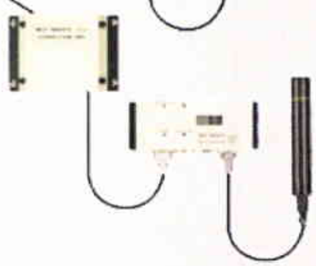
Stack monitoring

- On-line Total Released Activity + Concentration (µCi + nCi/m^3, Bq + Bq/m^3).
- Five user defined threshold levels.
- Two dry contacts for actuating air duct vents.
- Full background reduction – actual release report .



Area Monitoring

- Dose + Dose Rate (mR + mR/h, uSv +uSv/h).
- Five user defined threshold levels.
- 500,000 points per graph (2 sec. Interval).
- Accumulated Dose per defined period.



Production Monitoring – Hot Cells

- On-line total activity (µCi, Bq)
- Two dry contacts for interlocking system.

Control Station

RCTEM
Radiochemistry Solutions

The MediSmarts System

System main features:

Stack Monitoring:
- Quantitative measurement of the released activity
- Activity release report
- Automatic calculation of the accumulated dose or total activity for selected time interval using air flow data.
- Software calibration routine for the activity concentration in the duct.

Area Monitoring
- Online real time monitoring software
- Monitoring different areas of the facility.
- Local display of the detector radiation measurements
- Audio and visual alarms for exceeding radiation threshold level and malfunctions.
- Compatibility with many types of radiation detectors.
- Modularity, local alarms and optional control system.

Production Monitoring
- Q.A Management
- Monitoring various aspects of the production process (chemistry box and Cyclotron target).

MediSmarts Software
- On line graphs for trend analysis
- Five alarm threshold levels
- User friendly
- Easy to operate
- CE compatible
- Software automatic recovery after shutdown
- Software reports generator.
- Export data files in Microsoft excel format.

Recommended system for Radiation safety in cyclotron site consists of:

1. **Stack Monitoring**
   - PM11 - NaI (Tl) Scintillator detector
   - GM42 – GM high sensitive detector
   - Flow Rate Meter (option)
2. **Area Monitoring**
   - 2.1 Radiopharmacy, Radiochemistry, Quality Control, Service room.
     - Gm-42 high sensitive detector
   - 2.2 Cyclotron Vault + Hot Cells
     - GM41 – GM detector
     - Neutron Detector
3. **Control Station**
   - Computer
   - MediSmarts Analysis software
   - Gm-42 high sensitive detector

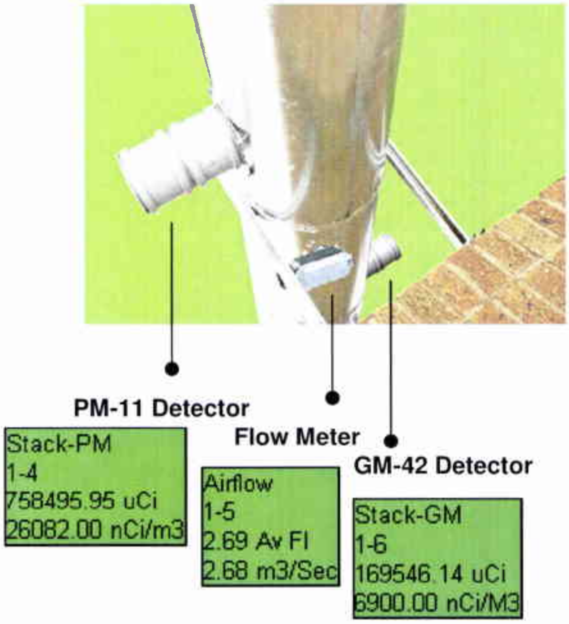
We reserve the right to change specifications without advance notice

Radiochemistry Solutions
Dan Conatser President
16 Berkshire Drive, Franklin, MA 02038 USA
Offices & cell 1-774-571-5369, Skype: danconatser

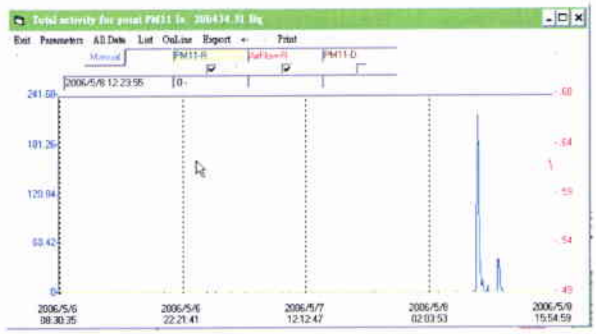
The MediSmarts System

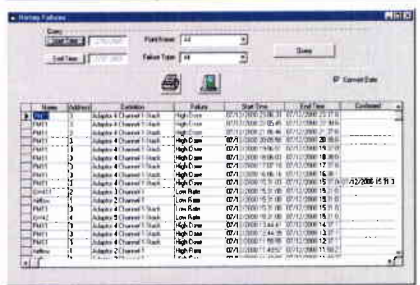
Stack monitoring module

Stack monitoring is required at all sites that produce radioactive materials. The site is required to document its radioactive releases according to isotope, concentration and total release activity.
Our Stack Monitoring system was developed specifically for cyclotron sites and is based on accumulated experience. The system is based on radiation detectors measuring a wide range of concentration levels, a flow rate meter, Electronic Data Processing Units and unique software algorithms.



Online trend graphs





Reports

System Highlights

- Quantitative activity release measurement
- Complies with environmental regulation
- Helps in the production process
- Local Alarm & Output relays
- Software calibration routine for converting the detector reading
- Automatic Activity release report
- Integrated on-line Air flow data for activity release report
- Measuring wide range of concentration levels from 0.05μCi/m^3 to 150mCi/m^3
- Automatic calculation of the total activity for selected time interval.
- Event messages/Alarms for: fail-safe, Lost contact, detector fail, overflow
- Automatic Archiving of data
- Historical Reports and Activity Logs.

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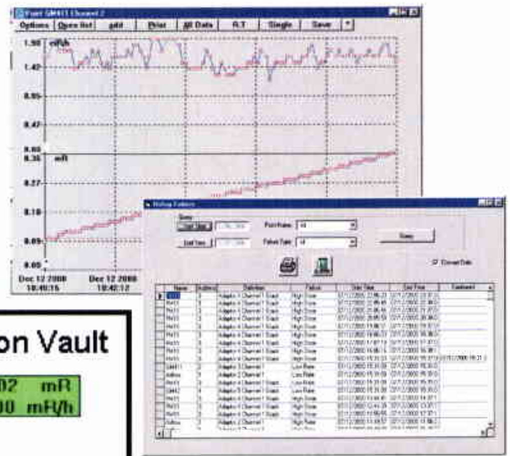
The MediSmarts System

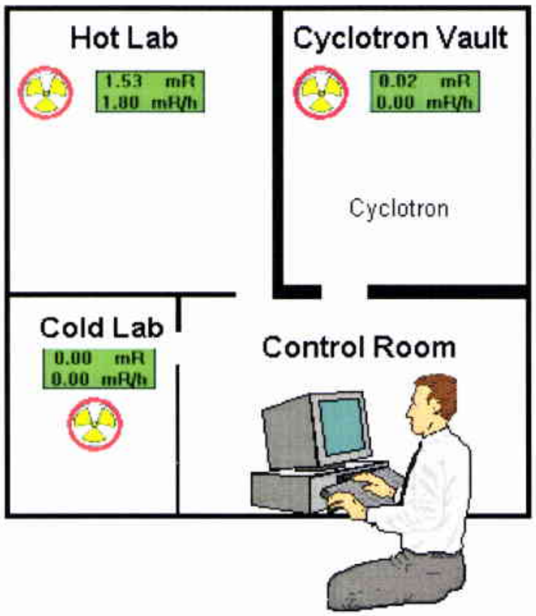
Area monitoring module

Our Area Radiation Monitoring is based on field proven, highly reliable radiation detectors, Electronics Data Processing Units and Unique Computer Software. The system provides real time on line radiation levels.
The data is used for both radiation safety and improving the site operation performance. Area Monitoring is recommended at the following locations:

Hot Laboratory
Radiochemistry
Cyclotron Vault.



* Health Physics
* Improve Site operation
* Sensitive Detectors
* Local Alarm
* Output Relays
* Unique Software
* Reports
* Trend Graphs



Online trend graphs & Reports

The Monitoring Channel:

- Sensitive detector
- Large, easy to read, digital LCD
- Automatic identification of the detector calibration factor.
- Output relay contacts to indicate exceeded radiation threshold levels and malfunction.
- Four indication LED's for Input supply voltage, Threshold & detector malfunction alarm and communication indication.

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Radiochemistry Solutions
Dan Conatser President
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The MediSmarts System

The MediSmarts software

The Medi SMARTS software collects the measured radiation data via an RS-485 communication network and displays it on the computer screen.
The software's main screen includes the on line radiation measurements levels presented on the site map with color-coded points showing their status. The historical data with a memory capability of up to 100,000 historical records for each point can be presented on a graph and analyzed. The reports generator records the alarms for Q.A documentation.
The proposed detectors for area monitoring are Rotem's GM -41/42 detectors.
The GM42 is a highly sensitive detector with a measuring range of between 0.1 uSv/h – 10 mSv/h.
The GM41 measuring range is between 01 uSv/h – 1 Sv/h, see the detector specifications below.

Detectors Specification

Type	GM-41	GM-42
Geiger Type	ZP1313	ZP1201
Measuring Range	1 uSv/h – 1Sv/h	0.1uSv/h – 10mSv/h
	0.1mR/h - 100R/h	0.01mR/h -1R/h
Sensitivity	1.7 cps/mR/h	17 cps/mR/h
Accuracy	± 10% reading within the measuring range	± 10% reading within the measuring range
Energy Range	50 keV - 1.3 MeV	50 keV - 1.3 MeV
Energy Dependence	± 15%	± 20%
Angular Dependence	Less than ± 20% for ±45° of preferred direction	Less than ± 20% for ±45° of preferred direction
Temperature Range	Operation: -10℃ to +50℃	Operation: -10℃ to 50℃
	Storage: -20℃ to +60℃	Storage: -20℃ to +60℃
Humidity Range	40% to 95% RH (non condensing)	40% to 95% RH (non condensing)
Dimensions:		
Length	170 mm (6.7")	197 mm (7.75")
Diameter	38 mm (1.5")	38 mm (1.5")
Weight	200 gr (0.44 lb)	250 gr (0.55 lb)
Casing	Aluminum, splash proof	Aluminum, splash proof
Hook-up cable length	up to 100 m	up to 100 m
Output signals	TTL pulses (5V, 5ms)	TTL pulses (5V, 5ms)
	Detector status logic:	Detector status logic:
	- identification	- identification
	- malfunction	- malfunction
	- radiation overflow	- radiation overflow

Related to ^{137}Cs

We reserve the right to change specifications without advance notice

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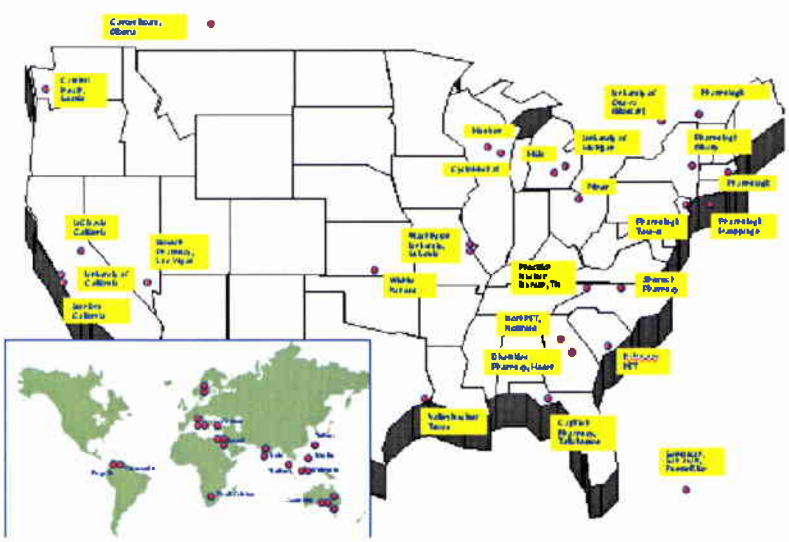
ROTEM

The MediSmarts System

Detector Specification

	PM-11
Radiation detection	Gamma above 50 keV
Scintillator	Crystal: NaI (Tl)
	Dimensions: 2" dia. x 2" thickness
	Window: 1 mm (0.04") aluminum
Count rate range	0 to 50,000 cps
Surface Sensitivity (in contact):	Radionuclide / Sensitivity cpm/Bq/cm2 / Minimum detectable level* Bq/cm2
	F-18 / 350 / 10
	I -125 / 25 / 150
	I -131 / 320 / 12
	Tc-99m / 315 / 12
	* Minimum detectable level calculations are based on background reading of 3600 cpm. The confidence level is 99%.
Output signals	TTL pulses (5V, 5μs)
	Detector status logic:
	identification, malfunction, radiation overflow
Temperature range	Operation: -10°C to + 50°C (15°F to 122°F)
	Storage: -20°C to + 60°C (-5°F to 140°F)
Humidity range	40% to 95% RH (non condensing)
Casing	Aluminum, splash proof
Dimensions	34 cm long x 7 cm diameter (13.4" long x 2.75" diameter)
Weight	1.75 kg (3.9 lb)
Option	Factory calibrated single channel analyzer (SCA) within the energy range

Our Customers



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Attachment D

Updated Pages to be Substituted in
Washington University in St. Louis New Production License Application
as Described in Response to Requests 2 & 6

Pages ACC-26 through 27

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

No additional response is required.

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

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 is 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, and personnel wear an immediate reading dosimeter and check the accumulated dose reading frequently. In most cases, personnel are able to limit their accumulated dose to less than 20 mrem per 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

No response is required.

ACC 10.9 Transportation

No response is required.

ACC 10.10 Minimization of Contamination

No response is required.

Attachment E

Updated Pages to be Substituted in
Washington University in St. Louis New Production License Application
as Described in Response to Request 7

Page ACC-28

ACCELERATOR PRODUCTION LICENSE (ACC)

ACC Item 11.

Waste Management

Radioactive material possessed under the production license will be disposed through decay-in-storage or ultimately be removed from the cyclotron vault and transferred to Washington University in St. Louis Broad Scope Medical Use Type A License No. 24-00167-11. The decay-in storage procedures used for the production license is the same as described in the University's Broad Scope License Application, Section BSL 11.1-2: "Authorization Decay-In-Storage."

Activated Havar foils, copper target grids and other items removed during target and cyclotron maintenance procedures can exhibit significant radiation levels and typically contain longer lived radioactive materials, such as Co-60. These activated items are carefully collected by trained cyclotron staff and stored in shielded areas inside the cyclotron vault for a period of time, usually three to six months, to allow for some decay prior to transfer to the University's Broad Scope License. Other radioactive waste materials are segregated according to half-life, chemical and physical form, and exposure rate.

Radiation Safety staff survey and package the radioactive waste materials into containers which are sealed, shielded as needed, and labeled for transfer out of the cyclotron vault to the University's Broad Scope License radioactive waste management program.

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* Call for Confirmation:

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