

RGE Audit Checklist

Item	Description
Operator's Manual	Paper/electronic manual provided by RGE vendor is readily available and complete.
RGE QA Manual	Human Use or Non-Human Use Quality Assurance (QA) manual provided by RSO. Information contained in the manual should be discussed with operators during area/lab specific training.
Unit-specific Operating Procedures	Short (usually 1 page) instructions on how to operate the RGE. Often created by an experienced worker with RGE-specific training or the vendor (e.g. Quick Start Guide).
Safe Operating Procedures	Different from unit-specific procedures. These procedures explicitly describe the safe use of RGE, such as wear dosimeters, how to follow procedures outlined in the QA manual, permitting only trained operators to use the device, and more.
Quarterly Checks	Operational RGE only. Quarterly checks performed and documented by RGE users demonstrating that safety features (e.g. interlocks, warning lights) are working.
Operator List	List of people who have been documented trained to safely operate the RGE. Auditor will compare this list to workers listed in Gamma 2.
Operator Training:	Required for all personnel to operate the RGE. Each unit/type of unit shall have separate training documentation.
<ul style="list-style-type: none"> Radiation Safety 	<ol style="list-style-type: none"> Basic Radiation Safety course OR Ancillary Awareness video AND (if applicable) Double-Edged Sword/X-ray Diffraction Hazards (XRD) course These courses are documented on the Compliance Training website.
<ul style="list-style-type: none"> Area/Lab Specific 	Documented in Gamma 2. Covers QA Manual, RGE-specific safety precautions, etc.
<ul style="list-style-type: none"> Machine Specific 	Documented training on how to operate the RGE. Training can be provided by the vendor or an RGE Worker that has been documented as trained by the vendor or by another documented trained user.
<ul style="list-style-type: none"> Annual Refresher 	Individual Responsible or Lab Contact gives an annual review of the program and continued competency of RGE use.
Maintenance Log	Documents any incidents, maintenance, repairs, or modifications performed on the RGE.
Use Log	Each time the RGE is energized, use should be documented. This includes RGE ID, date of operation, operator's name, and reason for use.
Safety Features	Operational RGE only. Checks performed to ensure safety features (e.g. lights, indicators, interlocks) to prevent accidental exposure are working correctly, and to ensure no changes to the safety interlocks have been made. X-ray Diffraction (XRD), handheld, high intensity x-ray units, cabinet systems, etc., require quarterly checks.
Lead Apron Check	Required annually for Human/Veterinary Use only. Must be available for RGE operators that may be in the patient (human or animal) area during x-ray generation.
Radiation Expert Testing	Only required for Human & Veterinary Use; required frequencies vary. Performed by UC/CCHMC medical physics or vendors.
Radiation Survey	Operational RGE only. RSO surveys to ensure no radiation leaks, no major changes in measured radiation from previous audit.
Policies & Procedures	Knowledge of all safety features/interlocks/posting requirements, UC radiation safety and control policies and procedures.
Notification Requirements	Handling incidents, RGE status changes, disposal, transfer, acquisition of new RGE.

Required Postings

ODH Notice to Employees <ul style="list-style-type: none"> UC version CCHMC version 	Green sheet posted in every RAM/RGE room that details employee and employer rights and responsibilities; includes ODH contact information. Provided by RSO.
Caution Sign	Posted on control panel of RGE.
Inoperable X-ray/RGE Form	Inoperable RGE only. Completed copy posted on the inoperable unit.