Radiation Protection Procedures for the Cincinnati Proton Therapy Center (CPTC)
Cincinnati Children’s Medical Center
University of Cincinnati

<table>
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<tr>
<th>Revision Number</th>
<th>Date of Revision</th>
<th>Changes Entered</th>
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<tbody>
<tr>
<td>Original-Ver 1</td>
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<tr>
<td>1.1</td>
<td>11/3/16</td>
<td>Amended 7. Audit section</td>
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<td>Typo and formatting edits</td>
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<td>Typos, clarifications. Added medical events to QA quarterly review in 7.1.2.4.</td>
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</tbody>
</table>
1. Regulatory Oversight
   1.1. The Ohio Department of Health (ODH) is responsible for regulating radiation safety aspects of the proton facility.
   1.2. The University of Cincinnati Radiation Safety Office (RSOf) is responsible for maintaining radiation safety and ensuring compliance with applicable radiation safety regulations within the facility.
   1.3. Contact information, manuals, policies, forms and other information can be found at http://researchcompliance.uc.edu/RadSafety.

2. Radiation Safety Notification
   2.1. RSOf must be notified immediately if the following occur:
       2.1.1. Unexpected radiation levels are measured;
       2.1.2. An unexpected exposure to radiation occurs;
       2.1.3. Any safety mechanism malfunction (e.g., interlock, radiation detector, lockout system).
       2.1.4. Any unintended treatment deviation from the written directive or approved treatment plan as described in ODH 3701:1-67-12, “Unintended treatment deviations and notifications of medical events”.

3. Emergency Notification
   3.1. Radiation Safety Officer………………………….513-558-4110
   3.2. Radiation Safety Main office…………………….513-558-4110
   3.3. After-hours emergency pager..............513-249-6812 (dial all ten digits)
   3.4. Medical Physics Office ..................513-517-0343 (office)

4. Any unintended treatment deviation from the written directive or approved treatment plan shall be identified, evaluated, documented and appropriate action taken as described in ODH 3701:1-67-12, “Unintended treatment deviations and notifications of medical events”.

5. Radiation Exposure
   5.1. Dose limits
       5.1.1. The annual whole body limit for occupationally exposed “radiation workers” is 5000 mrem (50 mSv).
   5.2. Pregnant Workers
       5.2.1. If someone is pregnant or believes they may be pregnant, they may contact RSOf:
           5.2.1.1. All conversations will be considered confidential.
           5.2.1.2. Pregnancies do not have to be declared.
           5.2.1.3. If the pregnancy is declared, the ODH dose limit to the fetus of a declared pregnant woman is 500 mrem (10% of the occupational dose limits for adults).
       5.2.2. The following steps may be taken:
           5.2.2.1. Provide an opportunity to declare pregnancy.
           5.2.2.2. Evaluate dose history and exposure potential.
           5.2.2.3. Provide information concerning risk.
           5.2.2.4. Provide suggestions for reducing exposure.
           5.2.2.5. Monitor radiation dose with respect to regulatory limits.

5.3. ALARA Policy
5.3.1. The acronym ALARA, "As Low As Reasonably Achievable", means that persons using sources of ionizing radiation should make every reasonable effort to keep radiation exposures to individuals, and releases of RAM to unrestricted areas, as far below the regulatory limits as is practicable.

5.3.2. Investigations of occupational dose will be performed as described in Section 10.5 of the Radiation Protection Procedures Manual (Authorized User Manual) for exposures exceeding 10% or 30% of allowable limits.

5.4. Radiation Dosimeters

5.4.1. The RSOf will supply quarterly radiation dosimeters (badges) for the CPTC staff.

5.4.2. Whole body dosimeters will measure gamma and neutron radiation.

5.4.3. Dosimeters supplied by the RSOf are for use under the University of Cincinnati’s Radiation Control and Safety Program only, and are not to be worn at any other facility.

5.4.4. If CPTC staff travel to other facilities, CPTC or the facility itself should supply a separate dosimeter for each staff member.

5.4.5. Electronic dosimeters that measure gamma radiation are available from CPTC and Radiation Safety. These dosimeters should be used for visitors that need a dosimeter, but do not have one.

6. Occupational exposure will be minimized by employing the following the mechanisms:

6.1. Time – minimize time around a source of radiation

6.2. Distance – maximize distance from the source (inverse square law)

6.3. Shielding – use of shielding when possible (there is a mobile lead shield in the vault that may be positioned when working around the degrader, etc.)

7. Audits

7.1. A certified radiation expert shall conduct oversight and maintenance of quality assurance programs for hospital registrants, by:

7.1.1. Serving on the quality assurance committee.

7.1.2. Performing quarterly reviews;

7.1.2.1. Each quarter, the certified radiation expert shall submit, to each appointed quality assurance committee member, a review of the quality assurance plan which shall contain, as applicable:

7.1.2.2. Radiation safety policy revisions proposed by the certified radiation expert;

7.1.2.3. A review of occupational exposure records by the certified radiation expert;

7.1.2.4. Radiation safety incidents and medical events;

7.1.2.5. Radiation-generating equipment performance evaluation summaries to include a description of any issues found; and
7.1.2.6. Any corrective actions recommended by the certified radiation expert necessary to comply with the quality assurance program.

7.1.3. Performing an annual audit.

7.1.3.1. Developing a written report of the audit findings.

7.1.3.2. The audit will address

7.1.3.2.1. Whether the quality assurance program properly addresses the rules for a quality assurance program (3701:1-66-04).

7.1.3.2.2. Whether the quality assurance program is being carried out in accordance with the written quality assurance program.

7.1.3.2.3. Any corrective actions taken to comply with the quality assurance program.

7.1.3.3. A record of the audit will be retained.

7.1.3.4. Submitting the report to the proton quality assurance committee with 30 days of completing the audit.

7.1.3.5. The quality assurance committee shall review the audit report and implement any corrective actions.

7.1.3.6. The certified radiation expert shall file the audit report with the CCHMC QA Committee.

7.1.3.7. The certified radiation expert will then file the report with the director within ninety days of completing the audit.

7.1.3.8. Completing and submitting all required information with the annual audit in accordance with “Ohio Department of Health CRE QA Annual Audit Report Form”

8. Training requirements

8.1. CPTC staff who receive, or could potentially receive, 10% of occupationally allowable doses will receive radiation safety training initially and annually thereafter.

8.1.1. The initial training will consist of Basic Training, Advanced Training, and Site Specific Training.

8.1.2. The Annual Training will be a review of Advanced and Site Specific Training.

8.2. The RSO, or their delegates, will provide the training.

8.3. Radiation safety training will be commensurate with their duties.

8.4. Ancillary training will be provided as necessary for those employees not expected to exceed doses allowable to the public, including Facilities Management, Environmental Services, Nursing, Protective Services, and Child Life.

8.5. Varian employees and their sub-contractors will be trained as described in the UC Radiation Safety / Varian Memo of Understanding.

8.6. University of Cincinnati Medical Center (UCMC) employees will be trained as described in the UC Radiation Safety / UC Medical Center Memo of Understanding.
8.7. Visitors who are only taking a tour of the proton facility do not need special radiation safety training but will be escorted by trained individuals if they are entering the cyclotron vault and beam transport system corridor.

8.8. Workers temporarily working in the vault or a treatment room may need special radiation safety training depending on their duties. Radiation safety training will be commensurate with their duties.

9. Posting and Labeling
   9.1. Entrances to the cyclotron vault must be properly posted with “High Radiation Area” signs.
   9.2. High radiation areas in the vault (i.e., area around the degrader) must be properly posted with “High Radiation Area” signs.
   9.3. Activated equipment and parts should be placed in the Radioactive Storage room and posted with a “Radioactive Materials” sign.

10. Shipping Activated or Contaminated Equipment
   10.1. RSOF must be contacted before any potentially activated piece of equipment or part that comes from the vault or treatment room is sent off-site.
   10.2. Only the RSOF will ship radioactive material from the proton facility.

11. Radiation Surveys
   11.1. Radiation level surveys with an ion chamber should be performed by CPTC staff prior to working on or near the beam line.
   11.2. These surveys will be documented and documents will be available in the Master Control Room (MCR).
   11.3. When CPTC staffs enter the vault to work on the equipment, self-reading electronic dosimeters should be worn.
   11.4. A record of who, date, electronic personal dosimeter SN, reading in and reading out will be retained.
   11.5. The RSOF or Varian employees should be contacted to perform a survey before any non-radiation worker enters the cyclotron vault to perform work.

12. Radioactive Contamination Surveys
   12.1. When working on the inside of the cyclotron, activated components can cause radioactive contamination. Personal protective equipment will be used to prevent contamination. Personal protective equipment will be surveyed prior to disposal.
   12.2. A GM meter should be used to check for contamination on any materials or equipment used as personal protective equipment. Any contaminated materials must be put in the trash can labeled “Radioactive Materials”.

13. Activated equipment
   13.1. Any part or piece of equipment in the vault or near the beam line should be surveyed before being removed.
   13.2. The part or piece of equipment should be surveyed with a GM meter. If the item is activated and removed, the item should be tagged and stored in the designated storage area in the RAM storage room.
   13.3. The storage area or item itself must be labeled with an appropriate “Radioactive” label.

14. Effluent Air Sampling
14.1. Since cyclotron vault air may be activated, RSOf will monitor air effluent exiting the vault at initial operation to assess the presence of activated components.

14.2. Dose to the general public, as well as to the staff, will be calculated.

14.3. If air activation is found to be at levels below concern, air effluent monitoring may be discontinued.

15. Access to Cyclotron Vault

15.1. No one is to be in the Cyclotron Vault while the cyclotron is in operation.

15.2. When the cyclotron is not in operation, only CPTC staff, Medical Physics staff or other radiation workers approved by the RSOf may enter unescorted.

15.3. A non-radiation worker (i.e., not badged) may only enter the vault to work with prior Radiation Safety approval or under the supervision of Varian staff, Physics staff or Radiation Safety staff while ensuring exposures are below 2 mR/hr.

15.4. Non-radiation workers may enter the vault when the cyclotron is not in operation if they are authorized and given instructions by Varian operators, Medical Physics or Radiation Safety.

15.5. Non-radiation workers shall wear electronic personnel dosimeters (EPD). A form in a binder in the Master Control Room will be completed indicating the name, time in, time out, and EPD reading.

15.6. No one 18 or under may enter the vault unless directly escorted by Medical Physics or Radiation Safety staff while wearing electronic personnel devices as described above.

15.7. Doors to the vault must be kept closed and locked and all times.

15.8. The Varian search-and-lock-out safety procedure will be followed after access to the vault prior to starting the cyclotron. Physical interlocks will never be overridden.

16. Tours of Cyclotron Vault and Treatment Rooms

16.1. Tours of the vault

16.1.1. Tours of the vault need to be led by a guide (CPTC staff, Medical Physicist or some other authorized person);

16.1.2. Tour group members will stay to the right of the red tape marked on the floor of the cyclotron vault. This line has been marked to keep tour group members in safe areas (<2mR/hr) based on radiation surveys;

16.1.3. Tours for non-radiation workers should be limited to 15 minutes;

16.1.4. Dosimeters need not be given for tours. General calculations will have been performed to verify regulatory compliance for members of the general public.

16.1.5. Radiation surveys will be performed upon initial entrance to the cyclotron vault prior to the tour.

16.2. Tours of treatment rooms

16.2.1. There are no restrictions of tours of treatment rooms escorted by CPTC staff based on radiation safety considerations.

17. Bypassing any safety interlock is not allowed.

18. Emergency Procedures
18.1. Individuals Detected in Vault or Treatment Room
18.1.1. If someone is detected (via of video system or other detection system) in a secured area when the beam is on, operators should immediately do the following:
18.1.2. Turn the master switch off.
18.1.3. Verify that beam is off and cannot be restarted (confirm RF is off and remove and take possession of the master key).
18.1.4. Go to the secured area.
18.1.5. Contact the person.
18.1.6. Evacuate the person from the area while keeping them under observation.
18.1.7. Contact RSOf.

18.2. Staff in Treatment Room While Beam is On
18.2.1. If inside vault or room when beam is on
18.2.1.1. Push the nearest emergency off button immediately.
18.2.1.2. Exit the area immediately.
18.2.1.3. Inform the Main Control Room operator immediately.
18.2.1.4. Contact RSOf immediately.
18.2.2. If an emergency off button is pushed, the following steps should be taken before the beam is requested in the treatment room again:
18.2.2.1. Terminate any use of the beam in that area until an investigation has been performed and the reason for the use of the emergency off button ascertained.
18.2.2.2. Resolve any issues related to the incident.
18.2.2.3. Discuss with RSOf.
18.2.2.4. Update safety procedures, if needed.

18.3. Beam is stuck “on” in a patient room during a patient treatment
18.3.1. If the beam does not stop:
18.3.1.1. when the preset dose count has been reached
18.3.1.2. when the time threshold has been reached
18.3.1.3. when requested to stop by depressing “Beam Off”
18.3.1.4. when paused
18.3.2. Immediately perform the following procedure:
18.3.2.1. Press the local crash button in the Treatment Control Room (TCR).
18.3.2.2. Turn the master key switch off.
18.3.2.3. Open the doors of the Treatment Room (TR), but do not enter it.
18.3.2.4. If this procedure fails to stop the irradiation, contact the Main Control Room (MCR)
18.3.2.5. Immediately and request the accelerator operator to shut off the RF.

19. Radioactive Waste
19.1. Activated (radioactive) equipment
19.1.1. Any part or piece of potentially activated equipment in the vault or treatment room must be surveyed before being removed.
19.1.2. The part or piece of equipment should be surveyed with a GM meter. If the item is activated, the item should be stored in the designated RAM storage area.

19.1.3. Only the RSoF will ship RAM.

19.2. Contaminated waste
19.2.1. Contaminated waste should be placed in the appropriately labeled garbage can in the vault or radioactive storage room. Radiation Safety should be contacted for disposal when needed.

19.3. Activated water
19.3.1. The RSoF will be contacted to survey potentially activated water before disposal.
19.3.2. A GM meter should be used to survey any potentially activated water before disposal.
19.3.3. Water in water phantoms can become activated. Cooling system water along with ion exchange and filter systems can become activated. Surveys should always be performed before disposal.

19.4. Storage
19.4.1. Any item or piece of equipment that is radioactive most be stored in the radioactive storage designated area. The storage area or item itself must be labeled with an appropriate “Radioactive” label and access restricted.

20. Equipment
20.1. Permanent Radiation Monitors
20.1.1. Permanent radiation monitors are located in the vault and treatment rooms. The monitors have a visual indication of radiation levels.
20.1.2. The purpose of these permanent radiation monitors is to let individuals who are inadvertently entering the vault or treatment room know that the beam has been turned on.
20.1.3. These monitors are checked for operation on an annual basis by RSoF.

20.2. Basic survey instruments
20.2.1.1. Geiger-Müller (GM) meter
20.2.1.1.1. Mainly used for detection of radiation/contamination
20.2.1.1.2. For qualitative measurement and assessment of the presence of radiation.
20.2.1.2. Ion chamber
20.2.1.2.1. Mainly used for determining photon radiation levels
20.2.1.2.2. For quantitative measurement of radiation level.
20.2.1.3. Prescila
20.2.1.3.1. Used for measuring neutron radiation levels
20.2.1.3.2. For quantitative measurement of neutron dose.

20.3. CCTV Monitors
20.3.1. The purpose of the CCTV cameras is to ensure no individuals other than the patient are present when turning the beam on, as well as to monitor patients.
20.3.2. CCTV cameras are located in multiple areas of the treatment room.
20.3.3. Patients will not be treated if visual and aural monitoring of the treatment room is not available.