ALLEGHENY
GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-3131

May 8, 2006

Betsy Ullrich
USNRC Region 1
Division of Nuclear Materials Safety
Commercial and R&D Branch
475 Allendale Rd.
King of Prussia, PA 19406-1415

MS 16
Q-5

RECEIVED
REGION I
2006 MAY 15 PM 1:26

Licensee: Allegheny General Hospital (AGH)
NRC License No.: 37-01317-01
Docket Number 030-02981

Dear Ms. Ullrich;

This letter is in response to your request for additional information, Mail Control Number 137180, dated February 16, 2006.

1a. Allegheny General Hospital, 320 East North Ave., Pittsburgh, PA 15212 is the main campus and will perform 90% of the radioactive material use. Everything listed in Item 5 can be used at this facility.

1a. This is the receiving dock for 1a.

1a. 1307 Federal Street, Pittsburgh, PA 15212 is a clinical lab facility. This is on the license in the event a test using a radioactive tracer is needed. Radioactive material is ordered on an as needed basis and no materials will be stored at this location.

1a. 100 South Jackson Ave., Pittsburgh, PA 15202 is a remote site that will perform nuclear medicine studies. They will use 35.100, 35.200, and 35.300 material. However, they will not use 35.300 material that would require patients to be hospitalized during treatments.

1. Upon review, Item 5.d. is not necessary. However, AGH wishes to increase Item 8.A. of the license to 1 Curie per radionuclide and 10 curies total and continue Condition 12 of the current license.

2. The sources formerly used by the Nucletron MicroSelection HDR has been shipped to Nucletron and should be removed from the license. See Attachment 1 for documentation.

137180

NMSS/RGN1 MATERIALS-002

3. The depleted uranium (DU) was used as shielding in a Varian linear accelerator. The device was given to Varian, the DU components were removed and sent to Varian. See Attachment 2 for documentation that Varian received the DU shipment.

4. The use of radioactive materials in animals must first be approved by the Radiation Safety Committee (RSC). This is done by a process by which an Authorised User submits a protocol application detailing the use of isotope in the animals. All aspects must be detailed in the application from the isotope to the type of animal, to how many and what state they will be in (alive or sacrificed), to where the isotope is administered, to where the animal is housed and for how long, to how the waste is handled. These are all considered and approved by the RSC.

5a. Animals containing radioactive material will be housed in separate cages/pens. These areas will be restricted from unauthorized access and will be maintained to prevent the spread of contamination and to limit radiation exposure to below regulatory limits.

5b. Animal care personnel shall be required to attend training as deemed necessary by the Radiation Safety Committee (RSC). The RSC will consider all hazards, facility constraints, and regulatory requirements to provide the proper level of training.

5c. Animal care personnel shall work with the Radiation Safety Office to determine the necessary actions to properly handle the animals, handle animal waste, bedding, carcasses, cleaning of the cages/pens and decontamination of the cages/pens. This will all be detailed prior to the animals receiving radioactive materials.

5. In the past, animals were not be released to unrestricted areas or returned to owners. AGH plans to continue this practice.

In the event that it should become necessary, the RSC will consider release of an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted. The RSC will ensure that the dose that members of the public will receive from the animal is within limits of 10 CFR 20.1301. 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the RSC will perform an assessment of the impact the byproduct material will have on the environment if there is a chance of environment impact.

Instructions to animal caretaker will be provided upon release. The instructions will be specific to the type of treatment given, such as radiopharmaceutical injection or permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions will not, however, interfere with or contradict the best medical judgment of a veterinarian. The instructions will include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions.

Sample instruction provided in Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers - Final Report (NUREG-1556, Vol. 7), Appendix H, will be used.

7a. AGH will not perform research that is not funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise AGH will apply for a specific amendment to the license before conducting such research.

7b. AGH does confirm that, prior to performing research on human subjects, we will obtain 1) review and approval of the research activity by an IRB; and 2) informed consent from each subject.

8a. The RSC will meet at least quarterly to discuss business at hand. Meeting must be conducted with a representative quorum. A quorum is established by having the Chairperson (or designee), Executive Management (or alternate), the RSO plus additional members to constitute a majority.
Standard items are discussed at each meeting, such as minutes from last meeting, ALARA reports, spills, radioactive material use audits, QMP audits, Administration report and Nursing report. Next, Old Business and open items are discussed and finally New Business. Under New Business, standard items such as human use research, non-human use research and authorized users are discussed and approved. To facilitate this, the Radiation Safety Office compiles the information to present to the RSC. Approval of voting issues are by majority vote.
The RSC will maintain minutes of its meetings. The minutes include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations and the results of votes. The RSC will document its review of new users, uses, and program changes. The minutes include information related to the ALARA program reviews and the annual audit review.

8b. Membership in the RSC will include the Chairperson, Executive Management, representative of the nursing service and the RSO. Additional members will include persons from the major areas of use of byproduct material and areas affected by that use.

Several factors are considered when selecting a chairperson for the RSC. The individual must have knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO will not be appointed as the chairperson of the Committee.

The selection for executive management must have authority to make decisions in the name of management. This typically will be at the vice-president level.

Additional RSC members must include an authorized user of each type of use permitted by the license and a representative for nursing.

8c. AGH confirms that we will meet the requirements of 10 CFR 35.24(f).

8d. See Attachment 3. The criteria for (2) through (4) are the same as described in Items 9 and 10 of the application.

8e. AGH confirms it will comply with 10 CFR 35.2 and will be equivalent to that detailed in 10 CFR 35.

8f. AGH does not currently use 35.1000 devices. In the event AGH should use 35.100 devices, we will seek guidance currently available or consult NRC for new applications.

9. A copy of the delegation of authority statement is enclosed, see attachment 4.

10. AGH confirms that the duties and responsibilities of the RSO will meet the description in Appendix I of NUREG 1556, Volume 9.

11. AGH will comply with the statements made in items 11 a, b, c, d and e of the request for additional information letter dated February 16, 2006.

12a. These were discussed under section 9 of the renewal application.

12b. The only special use areas AGH has are the iodination lab and animal facilities. Both of these areas are discussed in the application. The RSC and RSO will formally review and approve any proposed special use areas.

13. Survey instruments will be calibrated by the instrument manufacturer or a person/company specifically authorized by the U.S. NRC or an Agreement State to perform instrument calibration. In the event AGH should calibrate equipment, we will follow the manufacturer's written procedures or the model procedure in Appendix O of NUREG 1556, Volume 11. The lower limit of detection will be determined for instruments used to make quantitative sampling and analysis.

14. AGH confirms that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

15. Copies of the spot check procedures are enclosed, see attachment 5.

16a. The HDR unit is used and stored in a linear accelerator vault, Vault B. The vault conforms to specifications for entering a High Radiation Area. The door is interlocked with the control panel and delivery unit. It will shut down and retrieve the source when opened during a treatment. A warning light is lit when the source is exposed and there is a High Radiation Area sign on the door. The control consol has a warning light when the unit is activated. The HDR unit is secured by a lock on the vault door and it is chained to the wall.

16b. There is a continuous radiation monitor that is visible when entering the vault. It displays a red or green light to indicate if radiation is present. In addition, an ion chamber is kept at the control panel that is used when entering the room after a treatment.

16c. There are two cameras for viewing the patient. Also there is a mirror angled to view the patient from the window in the vault door. There is a 2-way intercom system to communicate with the patient. If the intercom system does not function, then treatments will be terminated until it is repaired.

16d. The vault has a lock-out switch to select either the linear accelerator or the HDR. This switch is checked every day of use.

16e. The control panel keys are kept in a lockbox when the unit is not in use. Only authorized personnel have access to the lockbox.

16f. Emergency response equipment consists of an ion chamber, wire cutters, long-handled forceps and a lead container.

16g. This does not apply to this unit.

17. The emergency response procedures for the remote afterloader unit is contained in attachment 6.

18. Trigger levels for ambient exposure surveys are established for restricted and unrestricted areas. Restricted areas can have a trigger level of up to 2 mR/hr, some restricted areas have a lower trigger level. Unrestricted areas have a trigger level of up to 0.1 mR/hr, again some unrestricted area have a lower trigger level. The reason some areas have lower trigger levels is, due to either some areas having the capability to keep better control of radiation sources, or using much less radioactivity than others. Exposure surveys are performed at the end of each day of radioactive material use, in all areas of use.

Trigger levels for contamination surveys are established for restricted and unrestricted areas. Restricted areas can have a trigger level of 500 dpm/100cm^2. Unrestricted areas have a trigger level 200 dpm/100cm^2.

AGH has set the contamination trigger levels very low because we feel we have the capability and training to use radioactive materials in a manor to minimize the amount of contamination from routine operations. Contamination surveys are performed weekly when radioactive material used, in all areas of use.

Airborne radioactive material is monitored and is discussed in the license renewal application on page 15, Airborne Radioactive material. The iodine 131 used for thyroid therapy is rarely in liquid form, most of the time it is in a capsule, in powder form. When it is in the powder form, the volatility is extremely low, however, the vial is initially opened in the fume hood.

Liquid effluent, excreta and sewer disposal monitoring are one in the same because they all go into the sanitary sewer system. All radionuclides disposed of into the sanitary sewer system are logged and a monthly concentration is calculated for each isotope. This is compared to the limit set in 10 CFR 20, Appendix B, Table 3. The method set in 10 CFR 20.2003 is then applied for compliance. If any isotope exceeds the limit set in 10 CFR20, Appendix, B, a complete investigation will be performed.

19. Many times there is a need to convert areas, a lab, or group of rooms that used radioactive materials into an unrestricted use area. In these situations, a dose-based release requirement is the preferred method of release. The permissible annual TEDE is 25 mrem for unrestricted areas. To meet this requirement, thorough surveys of the area are performed. The surveys will include an exposure survey and a contamination survey. The exposure survey will document ambient exposure levels and the contamination survey will look for gross beta/gamma contamination.

A particular item may be targeted for release. For example, if an area had a sink for radioactive liquid waste disposal, contamination surveys will be performed in the basin, the drain and the trap. Another situation may be if equipment would have radioactive material introduced like a centrifuge or freezer, then all accessible surfaces will be surveyed. If all surfaces can not be surveyed, it will be disposed of as radioactive waste, placed in another radioactive material lab, or for short lived isotopes, held for 10 half-lives.

The results of the surveys will be reviewed by a Physicist. The Physicist will determine if the results meet the unrestricted use criteria or if more data is needed. Once the Physicist has determined that criteria has been met, it is presented to the RSC for final approval. In all cases, the unrestricted use criteria for exposure and contamination must be met.

AGH wishes to make one additional change in the license. Please change Item 8J., the total possession limit to 21 curies. This will not affect source changes. The source in use and the new source are approximately 5 and12 curies respectively, for a total possession of 17-18 curies.

Should you have any questions or need additional information, please contact Joseph G. Och, RSO, at 412-359-6864 or Joseph Rizzi at 412-359-8297.

Sincerely,

Richard W. Early

Richard W. Early, P.E.
Vice President, Facilities Management

ATTACHMENT 1
Receipt Verification from Nucletron

From: "Prager, Cyndie" <cyndie.prager@us.nucletron.com>
To: <kblodget@wpahs.org>
Date: 4/5/06 3:26PM
Subject: Return of Depleted Ir-192 Source

Please be advised that AEA Technology has received your depleted Ir-192 source # 2625 on 11/15/2005. This was the last source provided by Nucletron for the Classic mHDR machine S/N 9651.

Respectfully,

Cyndie Prager
Source Logistics
Nucletron Corporation
1-800-445-9295
410-872-4485
410-312-4196 - fax
prager@nucusa.com

Cyndie Prager
Coordinator, Source Logistics
Nucletron Corporation
Office: +1 (410) 872 4485
cyndie.prager@us.nucletron.com
Visit our website:
www.nucletron.com

ATTACHMENT 2
Depleted Uranium Disposal

VARIAN
medical systems

Oncology Systems
200 E. Howard Avenue
Suite 230
Des Plaines, IL 60018
USA
tel +1 847 299 2600
fax +1 847 299 2651
www.varian.com

Joseph Rizzi
Allegheny General Hospital
Medical Physics Department
320 East North Avenue
Pittsburgh, PA 15212

2 May 2006

Dear Mr. Rizzi:

In response to your request for information regarding the removal of the depleted uranium components from Clinac 4-100 # 59 I have forwarded the following documents:

1. Remanufacturing Center Depleted Receipt Log - This documents the arrival of the material removed from 4-100 # 59.
2. Remanufacturing Center Depleted Uranium Inventory as of 10/18/2002 – This shows the addition of your material to the inventory.
3. Radiation and Contamination Survey Form – Which documents the arrival survey performed upon your material and indicated that the dose rates were within acceptable transportation limits and no removable contamination was present.
4. UNIFORM LOW-LEVEL RATIOACTIVE WASTE MANIFEST – Shipping Paper
5. UNIFORM LOW-LEVEL RATIOACTIVE WASTE MANIFEST – Container and waste Description
6. Remanufacturing Center Depleted Uranium Inventory as of 01/23/2003 – This document indicates the entire inventory listed as loose pieces was shipped for disposal.
7. Illinois Radioactive Material License Number IL-01143-01.

I hope that this information satisfies your reporting requirements. Please contact me if you require any additional information.

Sincerely,

Robert Gerber
Manager / RSO
Field Service Support Center

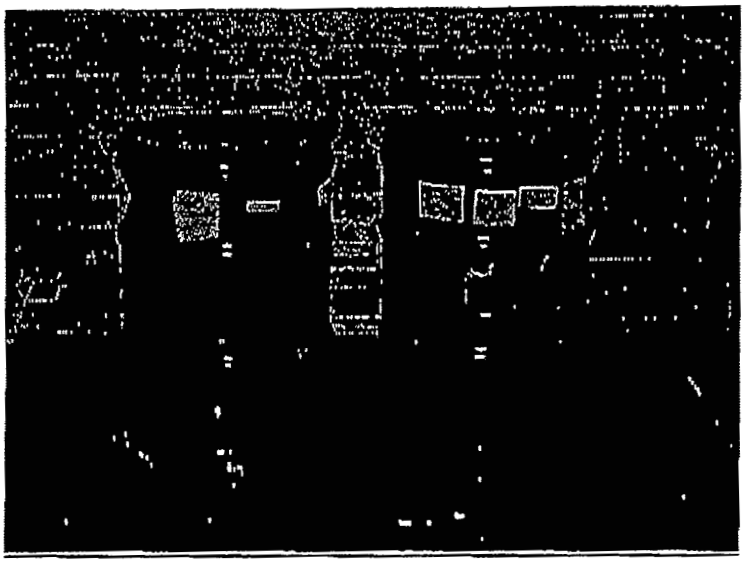
varian
oncology systems

Radiation and Contamination Survey Form

Rev 1

Date: 10/18/2002	Surveyor Name: Robert Gerber	Reviewed By:
Time: 1720	Signature: Robert Gerber	Location: Receiving Dock

Purpose of Survey: RECEIPT OF MATERIAL



#	Value	Units	Comments	#	Value	Units	Comments
1	13.1	CPS	DRUM 02-10	11			
2	13.1	CPS	DRUM 02-11	12			
3	0.18	mR/hr	DRUM 02-10	13			
4	0.47	mR/hr	DRUM 02-11	14			
5				15			
6				16			
7				17			
8				18			
9				19			
10				20			

Instrument	Serial #	Calibration Date
Berthold LB-122	3734	08/14/2002
Background	(circle one)	Correction Factor or Efficiency
13.1 CPS	α β χ n cpm (cps) mR/hr mrem/hr	0

Instrument	Serial #	Calibration Date
Victoreen 450P	1981	02/02/2002
Background	(circle one)	Correction Factor or Efficiency
9 uR/hr	~~α β χ n cpm cps mR/hr mrem/hr~~	0

Remarks:

ATTACHMENT 3
Criteria to become and Authorized User for non-human use of radioactive material

1. AUTHORIZED USERS

a. Responsibilities and duties

An Authorized User is a person granted the authority to use and supervise the use of radioactive material within specified guidelines. These guidelines must be applied for by the individual through the Radiation Safety Committee, see Section 1b. The applying Authorized User must agree to all the responsibilities and duties and guidelines before they can become an Authorized User.

Along with this authority come certain responsibilities and duties. These are listed below:

1. Ensure security of all licensed radioactive materials.

2. Use radioactive materials only for the purposes for which they have been approved.

3. Instruct all supervised individuals in the principles of radiation safety appropriate to the individual's use of Byproduct material, to ensure comprehension and compliance.

4. Ensure that any proposed change in equipment or location is approved by the Radiation Safety Officer prior to implementation.

5. Periodically review supervised individuals' use of Byproduct material and records kept to reflect this use.

6. Ensure that work involving volatile radioactivity is performed in fume hoods, and areas with adequate ventilation.

7. Create and implement procedures for the use of Byproduct material, and ensure that all radiation safety procedures are properly carried out.

8. Ensure radioactive waste is disposed of properly.

9. Explain the ALARA concept and the need to maintain all exposures ALARA.

10. Perform all surveys as required by the License and Research Protocol.

11. Ensure that possession, use, and ordering limits for radioactive materials are not exceeded.

12. Consult with the Radiation Safety Officer and/or the Radiation Safety Committee and obtain all necessary approvals before instituting any change in research protocols.

13. Ensure that all staff is knowledgeable in the proper response to emergencies; including proper notification procedure.

14. Ensure that personnel radiation exposure monitors are worn correctly.

15. Ensure that required posting remains in place and visible.

16. Ensure all records relating to the safe use of radioactive materials are kept and available for

inspection by the Medical Physics Dept., DEP and NRC.

A Responsibilities and Duties Form, Form 1-1, is attached to the Authorized User Application Form, Form 1-2, and lists all of the responsibilities and duties. In addition, these responsibilities and duties must be renewed annually, as long as the person wishes to be an authorized user.

Forms may be obtained from the Medical Physics Department by calling ext. 6868. Upon completion of the Forms, return them to the Medical Physics Dept. for review. The Medical Physics Dept. will submit the forms to the Radiation Safety Committee for approval. A letter of approval will be sent to the applicant stating approval by the Chairman of the Committee.

b. How to become an Authorized User

An Authorized User is a person that has been granted the authority to use and supervise the use of radioactive material within specified guidelines. This authority is granted by the Radiation Safety Committee. Refer to Section 1.a for Authorized User's responsibilities and duties.

To apply for Authorized User status you must obtain the Application for Authorized User of Radioactive Materia for Non-Human Use Form, see Form 1-2, from the Medical Physics Dept. The application must be completed and submitted to the Medical Physics Dept. for review. The Medical Physics Dept. will review the application to verify all criteria are met and then forward the application to the Radiation Safety Committee for approval. You will be notified as to the Committee's decision.

How to complete Form 1-2.

Read the requirements to become an Authorized User to verify you meet them.

1. Complete date and name.
2. State the department you will be working in, the section of that department when applicable and the position you will hold.
3. Indicate what activities you will be performing that require the use of radioactive material, for instance, cell labeling, radioiodinations, cell tracers, etc.
4. State if you were an Authorized User on another license and obtain the facility's license number. If you were an Authorized User on another license, you do not have to complete the remainder of the Form. If not, complete the remainder of the Form.
5. List all supervised experience, please be as precise as you can.
6. List all the training in radiation safety you received, please be as precise as you can. Attach any course certificates you may have.
7. Finally, give a brief description of your past work with radioactive material. Include which isotopes you used, the activities, chemical forms, list and special safety precautions you had to use, and what projects these were associated with. You may also state any additional information that will help use determine you have the qualifications to be an Authorized User.

After the Application has been submitted and approved by the Radiation Safety Committee, the new Authorized User will receive a Radioactive Material Permit, see Form 1-3. The Permit specifies who the authorized user is, the department of use, authorized usage and what radioisotopes the Authorized User can use. The radioisotopes are divided into three (3) groups, I, II, III. The radioisotope groups are based on hazard. Group I is the most hazardous and Group III the least hazardous. If an Authorized User wants to be able to use radioisotopes in a more hazardous group than they are authorized for, then they must supply the Radiation Safety Committee with information to determine if the Authorized user is able to provide supervision for isotopes in that group.

Authorized User
Responsibilities and Duties
Research and Development

Authorized Users of radioactive materials are delegated authority by the Radiation Safety Committee, to use, and direct the use of radioactive materials for specified purposes. Along with this authority comes certain responsibilities and duties. These are listed below:

1. Ensure security of all licensed radioactive materials.

2. Use radioactive materials only for the purposes for which they have been approved,.

3. Instruct all supervised individuals in the principles of radiation safety appropriate to that individual's use of Byproduct material, to ensure comprehensive and compliance.

4. Ensure that any proposed change in equipment or location is approved by the Radiation Safety Officer prior to implementation.

5. Periodically review supervised individual's use of Byproduct material and records kept to reflect this use.

6. Ensure that work involving volatile radioactivity is performed in fume hoods, and areas with adequate ventilation.

7. Create and implement procedures for the use of Byproduct material, and ensure that all radiation safety procedures are properly carried out.

8. Ensure radioactive waste is disposed of properly.

9. Explain the ALARA concept and the need to maintain all exposures ALARA.

10. Perform all surveys as required by the License and Research Protocol.

11. Ensure that possession, use, and ordering limits for radioactive materials are not exceeded.

12. Consult with the Radiation Safety Officer and/or the Radiation Safety Committee and obtain all necessary approvals before instituting any change in research protocols.

13. Ensure that all staff are knowledgeable in the proper response to emergencies; including proper notification procedure.

14. Ensure that personnel radiation exposure monitors are worn correctly.

15. Ensure that required posting remains in place and visible.

16. Ensure all records relating to the safe use of radioactive materials are kept and available for inspection by the Medical Physics Dept. And the NRC.

Print name _____

Signature _____ Date_____

APPLICATION FOR AUTHORIZED USER OF RADIOACTIVE MATERIAL FOR NON-HUMAN USE

Non-human use means any use of radioactive materials, sealed or unsealed, for any purpose not involving the administration of radioactive materials or radiation to humans.

Examples of uses include in-vitro assays, animal studies and research.

Minimum requirements include:

100 hours of supervised experience under the supervision of an authorized user within last 5 years, and

20 hours of classroom and laboratory training in:

radiation protection and instrumentation
radiation protection
radiation mathematics
radiobiology, and
radiochemistry,

The classroom and laboratory training may be acquired through in-services, college credits, formalized training courses, on-the-job training etc.

Applicants must complete Form 1-2 and sign the attached list of Responsibilities and Duties of Authorized Users. Signature indicates understanding and willingness to accept the responsibilities and duties of being an Authorized User.

Application for Authorized User of Radioactive Material for Non-Human Use

Date_____

1. Applicant's Name_____

2. Department_____
   Section_____
   Position_____

3. Indicate activity(s) for which radioactive material is needed.

   _____

   _____

   _____

   _____

   _____

4. Are you an approved Authorized User under another NRC or Agreement State License?

   If Yes, list facility's name_____ and licence #_____

   If No, complete the remainder of this form.

5. Supervised Experience

Location	Duration	Dates	Nature of Experience
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

6. Training

Course Name	Location	Dates	Credit Hours	Instructor

7. Describe your past use of radioactive material (what project, isotopes, chemical form, special safety precautions, etc.)

ALLEGHENY GENERAL HOSPITAL
RADIOACTIVE MATERIAL USE PERMIT

This permit grants *inset name* Authorized User status under NRC license 37-01317-01 and PA license PA-0031 and is authorized to receive, possess, transfer, and ship radioactive material of the type(s) listed below. The Authorized User is expected to comply with 1) the *Authorized User Responsibilities and Duties* Form, 2) applicable sections from Title 10, Code of Federal Regulations, 3) applicable sections from Title 25, Pennsylvania Code, and 4) any additional requirements mandated by the Radiation Safety Committee. Radioactive isotopes stated below may only be used at 320 East North Ave., Pittsburgh, PA 15212. Any reason to use or transfer radioactive material to a location other than those listed must be approved by the Radiation Safety Committee.

1. _____
Authorized User

2. _____
Permit Number

3. _____
Department or Section

4. _____
Approval Date

5. **Human Use Isotope Group**

____35.100 ____35.200 ____35.300 ____35.400 ____35.500 ____35.600
____ 35.1000 (OTHER)

6. **Authorized Use**

____ Group I ____ Group II ____ Group III

Group I isotopes (high radiotoxicity): beta $\geq$ 300 keV E_{avg}; gamma $\geq$ 300 keV
P-32, Ga-67, Rb-86, Sr-89, I-131

Group II isotopes (medium radiotoxicity): beta < 300 keV E_{avg}; gamma < 300 keV
Cr-51, Co-57, Tc-99m, I-123, I-125, Xe-133, Ce-141, Tl-201

Group III isotopes (low radiotoxicity): beta < 100 keV E_{avg}; gamma < 100 keV
H-3, C-14, S-35, Ca-45, Ru-103

7. **Restrictions**: NONE

Approval Signatures:

_____ _____
John Rehder, M.D. Date
Chairman, Radiation Safety Committee
Allegheny General Hospital

_____ _____
Joseph G. Och, M.S. Date
Radiation Safety Officer
Allegheny General Hospital

ATTACHMENT 4
Delegation of Authority Statement

ALLEGHENY
GENERAL HOSPITAL

WEST PENN ALLEGHENY HEALTH SYSTEM

320 EAST NORTH AVENUE, PITTSBURGH, PA 15212-4772
412-359-6583
FAX: 412-359-3888

CONNIE M. CIBRONE
President and Chief Executive Officer

To: Dr. John Rehder

Date: April 5, 2006

Subject: Delegation of Authority for Radiation Safety Officer

Joseph G. Och, M.S., is designated as the Radiation Safety Officer and is responsible for ensuring the safe use of byproduct material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of byproduct material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.

Connie M. Cibrone

xc: E. Banos
J. Och
R. Early
T. Robb

ATTACHMENT 5
Spot Check Procedures for Remote Afterloader Units

WEST PENN ALLEGHENY HEALTH SYSTEM
ALLEGHENY GENERAL HOSPITAL
RADIATION ONCOLOGY DEPARTMENT-PHYSICS

OPERATIONAL GUIDELINES

VARIAN HIGH DOSE REMOTE AFTERLOADER CALIBRATION AND QUALITY ASSURANCE

RESPONSIBILITY

The physics division will have the responsibility for calibrating and maintaining a quality assurance program on the Varian High Dose Remote After-loader System.

1. The Radiation Therapist will perform daily checks prior to the first patient treatment.
2. A Physicist using a certified calibration system will perform a monthly source activity calibration.
3. A Physicist will perform monthly and quarterly mechanical checks
4. A Physicist will do a full calibration after major repairs and/or after source changes and will be completed prior to being used clinically

RADIATION THERAPIST- DAILY CHECKS (Attachment A)

Prior to the treatment of any patient, the Radiation Therapist will complete the following checks:

1. **Viewing System**: Check the viewing window and camera
2. **Intercom System**: Check the intercom system
3. **Survey Meter**: Check the HV and check source
4. **Lead Container, Forceps, Wire**: In treatment room
5. **Linac/HDR Key Check**: Check door-interlock switch
6. **Door Stop Check**: Press "RED" button on readout at door
7. **Console Stop Check**: Press "RED" button on control console
8. **Console Key Test**: Turn key on console
9. **Afterloader Key Test**: Turn key on afterloader
10. **Display Test**: On control console
11. **Door Interlock**: "Open door" displayed on console
12. **"Radiation On" Light**: Note light above door with beam "ON"
13. **In-Room Radiation Monitor:** Note in-room radiation monitor
14. **Timer Accuracy**: Check against 40 seconds with stop watch. Stop watch display 38-42 seconds
15. **Visual Inspection of Source Guides:** Visual Check of integrity of unit
16. **Paper Supply:** Check paper in printer

A physicist will review and initial the results of these tests prior to the first patient treatment. If the results of the checks indicate the malfunction of any system, the licensee will lock the console in the off position and not use the unit except for repair, replacement or check of the malfunctioning system.

PHYSICIST- SOURCE ACTIVITY CALIBRATION

Using a calibrated well chamber, the activity measured is compared to the activity as stated on the calibration certificate. If the difference is >5%, an independent check must me conducted by another physicist prior to being used clinically.

PHYSICIST- MONTHLY SPOT CHECKS (Attachment B)

1. **Guide tube and applicators:** Visual Check of integrity of unit
2. **Source position verification:** Check position of dummy vs. active source wire at 80 and 140cm using the integrated camera.
3. **Timer linearity/end effect:** Complete excel spreadsheet, acceptable 0.98-1.02
4. **Timer accuracy:** Check against stop watch for 10, 20 and 40 seconds, acceptable +/- 0.5 sec
5. **Door interlock:** "Open door" displayed on console
6. **Emergency off at console:** Pressing emergency off should terminate treatment
7. **Interrupt on console:** Pressing interrupt should stop treatment

PHYSICIST- QUARTERLY SPOT CHECKS (Attachment B)

1. **Radiation monitor-AC power-** Check of radiation monitor when plugged into outlet.
2. **Radiation monitor-DC power** Check of radiation monitor when unplugged from outlet.
3. **Source inventory-** document certificate # of current source

(Attachment A)

ALLEGHENY GENERAL HOSPITAL
PITTSBURGH, PENNSYLVANIA
DEPARTMENT OF RADIATION ONCOLOGY

DAILY CHECKS - HDR

MACHINE: VariSource VS394

DATE:							
1. TV VIEWING	S U	S U	S U	S U	S U	S U	S U
2. INTERCOM SYSTEM	S U	S U	S U	S U	S U	S U	S U
3. SURVEY METER	S U	S U	S U	S U	S U	S U	S U
4. LEAD CONTAINER ,FORCEPS, WIRE	S U	S U	S U	S U	S U	S U	S U
5. LINAC/HDR KEY CHECK	S U	S U	S U	S U	S U	S U	S U
6. DOOR STOP TEST	S U	S U	S U	S U	S U	S U	S U
7. CONSOLE STOP TEST	S U	S U	S U	S U	S U	S U	S U
8. CONSOLE KEY TEST	S U	S U	S U	S U	S U	S U	S U
9. AFTERLOADER KEY TEST	S U	S U	S U	S U	S U	S U	S U
10. DISPLAY TEST	S U	S U	S U	S U	S U	S U	S U
11. DOOR INTERLOCK	S U	S U	S U	S U	S U	S U	S U
12. "RADIATION ON" LIGHT	S U	S U	S U	S U	S U	S U	S U
13 IN-ROOM RADIATION MONITOR	S U	S U	S U	S U	S U	S U	S U
14. TIMER ACCURACY	S U	S U	S U	S U	S U	S U	S U
15. VISUAL INSPECT SOURCE GUIDES	S U	S U	S U	S U	S U	S U	S U
16. PAPER SUPPLY	S U	S U	S U	S U	S U	S U	S U
PERFORMED BY:							
REVIEWED BY:							
DATE							

NOTE: Circle S - satisfactory; U - Unsatisfactory
COMMENTS:_____

(Attachment B)

ALLEGHENY GENERAL HOSPITAL
PITTSBURGH, PENNSYLVANIA
DEPARTMENT OF RADIATION ONCOLOGY
MONTHLY (M)/Quarterly (Q) CHECKS
MACHINE: VariSource VS394

NOTE Circle S - Satisfactory; U - Unsatisfactory

QA PARAMETERS	JANUARY	FEBRUARY	MARCH
1. GUIDE TUBES AND APPLICATOR (M)	S U	S U	S U
2. SOURCE OUTPUT (M)	S U	S U	S U
3. POSITION VERIFICATION TEST (M)	S U	S U	S U
4. TIMER LINEARITY/END EFFECT (M)	S U	S U	S U
5. TIMER ACCURACY (M)	S U	S U	S U
6. DOOR INTERLOCK (M)	S U	S U	S U
7. EMERGENCY OFF AT CONSOLE (M)	S U	S U	S U
8. INTERRUPT ON CONSOLE (M)	S U	S U	S U
9. RADIATION MONITOR (Q)- AC POWER	S U	S U	S U
10. RADIATION MONITOR (Q)- DC POWER	S U		
11. SOURCE INVENTORY (Q) Certificate #	S U		
PERFORMED BY:			
DATE			

ATTACHMENT 6
Emergency Response Procedures for the Remote Afterloader Unit

Emergency Procedures

It is essential that all users become familiar with, and regularly rehearse, the procedures outlined below.

U.S. only:
During all patient treatments, both the authorized user and the medical physicist or radiation safety officer must be physically present (this is a NRC requirement for HDR units).

Emergency equipment to be made readily available at all times:

- Two pairs of long handled forceps (~ 30cm)
- Shielded container
- Heavy duty cable cutters
- Emergency personnel dosimeters
- Portable survey meter
- Stop watch or timer

Should a system malfunction occur affecting source travel, the retract mechanism will automatically attempt to place the active source wire in the parked position within 30 seconds. If retraction has not occurred after 50 seconds, the 'manual retract' LED flashes and the console indicates that emergency procedures are required. This process is described in detail in the Emergency Retract Flow Chart (p. 53).

In the event of an emergency retract failure the system will display the message "***Possible emergency, check the source status***". In this instance a manually operated emergency retract handwheel, located on the side of the Afterloader, is available. Approximately 8 revolutions of the handwheel should be sufficient to place the active source wire in the safe and parked position.

Warning! Caution should be used when operating the emergency retract handwheel as it will be necessary to enter the room and radiation may be present. Where possible, approach the treatment unit in such a way that it is between you and the assumed location of the source.

If the room monitor or Afterloader console indicates that the active wire has failed to retract (i.e. "possible emergency, check source status" message displayed), proceed as follows:

Enter the room with a portable survey meter and a personal dosimeter.
Observe the emergency hand wheel:

- If the hand wheel is **not turning,** and radiation is present:

- Turn the handwheel clockwise through at least 8 revolutions, or until the independent radiation monitor no longer detects radiation. If after at least 8 revolutions of the handwheel radiation is still detected by the room monitor or portable survey meter, continue with the procedure outlined below.

- If the handwheel is **turning,** and radiation is present:

- If an end of the wire is visually detectable in a catheter, grasp the source in the catheter with long handled forceps. Cut the catheter above and below the source and place the removed section in a suitably shielded container.

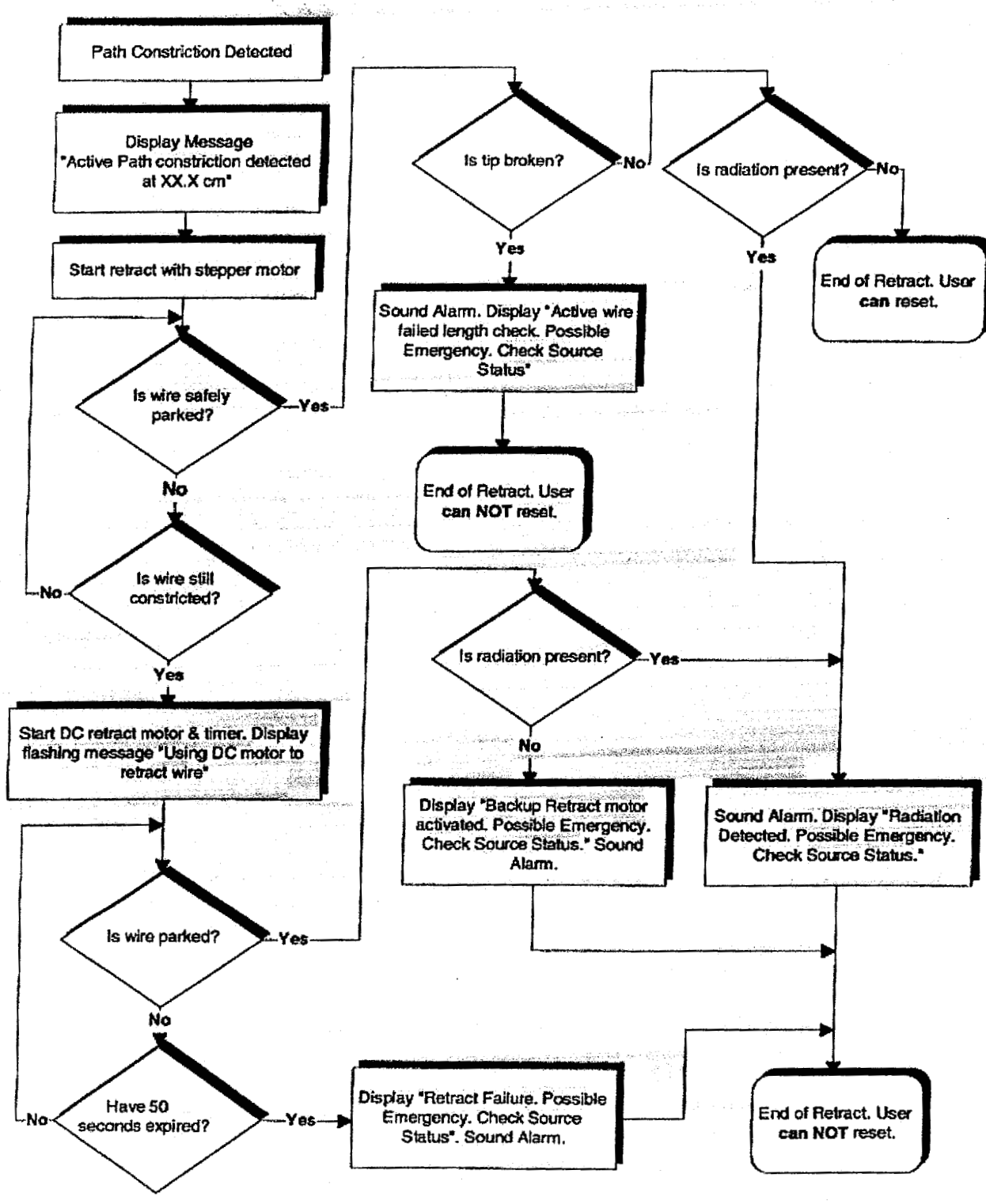
- If the end of the wire cannot be seen or radiation is still present, all applicators/ catheters should be removed from the patient without disconnection at any point. Care should be taken in this procedure to use forceps wherever possible, and maintain the maximum distance from the patient and the Afterloader.

In all cases above remove the patient from the immediate area, survey the patient, and if safe to do so, evacuate the patient from the room. Post a warning and notify all emergency contacts immediately. Estimate and record the additional dose to the patient. Also estimate and record any exposure to hospital staff.

Emergency contacts:

Physicist:	NAME:	Mark Johnson	NUMBER:	412-359-4689
Physician:	NAME:	Russell Fuhrer	NUMBER:	412-359-3154

VARIAN NUMBER: +44 1293-531244



Emergency Retract Flow Chart