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Radiation Generating Devices

Approvals

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Procedure

1.0 Purpose

This procedure creates the framework for the requirements of Radiation Generating Devices and Equivalent Accelerators that are exempt from certain requirements in DOE O 420.2D, Safety of Accelerator Facilities.

2.0 Scope

The Radiation Generating Devices (RGDs) addressed in this procedure may be classified as either devices that are electrically energized to produce ionizing radiation or sealed radioactive sources that emit radiation continuously. For sealed radioactive sources this procedure only applies to a device with a source that produces radiation fields exceeding 100 millirem on out hour at one foot from the source.

This procedure addresses RGDs used for industrial and research applications but does not address RGDs used for patient diagnostic or therapeutic medical applications. Specific examples of RGDs addressed by this procedure include sealed photon- or neutron-emitting radioactive sources, X-ray producing radiography equipment, research and analytical X-ray or electron beam machines, sealed radioactive sources used as irradiators, particle accelerators, neutron generators, Van de Graff generators, electromagnetic pulse generators (if capable of producing ionizing radiation), electron microscopes, electron arc welders, microwave cavities that produce X-rays incidentally, and cabinet X-ray machines used for security applications.

Equivalent Accelerators addressed in this procedure follow the same requirements as RGDs. An RGD becomes an Accelerator when the device can create a radiological area as defined by 10 CFR 835. Accelerator components include injectors, targets, beam dumps, detectors, experimental enclosures, accelerator enclosures, experimental areas, and experimental apparatus utilizing the accelerator. The accelerator also includes associated support and test facilities, equipment, systems, and utilities necessary to operate the accelerator or utilize the accelerated beam. An Equivalent Accelerator meets the equivalency requirements of DOE O 420.2D to reduce the controls on the Device and managed as an RGD.

3.0 Summary

This administrative procedure outlines the requirements for installation and operation a new Radiation Generating Device or Equivalent Accelerator (Device) at Fermilab, based on the recommendations within DOE G 441.1-1C as well as requirements from the Standards Invoked by DOE Order 420.2D.

4.0 Definitions

Abnormal Operation – Operation under conditions beyond normal operation defined by the operation envelope. Examples include delivering beam to unauthorized locations, delivering beam beyond authorized beam energy or current, delivering beam beyond conditions governed by the radiation safety system (RSS), and delivering beam to an area with deficient shielding.

Accelerator – A device and its components employing electrostatic or electromagnetic fields to impart kinetic energy to molecular, atomic, or sub-atomic particles and capable of creating a radiological area as defined by 10 CFR Part 835, Occupational Radiation Protection. Accelerator components include injectors, targets, beam dumps, detectors, experimental enclosures,

accelerator enclosures, experimental areas, and experimental apparatus utilizing the accelerator. The accelerator also includes associated support and test facilities, equipment, systems, and utilities necessary to operate the accelerator or utilize the accelerated beam.

Access Panel – Any barrier or panel that is designed to be removed or opened for maintenance or service purposes, permitting access to the interior of the cabinet.

Accessible Area – Any area where the body or a part of the body may be exposed to radiation without necessitating a shutdown of the radiation source.

Administrative Controls – Controls employing human actions such as access control using rope(s) or warning sign(s), search procedures, administrative locks, etc.

Analytical X-ray Equipment – Laboratory equipment utilizing x-ray radiation to analyze or obtain information about material properties (e.g., surface characteristics, elemental composition, material structure, etc.) by means of diffraction or fluorescence techniques.

Area Monitor – An area monitor is an active stationary x-ray radiation detector mounted in the area of the x-ray machine to provide warning of unusual x-ray fields. It can be set as close to background radiation as is reasonably achievable and shall be of sufficient energy and exposure sensitivity as to provide a meaningful alert.

Attenuation – The reduction of a radiation quantity upon passage of radiation through matter, resulting from all types of interaction with that matter. The radiation quantity may be, for example, the particle fluence rate.

Beam – The flow of particles or electromagnetic radiation that is either collimated (generally unidirectional) or divergent from a small source but restricted to a small solid angle (NCRP-144, p. 406).

Beam Parameters – Beam characteristics that include, but are not limited to, particle type, size, power, current, energy, pulse repetition rate (macro and micro pulse rates), and so on.

Certified Cabinet X-Ray Systems – This class consists of equipment meeting the requirements of 21 CFR 1020.40. The inherent radiation safety of such equipment may make installation possible in an uncontrolled area. Typically, these are small x-ray machines such as those deployed at office buildings and airports. The Food and Drug Administration, however, does not certify each machine; the manufacturers are required to ensure that their machines comply with the regulation.

Collimator – A device used to limit the size, shape, and direction of the primary beam.

Configuration Control – A program or process that maintains a safety system's viability by ensuring that no unauthorized and undocumented changes occur.

Dark Current – Charged particles generated within accelerator cavities or RF waveguides with RF power generating high-voltage gradients.

Dose Assessment – The process of determining radiological dose and uncertainty included in the dose estimate, using exposure scenarios, bioassay results, monitoring data, source term information, and pathway analysis.

Electron Volt (eV) – A unit of energy equal to the kinetic energy gained in a vacuum by a particle having one electronic charge when it passes through a potential difference of 1 volt: 1 eV = 1.60 x 10^{-19} J.

Escort – An individual with the prerequisite training necessary for unescorted access to the area(s) where the escort activities will be performed and who is authorized to accompany and ensure the safety of individuals who lack such training.

Exclusion Area – An area in which access by personnel is prohibited and/or restricted by physical barriers with at least a locked entryway door/gate (interlock is also recommended). Areas with a prompt radiation dose level > 10 mSv h^{-1} (1 rem h^{-1}) are classified as exclusion areas. An area secure system is required to ensure no one is left inside the exclusion area prior to accelerator operation.

Exposure Area – Any controlled area in which an actively used radiation source or x-ray production target may be present.

Exposure Rate – Exposure per unit time. In the case of a pulsed x-ray–generating device, the exposure rate is the time-weighted average over a full cycle, not an instantaneous rate.

Fail-safe – A feature of an interlocked safety system that renders the accelerator system safe when a component of the safety system fails.

Fluence (particle fluence) – The number of particles which enter a sphere per unit cross-sectional area of that sphere. The unit of fluence is m^{-2}.

Fluence Rate (flux density) – The increment of (particle) fluence per unit time, i.e., the time derivative of fluence. The unit of fluence rate is $m^{-2}s^{-1}$.

Interlock – A device for precluding access to an area of radiation hazard by either preventing entry or by automatically removing the hazard. One example is an electro-mechanical control mechanism that interrupts the beam of ionizing radiation or shuts down the radiation installation whenever the interlock is challenged.

Leakage Radiation – All radiation, except the useful beam, coming from the x-ray–generating device (XGD) or source housing.

Occupied (occupiable) area – An area or location that may be physically accessible by individuals (or body parts thereof) while a radiation-generating device is in operation.

Primary Radiation – Radiation coming directly from the x-ray tube target or from the sealed source.

Normal Operation – Operation under conditions as recommended by the manufacturer of the RGD with recommended shielding and barriers in place, and as specified in the operating procedures and requirements for the RGD installation.

Modification – Any alteration of the shielding configuration, device or installation operating practices, or the replacement of the original RGD (or component part thereof) with another that has not been previously evaluated, inspected, monitored, and documented by the radiological control organization. This definition also includes the collocation of additional or multiple unevaluated RGDs within a previously evaluated installation.

Radiation Generating Device (RGD) – Collective term for devices which produce ionizing radiation, including, certain sealed radioactive sources, small particle accelerators used for single purpose applications which produce ionizing radiation (e.g., radiography), and electron generating devices that produce X-rays incidentally.

Radiation Protection Survey – Evaluation of the radiation hazards in and around an installation. It customarily includes a physical survey of the arrangement and use of the equipment and measurements of the exposure rates under the full range of expected operating conditions.

Radiation Source – An apparatus or a material emitting, or capable of emitting, ionizing radiation in its current configuration.

Radiation Warning Light (Warning Light) – A visual system (generally a flashing magenta, red, yellow, or purple light) that denotes radiation hazards and alerts operators and/or personnel of potential exposure to radiation.

RGD Custodian – An individual who is trained and designated to maintain cognizance over accountability control of radiation-generating devices assigned to him or her.

RGD installation – The sum of the radiation source (e.g., sealed radioactive material or x-ray tube), the associated equipment and component items, and the space in which they are operated. Six types of installations are defined as follows:

Shielded Installation – A shielded installation is one in which shielding is used to reduce radiation exposure; unless otherwise specified, a shielded installation is also known as a nonexempt shielding installation. A shielded installation may require other operational limitations to ensure that radiation dose limits are not exceeded. Such limitations may include limits on current, voltage, or operating time; restrictions on occupancy outside the enclosure; or other administrative and/or engineered controls. This class usually offers the greatest cost advantage for fixed installations. This is particularly true for high-energy sources where a reduction in shielding may result in significant cost savings. The shielding requirements for a nonexempt shielded installation are considerably lower than for the exempt shielded installation; yet the inherent protection is such that the possibility of significant exposure is remote. With proper supervision, this class offers a degree of protection similar to the exempt shielded installation.

Exempt Shielded Installation – This class provides the highest degree of inherent safety because the protection does not depend on compliance with any operating limitations. This type of installation also has the advantage of not requiring restrictions on occupancy outside the enclosure since inherent shielding is sufficient to meet the maximum permissible dose equivalent requirements for uncontrolled areas.

Unattended Installation – This class consists of equipment designed and manufactured for a specific purpose and does not require personnel in attendance for its operation. The inherent radiation safety of such equipment may make installation possible in an uncontrolled area.

Open Air Installation – This class shall be selected only if operational requirements prevent the use of one of the other classes. Its use should be limited mainly to mobile, portable, or experimental equipment where fixed shielding cannot be used. The protection of personnel and the public depends almost entirely on strict adherence to safe operating procedures. Increased levels of safety oversight, personal vigilance, and task-specific training are needed to mitigate the inherently higher levels of risk associated with reliance on administrative controls.

X-Ray Diffraction & Fluorescence Analysis Equipment – including both open and closed beam installations; and

Incidental – including devices that emit low levels of ionizing radiation as a byproduct of their normal function, such as electron beam welders, electronic microscopes, and pulse generators.

RGD Operator – An individual who is trained and deemed qualified to use a radiation-generating device.

Shield or Shielding – Attenuating material used to reduce the transmission of radiation.

Primary Shielding – Material sufficient to attenuate the useful beam to the required level.

Secondary Shielding – Material sufficient to attenuate stray radiation to the required level.

Stray Radiation – Radiation other than the useful beam. It includes leakage and scattered radiation.

Technical work document (TWD) – A term used to generically identify formally approved documents that direct work, such as procedures, work packages, or job or research plans. TWDs provide radiological and ALARA controls applicable to the task.

Uncontrolled Area – Any area to which access is not managed to protect individuals from exposure to radiation and/or radioactive material.

Uniform exposure – Hypothetical radiation field in which the fluence and its angular and energy distributions are the same throughout the volume of interest.

Useful beam – That part of the primary and secondary radiation beam that passes through the aperture, cone, or other device used for collimation.

X-ray Accessory Apparatus – Any portion of an x-ray installation which is external to the radiation source housing and into which an x-ray beam is directed for making x-ray measurements or for other uses.

X-Ray–Generating Device (XGD) – A device that generates characteristic x-rays or bremsstrahlung radiation. For this procedure, this definition only includes photon radiation up to 10 MeV. There are two categories of XGDs, intentional and incidental.

Intentional XGD – Category of XGD, typically housed within a fixed, interlocked, and/or shielded enclosure/room specifically designed to intentionally produce and convey beyond the vacuum surrounding the electron acceleration chamber, ionizing bremsstrahlung and/or characteristic x-rays that are then used for purposes of imaging, analysis, or research for which such radiation is essential to the process. Examples include facilities housing conventional (Coolidge) XGDs; magnetic induction devices (betatrons) used to intentionally produce x-rays; electron linear accelerators (LINAC) used to produce x-rays; portable and fixed flash XGDs; portable pulsed XGDs; analytical XGDs; cabinet XGDs; and Van de Graaff generators used to intentionally produce x-rays.

Incidental XGD – An XGD that emits or produces x-rays or bremsstrahlung during its normal operation where the x-rays or bremsstrahlung are an unwanted byproduct of the device's intended purpose. The x-rays are produced only when electrons are accelerated under vacuum, are not put to any constructive use in a particular application and are not intentionally conveyed beyond the contiguous vacuum in which they are produced. Examples include electron microscopes; video display terminals; high-voltage electron guns (cathode ray tubes) or electron pulse generators; electron beam welders; high-voltage switches and power supplies; field emission electron beam diodes; televisions; ion implantation devices; electron beam furnaces; magnetrons, klystrons, and other radiofrequency (RF) tubes; Auger electron generators; and vacuum ion sputterers. Incidental XGDs are not within the scope of ANSI N43.3-2008 – Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV.

5.0 Responsibilities

5.1 **Directorate / Division Management**

- 5.1.1 Appoint an RGD Custodian.
- 5.1.2 Work with SRSO to confirm classification of Device.
- 5.1.3 Notify the assigned Radiation Safety Officer (RSO) if the RGD Custodian appointment changes.
- 5.1.4 Exercise supervision to ensure safe Device Operation.
- 5.1.5 Schedule and otherwise provide for training to ensure that RGD Custodians and Operators are trained and recertified.
- 5.1.6 Promptly terminate the operation of the Device for any abnormal conditions.

5.2 **RGD Custodian**

- 5.2.1 Shall be a permanent Fermilab employee.
- 5.2.2 Generate and review Device operational and maintenance logs.
- 5.2.3 Schedule periodic inspections and monitoring.
- 5.2.4 Control the keys to Device installations, Devices, and/or Device storage facilities and authorize the operation of the Device installation.
- 5.2.5 Ensure that an approved Radiological Work Permit (RWP) or other work control document is in place prior to starting of the Device, and the document incorporates an approved Standard Operating Procedure.

5.2.6 Ensure either the manufacturer provides a Standard Operating Procedure or generate a Standard Operating Procedure for the Device with assistance from the assigned RSO.

5.2.7 Ensure either the manufacturer provides an Emergency Procedure or generate an Emergency Procedure for the Device with assistance from the assigned RSO.

5.2.8 Develop a training class specific to the Device and ensure all Operators are trained appropriately.

5.2.9 Ensure that Operators follow applicable procedures

5.2.10 Ensure that Operators follow the applicable Radiological Work Permit (RWP), or other written authorization.

5.2.11 Ensure that required dosimeters are properly worn.

5.2.12 Ensure that inspections of Device interlocks, warning lights, and other safety features are performed and documented.

5.2.13 Ensure that all required monitoring is performed and documented.

5.2.14 Maintain a list of approved RGD Operators and provide updates of the list to the assigned RSO.

- This may be done through the approved Fermilab Training System.

5.2.15 Ensure that records of assigned Devices are maintained

5.2.16 Notify the assigned RSO of changes in shielding configuration, use, storage, disposal, or loss of a Device.

5.2.17 Ensure proper disposition of unneeded Devices.

5.2.18 Ensure that sealed radioactive source integrity tests are performed through the Radiation Source Physicist.

5.2.19 Maintain schematics (mechanical and electrical), safety device wiring diagrams, manufacturer provided instruction manuals, and operations and maintenance records.

5.3 **RGD Operator**

5.3.1 Ensure proper control of the Device installation and/or area.

5.3.2 Ensure that inspections and monitoring are performed and documented as assigned.

5.3.3 Ensure that required dosimeters are worn properly by all individuals in the vicinity of Device operations based on the initial survey and the RWP.

5.3.4 Follow the applicable RWP, or alternative authorization, and ensure that other individuals in the area also adhere to the requirements of those documents.

5.3.5 Ensure controls are in place for all adjacent areas where individuals could receive a dose approaching administrative limits and ensure that those areas are unoccupied during Device operations.

5.3.6 Maintain access control over the actual Device exposure area.

5.3.7 Follow all applicable Standard Operating Procedures and Emergency Procedures.

5.3.8 Promptly terminate unsafe Device operations.

5.4 **Senior Radiation Safety Officer (SRSO)**

5.4.1 Develop memo with Division/Directorate Management to Fermilab DOE Site Office notifying them of an exempt or equivalent Device from DOE O 420.2D.

5.4.2 Develop a memo with Division/Directorate Management accepting the classification of a Device as a Radiation Generating Device.

5.5 **Assigned Radiation Safety Officer (RSO)**

5.5.1 Review and approve the design and modification of Device installations.

5.5.2 Review and approve results of pre-operational inspections and radiological monitoring.
5.5.3 Review and approve the engineered safety features and administrative controls.
5.5.4 Determine the need for and adequacy of the personnel monitoring program for the installation.
5.5.5 Review and approve training materials used for the RGD Custodians and Operators. Additionally, review and approve any revisions to the training.
5.5.6 Determine if area monitoring is required and adding them to the Area Monitoring Program.
5.5.7 Determine what routine monitoring surveys are required and adding them to the Routine Monitoring Program.
5.5.8 Annually review operational and maintenance logs maintained by RGD Custodians and Operators to ensure that controls are commensurate with existing or potential radiological hazards.

5.6 **Radiological Control Technician (RCT)**

5.6.1 Conducting pre-operational and periodic inspections and radiation monitoring of Device installations.
5.6.2 Provide radiological support to RGD Custodians and Operators.
5.6.3 Ensure that all inspections and monitoring are performed and documented in accordance with applicable procedures.
5.6.4 Perform radiation monitoring of open installations to verify proper posting and control of boundaries during operations and removal of hazards (and associated temporary postings and barriers) after operations.
5.6.5 Monitor all Device installations for potential or actual unsafe operations or conditions and conformity to the FRCM and this procedure.

6.0 Health and Safety Warnings

N/A, this is an administrative procedure

7.0 Prerequisites

RP Form 108 – List of Radiation-Generating Devices (FRCM Article 362)

RP Form 113 – Preliminary Hazard Assessment Checklist for Deuterium-Based Generators

RP Form 133 – Radiation Generating Device Checklist

8.0 Procedural Steps

8.1 Delegation of Authority for a Specific Device

Upon identification of a new Device coming on site, Directorate / Division Management should begin RP Form 133 Radiation Generating Device Checklist. The Assigned RSO may notify Management of the requirement to begin this form.

Management will document the specific Device, and delegate an RGD Custodian for the device. Both the RGD Custodian and Management must agree to the responsibilities and sign the first page of the form.

8.2 Deuterium-Based Neutron Generators

If the Device is a Deuterium-Based Neutron Generator, mark the "Yes" box on RP Form 133. This directs the RGD Custodian to also complete RP Form 113. This will be addressed in Section 8.17 of this procedure.

8.3 Site-Specific Documents

10 CFR 835.104 requires that written procedures be developed and implemented as necessary to ensure compliance with that regulation, commensurate with the radiological hazards created by the activity and consistent with the education, training, and skills of the individuals exposed to the hazards. Written procedures should be developed and implemented as necessary to ensure proper implementation of the radiation protection program elements addressed in this procedure and the Fermilab Radiological Control Manual (FRCM).

The Standard Operating Procedures and Emergency Procedures should be developed for the specific Device, and their names, document numbers, and storage locations should be listed in Section 2 of RP Form 133.

8.4 Device Operational Conditions

Device Operational Conditions are essential for classifying the Device prior to initial operation. Items to be recorded in RP Form 133 include:

- Maximum pulse repetition rate
- Normal running pulse repetition rate
- Maximum value of applied voltage and/or current
- Normal running applied voltage and/or current
- Any Mechanical or Electrical devices that restrict radiation generated, and the magnitude of the restriction (values with and without these listed devices)
- If the Device is fully enclosed with no ports, windows, etc. that radiation may easily escape from.
- If the Device contains a radioactive source, list the source and activity
- If the Device contains a radioactive source, identify the maximum exposed position of the source
- If the Device contains a radioactive source, describe the physical characteristics of the source – solid, liquid, gas, sealed source, bonded with other materials, etc.

8.5 Training

The RGD Custodian and Operators must have the following courses, at minimum, assigned on their ITNA:

- Radiological Worker – Classroom (Virtual) [FN000470]
- Radiological Worker – Practical Factors [FN000471]
- Radiological Worker – Just in Time [FN000731]

In addition to the above required training, the RGD Custodian must develop specific on-the-job training for the Device. This may be based on the Vendor's Manual, site developed

Standard Operating Procedures, or other sources. The developed training must be approved by the assigned RSO prior to implementation and will need to be entered into the Official Fermilab Training Program. A course code should be included in Section 2 of RP Form 133.

8.6 Engineered Safety Controls

Requirement:

List all engineered safety controls included in the Device setup in Section 2 of RP Form 133. This includes shielding, filtered ventilation systems, remote controls, containment devices, temporary shielding, temporary confinement, and temporary ventilation systems. Engineered safety controls may be mentioned in the Shielding Assessment or Dose Assessment Calculation document.

Discussion on Requirements:

Engineered controls typically include features that are used to control the work environment, such as permanent structures, systems, and controls, including shielding, filtered ventilation systems, remote controls, containment devices, and the use of designs and materials that facilitate operations, maintenance, and other activities. Temporary engineered controls (e.g., temporary shielding, confinement, and ventilation systems) are typically used to facilitate short-term or emergent operations when the installed engineered controls do not provide the desired level of protection. Administrative controls typically include controls that are implemented by the individual at the work site, including written procedures, technical work documents, work authorizations, and other controls that are used to guide individual actions in a manner that will facilitate implementation of the ALARA process (10 CFR 835.1001).

ANSI N43.3 and N43.2 provide specific guidance that should be considered for exempt shielded (including cabinet X-ray), shielded, unattended, and open installations. Not all the ANSI guidance for shielded, unattended, and open installations meet the requirements of 10 CFR 835. If the design of the facility cannot be upgraded in a practical manner to meet the 10 CFR 835 exposure rate criteria, then the alternative is the implementation of additional access and occupancy controls to meet the design objectives.

8.7 Shielding

A Shielding Assessment or Dose Assessment Calculation shall be performed for the Device. The Assessment shall include projected dose rates with and without shielding, any addition of engineered safety controls, access control and safety devices, etc. Shielding should be designed and installed consistent with the guidance provided in ANSI N43.3, which is available from the assigned RSO. The Assessment should be stored in an official Fermilab Document Control System (i.e., specific DocDB, SharePoint, etc.), and the location should be noted in Section 2 of RP Form 133.

8.8 Access Control and Safety Devices

The purpose of access control devices is to prevent unauthorized or inadvertent entry into a radiological area and/or to warn of a hazard. These control devices should be listed in Section 2 of RP Form 133. They may also be documented in the Shielding Assessment or Dose Assessment Calculation. Attachment C contains a table of graded access control system features for prompt radiation hazards for reference. Items to consider are as follows:

8.8.1 If locked entryways are used, the keys used for one Device installation or storage facility should not provide access to another area.

8.8.2 Additional measures shall be implemented to ensure individuals are not able to gain unauthorized or inadvertent access to very high radiation areas. Such measures (i.e., physical constraints) should include locking or securing service doors and panels with tamper resistant fasteners or the use of multiple and redundant access controls.

8.8.3 Due to the lack of intrinsic shielding and the nature of use, access to a very high radiation area could be possible for an “open” installation. Additional measures (e.g., interlocked “photoelectric eye” light beams) should be established to meet this requirement.

8.8.4 There are many situations where, when the access points of a radioactive material container are closed, there are no physically controlled high radiation areas exterior to the container. In some of these situations, opening an access point creates a physically controlled high radiation area exterior to the container. An acceptable approach for these situations is to implement one or more of the features of 10 CFR 835.502 for the container. This approach would be consistent with the requirements of 10 CFR 835.502 in acting to prevent uncontrolled or unplanned exposures to individuals.

8.8.5 In situations where an individual could enter a container and access a physically controlled high radiation area, one or more of the features of 10 CFR 835.502 should also be implemented for the container. In this case, the walls of the container form the boundary of an accessible physically controlled high radiation area. This can be accomplished by controlling access to the container itself or controlling access to the room where the container is residing.

8.8.6 Generally, entryways that are secured closed in such a manner that a tool, such as a hoist, must be used to gain access, may be considered locked. However, if the opening tool was left in place such that an individual would not need to make a determined effort to gain access to the entry, in this situation, would not be considered adequately locked or otherwise secured. Similar unacceptable examples would include leaving a ladder secured adjacent to a fence meant to restrict access or securing an entryway with a single bolt and leaving the wrench attached to the bolt. These examples are not considered consistent with 10 CFR 835.501(b), which requires that the degree of control be commensurate with existing and potential radiological hazards within the area.

8.8.7 While the purpose of locking these areas is to maintain a high level of positive access control, it is recognized that these controls cannot absolutely prevent determined circumvention of the physical barrier such as with the use of wire cutters or unbolting the hinges to a doorway. Instances of such determined circumvention should be addressed with appropriate disciplinary action.

8.8.8 In addition to the above-mentioned controls, the entryway or access point to the container would also need to be labeled, per 10 CFR 835.601, if adequate warning is not provided by control measures and required posting. The label should specify that the entryways should not be opened without radiological control approval and that significant levels of radiation may exist.

8.9 Interlocks

8.9.1 Per FRCM Article 362, Radiation safety interlock systems provided for the Device shall comply with the requirements set forth in FRCM Chapter 10 or be approved by a documented review to provide an equivalent level of protection.

8.9.2 Doors and/or access panels in exempt shielded, shielded, and unattended installations should be equipped with one or more fail-safe safety interlocks to prevent irradiation of an individual [ANSI N43.3(6.5.2)].

8.9.3 If an area radiation monitor is incorporated into a safety interlock system, the circuitry should be such that a failure of the radiation monitor shall either prevent normal access into the area or operation of the Device.

8.10 Device Controls

8.10.1 One or more physical control devices should be used to secure the Device to prevent unauthorized access and use.

8.10.2 The control system governing the production of radiation should be equipped with a lock and key to prevent to prevent unauthorized use. The key controlling production of radiation in one Device should not control the production in another. This may include password protection of the Device. The method for ensuring only Authorized Personnel should be described.

8.10.3 Control devices used to limit Device time, position (irradiation geometry), current, voltage, beam intensity, or control panel lights or system indicators should be fail-safe.

8.11 Run-Safe and Emergency Shutdown Devices

Administrative procedures should be implemented to ensure that the Device installation and the Device safety interlock control devices are such that:

- Radiation cannot be produced until the interlock system logic has been completely satisfied,
- Production of radiation cannot be resumed by merely reestablishing the interlock circuit at the location where an interlock was tripped, and
- The safety circuit cannot be re-energized or reestablished automatically (i.e., there should be a manual safety circuit reset on or near the main control console).

For each area designated as a high radiation area or very high radiation area, 10 CFR 835.502 provides an option that permits a control device to automatically generate audible or visible alarm signals to alert individuals and the cognizant Device Operator of a potential entry into the area before it occurs. To meet ANSI N43.3 guidance, warning devices should be provided as an addition to any other access control feature in accordance with the installation specific requirements delineated in Sections 8.8-8.10 of this procedure. These warning devices are typically warning lights.

All Device warning lights should be red or magenta for consistency. Enough lights should be installed so that at least one light is easily visible from all reasonably occupied areas that may have dangerous radiation levels and from reasonable avenues of approach to such areas.

However, warning lights (even if interlocked to fail-safe if burnt out) are only passive in nature. When operating, they generally do not prevent an individual from physical access to a radiation beam unless they are used as part of a photosensitive circuit. Such a circuit would remove the radiation beam or field if any individual intercepted the beam.

Due to the passiveness (i.e., reliance on worker attention and action) of this safety feature and the potential for failure, at least one interlocked warning light should be used in all circumstances. The interlocked warning light should be used to provide visual indication that radiation is being produced and should be used in conjunction with any interlocked safety device which restricts physical access to a radiation beam or field. When used in this fashion, the Device should not be operable when the warning light is out.

It should not be possible to override the operation of any warning devices activated by a fail-safe function without positive actions by the operator such as resetting controls at the control console. Where feasible, i.e., for new or significantly modified Devices that can produce very high acute doses, i.e., that must be analyzed in the documented safety analysis, safety system hardware and software should provide additional safety via computer-assisted operations as well as indicate all abnormal events at the console and remotely notify cognizant personnel of abnormal events and conditions.

8.12 Experiment or Device Approval

Each RGD or Equivalent Accelerator shall go through an official review process prior to initial operation or modification of the Device. This could be the TSW/ORC system. See FESHM Chapter 2005 for guidance on this process. The number of the official review used should be indicated. After this, the RGD Custodian signs the form to verify all information they have entered is complete and correct.

8.13 DOE Order 420.2D Applicability and Equivalency Determination

For this section, the RGD Custodian and assigned RSO work together to determine which classification the Device falls under – RGD, Equivalent Accelerator, or Non-Equivalent Accelerator.

- If the Device is an RGD, the Device may be managed as an RGD and all requirements of this procedure are applicable.

- If the Device is an Equivalent Accelerator, the Device may be managed as an RGD and all requirements of this procedure are applicable. Additional approvals are necessary prior to running the Device.
- If the Device is a Non-Equivalent Accelerator, the Device may not be managed as an RGD, and the Accelerator Safety Department should be consulted for further guidance.

After the determination is agreed upon by both the RGD Custodian and the assigned RSO, this form and a memo are sent to the Senior Radiation Safety Officer and Division/Directorate Management discussing the device classification. If both agree, the SRSO and Division/Directorate Management sign and return the memo to the assigned RSO. This Memo is attached to the RP Form 133 for storage.

- If it was determined that the Device an Equivalent Accelerator, the Fermilab Site Office must also concur with the determination. Any conditions of approval should be noted on the form. The Memo from the Fermilab Site Office will be attached to the RP Form 133 for storage.

8.14 Walkdowns and Survey Plans

The assigned RSO, the RGD Custodian, and the personnel developing the Radiation Survey Map will need to walk through the area where the Device is installed to generate the appropriate map and discuss any additional concerns. At this point, the Area around the Device should be posted with Radiation Signage indicating the expected hazard based on the Assessment.

If the Device contains a sealed radioactive source, the assigned RSO should work with the Source Physicist to verify appropriate leak tests and integrity tests were performed on the source. The results should be attached to the RP Form 133.

The Assigned RSO will develop a Routine Radiological Monitoring OJT and Survey Map for the specific Device, ensuring RCTs are appropriately trained on the specifics of the Device and appropriate survey methods.

At this point, the Device may start up with Radiation Safety present to perform the initial Start Up Survey based on the Survey Plan developed. Upon completion of the survey, the results should be attached to the RP Form 133.

8.15 Area Postings

If based on the Start Up Survey the Radiological Postings need to be updated, this should be completed as soon as possible by the assigned RSO or an RCT. This should preferably be done at the time of the Survey. Postings should be installed in accordance with ESH-RPO-POST-01 requirements.

Additional postings such as “**CAUTION: RADIOATION BEING PRODUCED”** or **“RADIATION AREA EXISTS WHEN RED LIGHT IS ON**” have been added as appropriate. The phrasing may be different based on each individual Device need, but all should contain the appropriate radiation symbol and verbiage.

The Assigned RSO will independently walk down the Device to ensure all postings are correct and adequate.

8.16 Additional Required Documentation

Additional paperwork should be updated regarding each new Device. This includes addition to RP Form 108, List of Radiation Generating Devices, adding the device survey to the appropriate routine survey package, and ensuring appropriate Area Monitors are installed and added to the Area Monitor list.

Upon completion, the Assigned RSO completes RP Form 133 and records it in the ESH DocDB under a specific number assigned for the Device.

Note: The ESH DocDB Record may be assigned at any point in this process, but all documentation should be added to this record at the end of the process.

8.17 RP Form 113 - Preliminary Hazard Assessment Checklist for Deuterium-Based Neutron Generators

Deuterium Based Neutron Generators have additional requirements and necessary information that must be captured to classify and appropriately control the Device. These requirements are based on NCRP Report No. 72, which is available from the assigned RSO.

The total quantity of deuterium and tritium are needed to verify compliance with DOE O 474.2A. The quantities should be listed on RP Form 113 in grams. If the thresholds listed on the form are met or exceeded, the Material Control and Accountability (MC&A) Subject Matter Expert should be notified to ensure appropriate controls are in place.

Next the RP Form 113 asks for different parameters of x-rays (photons) and neutrons based on the maximum beam current and voltage. These values can be used to calculate the maximum effective dose rate (unshielded) from the generator to assist with required shielding determinations.

When shielding is required to meet the provisions of FRCM Article 236 for the accessibility conditions desired for the generator for these maximal operating conditions, a shielding analysis should be performed. This shielding analysis must be evaluated, documented appropriately in an Official Fermilab Storage System (i.e., DocDB, SharePoint, etc.), and reviewed and approved by the assigned Radiation Safety Officer.

If the accelerating potential and/or the beam current need to be limited to levels below those constrained by the intrinsic design of the generator to achieve acceptable operating conditions, the Interlocks Engineer must perform an evaluation of the generator and controls to ensure appropriate measures are in place. This evaluation should be attached to the RP Form 113.

As a reminder of hazards other than radiation, a Conventional Hazards section is listed. This helps identify non-radiation safety Authorities Having Jurisdiction (AHJs) or Subject Matter Experts that should also review the generator. This is often done during the ORC process for new equipment.

In addition to the training requirements listed in RP Form 133, the RGD Custodian and Operators are required to take "Using Neutron Generators at Fermilab – FN000672."

Upon completion of RP Form 113, it is signed by the RGD Custodian, the DSO, and the Assigned Radiation Safety Officer. It will be attached to the associated RP Form 133 for record retention.

8.18 Additional Information – Radiological Monitoring

Radiological monitoring shall be conducted by Radiation Safety to determine and document the integrity and adequacy of the shielding and to verify that posting and access control requirements are satisfactory before the Device is turned over to the RGD Custodian for routine operation and periodically thereafter. If there is a potential for exposure in accessible areas adjacent to the installation, then the adjacent areas should be monitored and should be vacated when pre-operational monitoring is performed.

8.18.1 Pre-operational monitoring should include the following:

- Determine dose rate or integrated dose received in any 1 hour as dependent upon the pulse capability of the RGD
- Evaluate the exposure potential of the RGD at the maximum value of applied voltage or current, or at the maximum exposed position of the source for sealed radioactive source installations. RGDs should be operated in steps of increasing beam strength until the highest values are achieved
- Include the use of mechanical or electrical devices that restrict beam orientation and magnitude, and determine the degree of beam restriction, with and without those devices
- Detect and measure potential leaks in the shielding and barriers
- Encompass all geometries in which the useful beam can be directed

8.18.2 Special monitoring should be conducted as follows:

- During the performance of maintenance and alignment procedures if the procedures require the presence of a primary beam
- When any component in the system is disassembled or removed
- Any time an inspection of the components in the system reveals an abnormal condition
- Whenever personnel monitoring dosimeters or area monitoring show a significant increase over a previous monitoring period or are approaching administrative limits
- Following maintenance or calibration prior to restoration to fully operable status
- After any modification

NOTE: It is not necessary to perform radiological monitoring of electrically energized Devices during periods when they been removed from service and placed in storage. However, when any Device which has been in "storage" is being reactivated for use,

functional and operational inspections and radiological monitoring should be performed prior to initial use. See Section 8.25 for Removing and Restoring a Device from Storage.

NOTE: For open installations, where irradiation configurations and boundary conditions are likely to change frequently, radiation monitoring shall be conducted in response to changing working parameters.

NOTE: After the initial assessment, independent inspections and monitoring should be conducted as necessary to verify that Device operations continue to remain safe, that during the operation of any open installation the proper location and posting of boundaries are maintained, and that after any modification or removal from storage of a Device installation, effectiveness and operability of safety features are adequate.

8.19 Additional Information – Area Posting

Any time an installation requires maintenance, the entrance to the area in which the installation is located and the inside of the installation should be conspicuously posted by Radiation Safety to indicate the maintenance status of the installation. Posting should be established:

- During the performance of maintenance and alignment procedures if the procedures require the presence of radiation, and
- Any time an inspection or monitoring reveals a deficient condition for any safety device.

When a safety device or interlock has been approved to be by-passed or is awaiting repair, the entrance to the installation and the Device enclosure should be posted with a prominent sign bearing the words "**SAFETY DEVICE NOT FUNCTIONING**" or a similar message.

The Assigned RSO should be notified of status changes and pertinent details, e.g., safety system software errors as well as safety devices affected by maintenance or malfunction. The Assigned RSO will determine the appropriate method to prevent exposure during this period (i.e., locking off the source, lockup up the control key, etc.).

8.20 Equivalent Accelerators

Small (low voltage, less than or equal to 10 MeV) accelerators used for radiography, ion implantation, or the production of incidental photons or particles (e.g., neutron generators) in exempt shielded, shielded, or open installations should be operated in accordance with the guidance specified by this procedure. When accelerators are used outside of exempt shielded or shielded installations, requirements for open-air radiography (Section 8.24) prevail.

When used within shielded installations, determination must be made whether the requirements for the exempt shielded or shielded installations (Section 8.23) prevail. Additional requirements for those Devices with particle energies exceeding 10 MeV are provided in DOE O 420.2D, Safety of Accelerator Facilities.

8.21 Electron Devices that Generate X-Rays Incidentally

These Devices are usually shielded to attenuate the emission of X-rays. Requirements for the exempt shielded or shielded installations (Section 8.23) prevail. Examples include electron beam welders, electron microscopes, pulse generators, etc., and microwave cavities if used as beam guides.

Preoperational inspections and monitoring should be performed initially upon receipt. However, the requirement for the routine inspections and monitoring may be modified at the discretion of the assigned RSO.

8.22 Cabinet X-Ray Systems

These Devices are primarily used in security applications and are commercially available; manufacturer requirements for these devices are delineated in 21 CFR Part 1020.40.

These Devices should be procured, categorized, inventoried, operated, inspected and monitored, and decommissioned in accordance with this procedure to ensure compliance with 10 CFR 835.1001 and 1003. Inspections and surveys should be performed as specified in Section 8.18 of this procedure.

If not commercially obtained, the requirements for an exempt shielded installation (Section 8.23) prevail.

8.23 Shielded and Exempt Shielded Installations

A shielded installation, or nonexempt shielded installation, is when shielding and other administrative and/or engineering controls are in place to reduce exposure outside of the shielded area. See the Definitions section for a more complete definition.

An exempt shielded installation is when the shielding is effective enough to meet the maximum permissible dose equivalent requirements for uncontrolled areas without additional administrative and/or engineering controls. See the Definitions section for a more complete definition.

Shielded and exempt shielded installations are the most common type of Device and are the primary focus of this procedure. The Shielding Assessments or Dose Assessments, RWPs, Operating Limits, and radiation monitoring devices act as the administrative and/or engineering controls used to control the exposure below the maximum permissible dose-equivalent requirements for the area.

8.24 Open-Air Installations

Open-Air Installations cannot meet the requirements of shielded or exempt shielded installations due to the mobile, portable, or experimental equipment used where fixed shielding cannot be used. The protection of personnel and the public depends on strict adherence to procedures and other administrative controls.

If any Device is used as an open-air installation, use of the Integrated Management Planning and Control Tool (IMPACT) is required. The assigned RSO will assign an RCT to verify radiation safety requirements are being met and perform a survey during initial

operation. Depending on the results of the survey, additional RCT coverage may be needed for each Device operation. This is dependent on each specific Device.

8.25 Removing and Restoring a Device from Service

When the Device is removed from service, the RGD Custodian should notify the assigned RSO. The assigned RSO will determine an appropriate method for ensuring the Device cannot be operated i.e., placing a lock on the power supply, removing the operation key, changing the password for the program, etc. The Device and method of ensuring the Device cannot be operated will be stored in the Radiation Safety Configuration Control Log. The RWP for the Device will be rescinded, and the RP Form 108 will be updated with the status.

When a Device is returned to service, all requirements in the active RP Form 133 will be reviewed to ensure no updates are required. If updates are required, the RP Form 133 will need to be updated. When all information is updated and/or verified, the assigned RSO will issue a new RWP, unlock the Device, and updated the Radiation Safety Configuration Control Log and RP Form 108. On startup, an initial start survey will need to be performed for the Device.

9.0 Data and Records Management

Evaluations of the Devices are recorded on RP Form 133 – Radiation Generating Devices which are stored on ESH DocDB. RP Form 108 is the official list of Devices, which will include their status. This is stored in ESH DocDB.

10.0 Quality Assurance/Quality Control

This procedure is subject to a review frequency requirement of 3 years and is due in August 2026.

11.0 References

ANSI/HPS N43.1-2011 – Radiation Safety for the Design and Operation of Particle Accelerators

ANSI/HPS N43.2-2021 – Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment

ANSI/HPS N43.3-2008 – Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV

DOE G 441.1-1C – Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection

NRCP Report No. 72 – Radiation Protection and Measurement for Low-Voltage Neutron Generators

12.0 Attachments

Attachment A – Requirement Checklist for RP Form 133

Requirement:	Requirements Met By	Responsible Party
Assigning Custodian	Division / Directorate Management will assign RGD Custodian duties. RGD Custodian must be an FRA employee on site.	Division / Directorate Management
RP Form 113: Prelim Hazard Assessment Checklist for Deuterium Based Neutron Generators	Completion of RP Form 113 for Deuterium Based Neutron Generators	RGD Custodian
Develop Site-Specific Documents	Develop Standard Operating Procedures and Emergency Procedures for the Device.	RGD Custodian
Determine and Record Device Operational Conditions	Record the maximum and normal operating parameters of the Device, as well as other specifics on the Device.	RGD Custodian
Develop Training	Develop training in the official Fermilab Training System specific for the Device based on the procedures.	RGD Custodian with RSO assistance
Implement and List Engineered Safety Controls	Generate a list of Engineered Safety Controls for the Device or direct to the appropriate documentation.	RGD Custodian
Generate Shielding Assessment or Dose Assessment Calculation	Generate an appropriate document identifying radiation hazards and mitigation methods	RGD Custodian or Designee
Implement and List Access Control and Safety Devices	Generate a list of access control and safety devices or direct to the appropriate documentation	RGD Custodian
Install Interlocks	Ensure interlocks are installed and tested in accordance with FRCM Chapter 10	RGD Custodian with Interlocks Department assistance
Implement Device Controls	Develop and describe how the Device is only operated by Authorized Personnel	RGD Custodian
Implement and List Run-Safe and Emergency Shutdown Devices	Verify these devices are in place and operational	RGD Custodian
Classify Device	Determine appropriate Device Classification based on information in RP Form 133	RGD Custodian with RSO assistance

Approve of Classification	Memo agreeing with Device categorization and authorization to generate RWP	SRSO and Division/Directorate Management
Memo to Site Office	Exemption/Equivalency letter for DOE O 420.D requirements to the Fermilab Site Office	SRSO
Monitoring	Surveys on initial startup and any time they start running the device after shutting off	RSO
Postings	10 CFR 835 postings;	RSO
Area Monitoring	Area badges, chipmunks, etc. installed based on results from Shielding Assessment	RSO
List of RGDs	Add to Fermilab's List of RGDs (RP Form 108)	RSO
Routine Monitoring	Add Device to the Routine Monitoring program	RSO
RWP	Generate the RWP as the official document allowing running of the device, noting the operating limits and controls in place.	RSO

Attachment B – Initial Device Survey Table Template

Power Level of Device (%)	Accelerating Potential	Current	Dose Rate (mR/hr)	Location

Attachment C – Graded Access Control System (ACS) Features For Prompt Radiation Hazards

Dose Rate (mrem h^{-1})	**Dose Category**	**Start-Up Warning**	**Enclosure**	**Personnel entryway door/gate**	**Interlock Redundancy**	**Area Secure System**
5-100	Minimum	None	Rope	No Restriction	None	Not Required
100-1,000	Low	Visible & Audible	Barrier	Locked or Interlocked	Recommended	Not Required
1,000-10,000	Medium	Visible & Audible; Emergency-Off Recommended	Barrier	Locked; Interlock Recommended	Recommended	Required (Exclusion Area)
> 10,000	High	Visible & Audible; Emergency-Off	Barrier	Locked and Interlocked	Required	Required (Exclusion Area)