

CASE WESTERN RESERVE UNIVERSITY
DEPARTMENT OF ENVIRONMENTAL HEALTH & SAFETY
RADIATION SAFETY
ANNUAL REPORT 2022-2023

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INTRODUCTION

This report is submitted to the president and designated members of the senior administration of the University as required by the Radiation Safety Committee's (RSC) operating guidelines and Case Western Reserve University's State of Ohio (Nuclear Regulatory Commission Agreement State) Broad Scope License. The report summarizes the activities of the Radiation Safety Office (RSOF) of the Department of Environmental Health & Safety (EHS) at Case Western Reserve University (CWRU). Its contents cover the period from 7/1/2022 – 6/30/2023.

SUMMARY

DEPARTMENT STRENGTHS

The RSOF is comprised of a staff with extensive and diverse backgrounds who can address and resolve a wide range of issues faced in radiation safety at CWRU. The RSOF has developed programs that meet or exceed regulatory requirements. These programs proactively anticipate new safety requirements by promulgation of new programs through the RSC of the University. The success of these agendas is enhanced by excellent administrative support.

DEPARTMENT OPPORTUNITIES

The RSOF enjoys excellent interaction with other departments that are developing safety-related initiatives and outside agencies that are dedicated to improving environmental quality in our facilities.

RADIATION SAFETY ACCOMPLISHMENTS FOR 2022-2023

Over the past year, the radiation safety division of EHS continued to improve the effectiveness of the Radiation Safety Program. Notable new accomplishments include:

- Returned to in-person training for Radiation, Laser, and X-Ray training.
- Generated in-house savings accrued from meter calibration, recycling and decay-in-storage programs amounting to more than \$13,070 in 2022-2023 through its services to the research community at CWRU.

RADIATION SAFETY GOALS FOR 2023-2024

The continuing goal of the radiation safety Program is to position EHS for more effective interaction with the educational and research goals of the University through training and training development. A secondary goal is to increase the positive impact of CWRU safety programs within and around the adjacent community through educational and programmatic interaction with local partners and emergency responders. Specific efforts currently address:

- Planning and Preparation for Irradiator disposal as well as review of possible purchase of an X-Ray Irradiator the Office of Radiological Security (ORS).
- Hire of a Radiation Safety Specialist to fill open position since 10/2022.
- Organize a meeting with Cleveland Clinic radioactive materials (RAM) program leaders to examine the new joint program interfaces that arise in the new medical school.
- Jointly consider including a Cleveland Clinic program representative on the CWRU RSC to coincide with opening of new Facilities at the Cleveland Clinic location.

OHIO DEPARTMENT OF HEALTH LICENSE

CWRU has one Ohio Department of Health (ODH) broad scope license. The license covers possession and use of both nuclear accelerator-produced RAM and naturally occurring RAM for experimental purposes. It also allows for the licensed use of four irradiators. The ODH broad scope license site visit was last conducted on 10/27/2022.

The University has two ODH radiation-generating equipment (RGE) registrations. The registrations cover the receipt, possession, use, storage, and disposal of radiation generating equipment including dental X-ray machines, X-ray diffraction units, and fluoroscopy units. The ODH RGE (X-ray) inspection for the dental bus mobile units was conducted on 7/16/2019. The ODH RGE (X-ray) general inspection was conducted on 7/21-22/2020.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2025	Broad Scope License
09-M-06944-12	May 31, 2024	Radiation-Generating Equipment Registration (All)
06-E-06944-020	March 31, 2024	Radiation-Generating Equipment Registration (Mobile Units)

DECOMMISSIONING FUNDING PLAN

The CWRU broad scope license and the decommissioning funding plan became effective 10/2019. Until that time, the University was required to maintain a standby letter of credit to cover possible costs if the University's broad scope license was required to cover costs of rapid decommissioning. The funds required for this letter of credit depended on the kind and amounts of RAM maintained in active use or waste by the University. The University now operates under an agreement with ODH that requires no letter of credit but is dependent on the University's good financial standing. This agreement covers all possible decommissioning costs for RAM located at the University as long as the University's credit rating is maintained.

RADIOACTIVE MATERIAL USE AND STORAGE LOCATIONS

RAM and/or RGE are located at the following facilities:

- Main campus of Case Western Reserve University, 10900 Euclid Avenue, Cleveland, Ohio 44106
- University Hospitals (UH), 2065 Adelbert Road, Cleveland, Ohio 44106
- Wolstein Research Building (WRB), 2103 Cornell Road, Cleveland, Ohio 44106
- Health Education Campus (HEC) Dental Clinic, 9601 Chester Avenue., Cleveland, Ohio 44106 (no RAM)
- Health Education Campus (HEC) Main Building, 9501 Euclid Avenue., Cleveland, Ohio 44106

RAM and/or RGE are received and/or stored at the following sites:

- Shipping and receiving, 2232 Circle Drive, Cleveland, Ohio 44106
- Wolstein Research Building, 2103 Cornell Road, Cleveland, Ohio 44106
- Health Education Campus (HEC) Dental Clinic, 9601 Chester Avenue, Cleveland, Ohio 44106 (no RAM)
- Health Education Campus (HEC) Main Building, 9501 Euclid Avenue, Cleveland, Ohio 44106 (no RAM)

PURPOSE FOR RAM USE

The majority of isotopes used at the University are for biomedical research. The most typical isotopes used are ^{14}C , ^{18}F , ^3H , ^{124}I , ^{125}I , ^{32}P , ^{33}P , and ^{35}S . Isotopes used in sealed sources contained within irradiators, scintillation counters, gamma counters, check sources and calibration standards are most commonly ^{137}Cs , ^{133}Ba , and ^{241}Am .

RADIATION SAFETY PROGRAM – RESPONSIBLE PARTIES

RADIATION SAFETY COMMITTEE

The RSC sets the policy for the use of RAM for the University's committee. Members of this committee are appointed by the president of the University and has responsibility for monitoring and enforcing compliance with the University's radiation safety program as outlined in the University's ODH broad scope license. RSC members are chosen from diverse disciplines to provide comprehensive expertise. The committee reviews all applications for the use of RAM.

The 2022-2023 RSC membership and their affiliations are listed below. The ODH is informed of committee membership changes. The committee is also aided by input from ex-officio (non-voting) and visiting members (non-voting).

VOTING MEMBERS

Dr. Thomas McCormick Dept. of Dermatology BRB 530 Term Expires: 10/15/2023 Chairperson Term Expires:10/15/2023	Felice T. Porter EHS Asst. Dir./Asst. RSO Quality Assurance Specialist Service Bldg., First Floor	Dr. Saba Valadkhan Dept. of Molecular & Microbiology HG Wood 210A Term Expires: 10/1/2022
Dr. Colleen Croniger Dept. of Nutrition BRB 925 Term Expires: 10/1/2022	Dr. Suhrim Fisher Animal Resource Center BRB RB5P Term Expires: 9/1/2023	Dr. Christine Duval Dept. of Chemical Engineering AW Smith Building 147 Term Expires: 9/1/2023
Dr. Zhenghong Lee Dept. of Radiology Bolwell Building S107 Term Expires: 9/1/2023	Dr. Thomas Gerken Dept of Biochemistry Wood 477 Term Exp: 9/30/2025	

EX-OFFICIO MEMBERS

Richard Jamieson Vice President Dept. of Campus Services Administration Adelbert Hall 229	Marc Rubin EHS Senior Director Service Bldg. First Floor
Bruce DeMeza University Hospitals Asst. RSO Bishop S621	Joseph Nikstenas EHS Laser Safety Officer & Safety Specialist Service Bldg. First Floor

SUPPORT STAFF

Naomi Boles Department Assistant Service Bldg., First Floor

The RSC acts as an advisory and enforcement body to ensure that all RAM is safely used in accordance with the 'As Low As Reasonably Achievable' (ALARA) principles. The committee conducts audits each trimester, which address programmatic compliance. The RSC also conducts an annual audit in which the entire program is reviewed.

The audits ensure that:

- Specific program components conform to the licensed program as described in the CWRU Radiation Safety Manual and License
- Accurate documentation for program conformance and license compliance is maintained.
- Adequate training is provided for all classes of workers.
- Oversight for RSOF activities is maintained through RSC familiarity with the daily function of the University radiation safety program.

The RSC met via Zoom and in person on 6 occasions during the 2022-2023 fiscal years to review applications for radioisotope use and action on other business. There was one quorum meeting. Five RSC meetings were canceled because agenda items did not require immediate address. The minutes of the RSC meetings and executive committee actions are available in the RSOF, through the RSC or through the University's administration. The presence of radioactive materials and use of irradiators required continuing audit activities over this period by both the RSOF staff and the RSC members.

APPLICATIONS	22/ 23	21/ 22	20/ 21	19/ 20	18/ 19	17/ 18	16/ 17	15/ 16	14/ 15
New AU	1	1	1	0	2	3	3	1	3
Additional Isotopes	1	2	3	2	1	2	0	2	2
Radioisotope use in Animals	1	1	1	1	0	2	2	4	1
Sealed Sources	1	2	3	0	0	1	5	0	6
Sealed Sources Update	0	1	1	2	2	1	0	0	0
AU Reactivation	0	0	0	0	0	0	0	0	0
Possession Limit Increase	0	0	0	0	0	0	0	0	2
AU Protocol Update	3	5	4	3	16	4	7	2	7
TOTAL APPROVALS	7	12	13	8	21	13	17	9	21

Important topics acted upon or discussed by the RSC:

- The Bioenterprise Building was bought by CWRU and renamed 'The Incubator'. (6/2023)
- The Yost building will be demolished and replaced with the ISBE building. (6/2023)
- Both cesium and cobalt irradiators will be removed, and an x-ray irradiator will replace them. (6/2023)
- The bridge by Lot 53 will open again. The bridge on Cornell will close 6/2023. (5/2023)
- RSC member, Christine Duval, received the prestigious early-career grant from the National Science Foundation. Congratulations! (5/2023)
- There has been an increase in requests for use of short-lived isotopes for Small Animal Imaging Research Center (SAIRC). The requests are for up to 20mCi of short-lived radioactive tracers in various types of animals. (5/2023)
- There has been an increase of UH clinical reviews for use of CWRU X-Ray equipment for the Dental School, IRB, and IACUC applications. (5/2023)
- There has been an increase of Irradiator use requests by Metro Health Researchers with connection to CWRU. Many Metro Health Researchers also have faculty appointments and conduct research through CWRU. (5/2023)
- Marc Rubin has agreed to assume the RSC Ex-Officio position for the Laser Program concerns as he is currently working on his PhD and has expertise with various lasers. (5/2023)
- Several RAM applications are due for the 5-year renewal, and they have been notified. (5/2023)
- RSC Audits for 4/2023 are completed. (5/2023)
- A Radon Test request was made by Public Safety in the basement of the building. The results showed below average radon levels. (5/2023)
- A package incident occurred with the delivery of a radioactive package delivered to the wrong laboratory. The package was not opened. The package was collected, surveyed by Radiation Safety, and delivered to

the correct laboratory. A complaint was submitted to FEDEX and the shipping and receiving address was updated in their system. (5/2023)

- Beckman Coulter will no longer maintain, repair, or decommission 137Cs Liquid Scintillation Counters (LS 6500) as of 12/2023 and no service contracts will be renewed. Radiation Safety will seek to find another vendor that can service our users and possible instrument-sharing opportunities for the departments. (5/2023)
- RSC Audits for 1/2023 are completed. (2/2023)
- CWRU has formally declared that COVID is officially over after 3 years. (2/2023)
- The Radiation Core has requested approval to conduct a project for a clinical trial that will produce NK cells injected into humans using the 137Cs irradiator. Human cells will be irradiated as a small step in the process vetted by the FDA (federally) and IRB (locally). Phase 1 is completed. The RSC has given approval to proceed. (2/2023)
- The Main Dispatch Move to the new facility has been postponed due to supply chain issues with equipment. (2/2023)
- Emergency Management Tabletop Exercise was completed. (2/2023)
- Irradiator Annual Training of Police & Security was completed. (2/2023)
- We have begun working with the Cesium Irradiator Replacement Project (CIRP) & Department of Energy (DOE) for the removal of two of our inactive irradiators and the purchase of a new x-ray irradiator subsidized by the government. (11/2022)
- Although there have been several inquiries, the Radiation Specialist position has not been filled. (11/2022)
- Radiation safety passed the ODH inspection of the CWRU Broad-Scope License and Increased Controls. (11/2022)
- There are no reports of high doses or fetal monitoring incidents. (11/2022)
- The Radiation Safety Office will resume in-person training for Radiation, X-Ray, and Laser users. (11/2022)
- The ODH has notified us that they will inspect the CWRU Broad-Scope License and High Security Protocols. (10/2022)
- The IRR Response Audit revealed some deficiencies in training, process, and procedures. Corrective steps were taken. A follow-up IRR Response Audit was successfully completed. (10/2022)
- With CWRU focus on growing research, \$200M will be added to increase research awards. (10/2022)
- Flu shots are available in October 2022. (10/2022)
- Several incidents of food and beverages found in laboratories have been reported and noted as serious offenses. (10/2022)
- Package Incident Summary Report sent to CWRU Senior Administration and RSC Chairperson. (10/2022)
- The Northeastern Ohio Certified Health Physics Society (NOCHPS) meeting is planned for 11/2022. (10/2022)
- It was suggested that we search for a RSC member with laser expertise to be added. (10/2022)
- Presentation of RSC Annual Report. (10/2022)
- A 600-bed residence hall will be completed in Fall 2024. (9/2022)
- One of CWRU largest incoming classes this year. (9/2022)
- Sent RSC Roster and RSC meeting schedule for 2022-2023. (9/2022)
- CWRU RSC Quarterly Audits are due in Oct 2022. (9/2022)
- CWRU High Security Equipment Quarterly Checks are due in Oct 2022. (9/2022)
- CWRU Human Resources Quarterly Audits of High Security personnel completed. (9/2022)
- Dispatch renovation in progress with relocation scheduled for the end of 2022. (9/2022)
- UH/CWRU Memorandum of Understanding final letter complete. (9/2022)
- RAM Package Incident 8/2022 confirmed not an NRC/DOT Sting. RAM package arrived with CWRU name and University Hospital address. All parties were contacted and advised of proper protocols. This is not reportable to the State as there was no RAM injury or contamination. Streamlining RAM ordering process with Purchasing. (9/2022)
- No high doses, no fetal monitoring. (9/2022)
- Sent RSC Guidelines to each member for review and revision. (9/2022)
- Sent reminder that all RAM Authorized Users must renew RAM applications every 5 years. (9/2022)
- Eckhard Jankowsky, RNA Chairperson, will leave CWRU in Jan 2023 and RNA Center will revert to the Biochemistry Department. (9/2022)
- LSC source removals, clearances, and decommissioning increased. (9/2022)
- EHS Radiation Safety changes include David Sedwick, PhD retired, Felice Porter is RSO, Joseph Nikstenas is ARSO, one Radiation Staff member resigned, and posted Radiation Specialist 2 position. (9/2022)
- Re-appointed two RSC members. (9/2022)
- Two Radiation staff members attended DOE Laser Safety Officer Conference in Berkeley, CA (9/2022)

- Welcomed Thomas Gerken, who has been at CWRU for 45 years in Pediatrics and then Biochemistry to the RSC. He replaced Donny Licatalosi who was on the RSC for 8 years and left CWRU. (9/2022)
- Approved applications were sent to RSC members on Zoom for their signatures following the meeting. (7/2022)
- Due to the death of Chris Dealwis, a RAM Authorized User, collection, and disposal of the RAM inventory as well as decommissioning of the laboratory was discussed and approved with the Department Chairperson. (7/2022)

SENIOR MANAGEMENT

The Radiation Safety Program monitors, inspects and audits RGE and sources used by AUs and their personnel. Senior management oversight and support of radiation safety-related activities is guaranteed by attendance of the vice president for campus security, or an appointed representative, at all RSC meetings. The RSC conducts independent audits of the Radiation Safety Program. The RSOF staff immediately responds to audit findings. Audit findings and responses are reported to senior management and the Committee. Richard Jamieson, vice president of campus services, continues to provide direct administrative representation for the Radiation Safety Program. In the absence of Richard Jamieson, Marc Rubin, EHS senior director, provides administrative representation.

RSOF AND AUTHORIZED USERS (AUs)

The AUs and the RSOF share responsibility for safety. The AU is directly responsible for the safe use of RAM in the laboratory. The radiation safety office is responsible for ensuring that appropriate safety procedures are implemented and that AUs are fulfilling their responsibilities for monitoring safety during experiments carried out in their laboratories. Audits of laboratories are conducted by the RSOF to ensure compliance with CWRU's license. The audit program includes routine unannounced inspections of each AU's laboratory.

ADMINISTRATIVE CONTROLS

Administrative controls are established and approved by the RSC for laboratories where RAM are/is used. Controls include signage, training, laboratory access and dosimetry. Written procedures document procurement, use and the disposal of all RAM at the University.

General safety compliance enforcement procedures prescribe sanctions for those who jeopardize safety or the continued favorable relationship between the University and the ODH. These procedures are designed to encourage the participation and cooperation of users of RAM and to promote safe use of such materials in a manner consistent with the rules and regulations of the ODH as interpreted by the RSC and the RSOF.

There are three classes of violations defined as minor, moderate and major severity.

Minor severity violations are listed under the following categories:

- Improper laboratory records
- Noncompliant RAM use and storage
- Maintenance of an unsafe laboratory environment

Moderate severity violations include the following:

- Food/cosmetics in laboratory
- RAM unsecured
- RAM in unauthorized areas
- Unapproved radiation laboratories
- Unapproved disposal of radioactive materials
- Unidentified contamination
- Failure to respond to written notices from the RSOF

Major severity violations include the following:

- Falsification of records
- Unreported loss or theft of RAM
- Unapproved transfer of RAM

There were no major severity violations assessed over this year. Of the moderate violations listed below, six were the result of unsecured RAM found during after-hours security checks and routine compliance reviews. No laboratories were assessed a moderate violation that had three or more minor violations during compliance reviews by radiation safety during routine audits. Documented follow up and resolutions were completed for all major and moderate violations.

VIOLATIONS	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Minor	16	31	24	19	38	43	70	78	81
Moderate	6	3	7	2	17	13	11	10	13
Major	0	0	0	0	0	0	0	0	0
Total	22	34	24	21	55	56	81	88	94

The assistant RSO, the RSOF staff and the RSO updated and revised most of the department manuals, training, licenses, certificates, and standard operating procedures in 2022-2023.

AU CATEGORIES:

RADIATION ACTIVE (RA)

AUs who actively use RAM are “radiation active.” Laboratories of these AUs are inspected by the RSOF three times per year. Audits are more frequent if there are particular concerns in a laboratory. A listing of AUs and their RAM can be found in the APPENDIX.

RADIATION INACTIVE (RI)

These AUs do not currently use or possess RAM.

RADIATION ACTIVE STORAGE MODE (SM)

AUs who did not actively use RAM, but who wish to maintain their RAM inventory will, by their request, have their inventory placed in storage mode status this fiscal year.

DEPARTED (D)

AUs, who no longer carry out research at CWRU, and whose laboratories have been decommissioned for RAM use, have been placed in the departed category this fiscal year.

AUs	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
RA	29	32	35	44	47	49	50	54	62
SM	12	16	18	16	18	20	15	20	8
RI	4	5	5	2	2	7	5	5	3
D	3	1	1	2	3	5	5	2	6
Total in Program	41	48	53	64	70	69	65	74	70

MASTER ISOTOPE LIST

The master isotope (see APPENDIX) list shows the University’s isotope inventory, the sum of the AUs’ inventory (excluding sealed sources) and the sum of the AUs’ possession limits relative to the National Regulatory Commission/ODH registration limit.

AU RADIOISOTOPE INVENTORY

The radioisotope inventory report (see APPENDIX) lists researchers, along with the amount of RAM material each is authorized to use, each AUs’ possession limits and the activity of isotopes on hand.

RADIATION SAFETY OFFICE (RSOF)

STAFFING

The RSOF operated under university approval with the following positions:

RSO (1)
Department assistant (1)
Student (1)

Specialist positions (4)
Asst. director/asst. RSO/quality assurance specialist (1)

Training and education are central to our department's goal in developing diversified skills among our personnel who are required to respond to safety incidents and for maintenance of regulatory mandates. Specialists are encouraged to attend training and continuing education. Seminars, training, and conferences attended or completed during 2022-2023 included radiological instrument training, RCRA selected hazardous waste training, 8-hour HAZWOPER refresher training and hazardous materials transportation security awareness. Training was provided by Zoom courses during the past year.

EHS staff are responsible for maintaining the EHS website that houses all online departmental training programs and schedules, safety manuals, safety newsletters, safety data sheets and safety information resources. The website is an essential resource for the campus community that requires continuous updating. EHS staff also monitors and backs up all departmental databases.

EHS EMAIL

Since implementing the EHS email, case.edu/ehs and cwruehs@gmail.com, the number of inquiries and safety concerns raised by CWRU personnel has averaged fifteen emails per day. This communication has led to swift response and follow-up of safety concerns reported by our user community.

To report concerns of unethical activity, employees may contact the integrity hotline and provide information anonymously. They can also call 866.483.9367 or go to <https://www.caseintegrityhotline.com>. They are encouraged to give the date, time, location, and any other pertinent information concerning the incident.

TRAINING SESSIONS

It is the responsibility of the RSC to ensure that individuals using RAM are adequately trained to keep doses to personnel and releases to the environment per ALARA (As Low As Reasonable Achievable). The RSOF provides training for all personnel that use RAM or RGE/X-ray. Initial training must be completed before use of any radioactive materials or RGE/X-ray equipment. Annual retraining is required for the continued use of RAM. Ancillary workers (non-radiation workers), who occasionally have contact with RAM, are retrained annually. Personnel who are trained include:

AU

An AU is a faculty member who has been approved by the RSC to use RAM.

RADIATION WORKER

A radiation worker is any person who uses RAM under the supervision of an AU.

ANCILLARY WORKER

An ancillary worker is a non-radiation worker who may have contact with laboratories or classrooms where RAM is used. This includes individuals working in facility services, protective services, in-house and contract custodial services, shipping/receiving, the ARC and research department assistants. During orientation, non-laboratory personnel are required to attend training that includes a radiation safety component.

RADIATION GENERATING EQUIPMENT (RGE) WORKER

An X-ray worker is any person who uses RGE as part of the research program of an AU.

IRRADIATOR USERS

Personnel using irradiators are required to attend initial radiation safety training conducted by the RSOF and site-specific training with the manager of the irradiator. An irradiator worker is any person who has met the requirements for unescorted room access, including background and fingerprint checks, radiation safety, and site-specific laboratory safety training.

TRAINING

The RSOF keeps a record of all dates of training, attendees, and content of training. Records of refresher training offered online are also maintained. Classes and online sessions attended are essential components of CWRU's safety philosophy. Training is audited on a monthly basis by the assistant RSO to ensure compliance. The RSOF maintains both a program description and other pertinent safety training materials for this purpose. It also monitors on-site training for irradiator use.

New isotope user training classes are offered at least two times per month. Annual radiation safety retraining is done online. X-ray training classes are conducted once a month. AUs are responsible for machine and performance-specific annual refresher training for workers who use X-ray equipment in their laboratory programs. Fluoroscopy users are required to complete a fluoroscopy training module (kindly provided by UH Cleveland Medical Center) in addition to the general X-ray and site-specific training. Fluoroscopy Right-To-Know training is provided on an as-needed basis to individuals who desire to observe fluoroscopy procedures. Additionally, there are monthly training classes for users of Class 3B and Class 4 lasers. The RSOF requires annual retraining for all workers involved with these units and this training is offered online.

All non-laboratory personnel are required to attend hazard communication and ancillary radiation training. Groups trained now include custodial, plant, ARC, shipping, security

departments, and contractor workers. Employees who do not complete training are restricted from working in areas where RAM are used.

TRAINING	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Radiation	91	70	69	108	143	133	118	61	92
Online Retraining	208	217	258	298	398	342	349	563	615
X-ray	10	7	15	12	32	22	43	58	50
Ancillary	865	1764	1651	725	1561	710	741	619	279
Laser	55	71	30	58	66	59	40	46	41
Laser Online	51	62	42	48	40	68	22	67	27

Over 1,280 laboratory workers were trained through the Radiation Safety Program in 2022-2023, which is a high point over the last five years. This increase reflects an effort on the part of the RSO to provide full training instead of ancillary training to all workers for laboratories where isotope is in active use.

FACILITIES AND EQUIPMENT

CWRU administration and the RSC ensure that appropriate facilities, equipment, and trained personnel are available for the safe operation, storage, and disposal of licensed material. The RSO and assistant RSO are responsible for overseeing the review of applications and inspection of all facilities, equipment and personnel that use licensed material. Facilities that are available at CWRU for the use of licensed material include:

AW Smith	Bingham	Bioenterprise
Biomedical Research	Bishop	Bolwell
DeGrace	Glennan	HEC Dental
HEC Main	HG Wood	Old Dental
Kent Hale Smith	Lerner Tower	Med East/Robbins
Millis	Olin	Pathology
Rockefeller	Service	Wearn
West Quad (CCSB)	White	Wickenden
Wolstein Research	Wood Research Tower	

LABORATORIES

There are 420 laboratories on campus equipped to use licensed material and equipment. The laboratories typically include chemical safety hoods, survey meters, protective clothing, analytical detection and measurement equipment, waste receptacles and decontamination supplies.

LABORATORY USE	# OF ROOMS
Radiation	201
X-ray	84
Laser	135

Radiation Safety Office (RSOF):

Facilities and equipment used by the RSOF to support laboratory inspection or isotope storage are in the service building on the first floor, the School of Medicine (DOA990) and the Wolstein Building (1118, 1119, & 1120).

RSOF Laboratory:

The RSOF is in the service building on the first floor, 2220 Circle Drive. The laboratory in the RSOF is equipped with a Perkin Elmer Tricarb 4910 liquid scintillation counter (additional machines are in both radioactive waste facilities) and a Packard Cobra II Auto gamma counter. The RSOF maintains bioassay equipment consisting of a single-channel analyzer and a detector for monitoring thyroid uptake of ^{125}I . The department also has a multi-channel analyzer with a sodium iodide detector. These instruments are used for bioassays and the quantification of air samples for the Environmental Protection Agency (EPA) audits as well as for identification of unknown isotopes found during radiation inspections. The RSOF laboratory also houses a chemical hood, survey meters, a multi-channel analyzer (MCA) that was upgraded (2016) to a universal serial bus (USB) version, new software & computer, decontamination supplies and essential analytical and calibration equipment. A Perkin Elmer 2470 automatic gamma counter (Wallac Wizard 2) was acquired.

Radioactive Waste Facilities:

Medical School Waste Facility (DOA990):

This facility has a separate office and a process/storage room for radioactive material and disposal activities. This facility is maintained at negative pressure and has a filtered air exhaust system. It also has a waste compactor, waste shredder, chemical and walk-in hood, survey meters, liquid scintillation counter, air monitoring equipment and emergency response equipment. The liquid scintillation counter was replaced due to water damage in 5/2018.

The storage area contains racks for the proper storage of solid and liquid waste. Waste streams consist of dry solid, bulk liquid and liquid scintillation vials. Dry solid waste and the liquid scintillation vials are packed in standard 55-gallon drums. Liquid waste is stored in five-gallon carboys and placed in spill trays to contain leakage. The floor of the waste facility was repaired for cracks and resurfaced in 2/2016. Radioactive animal carcasses are kept in a designated freezer in the ARC until they are disposed. More than half of the racks, which were not being used, were disassembled in 2017. In addition, old, broken, and unwanted equipment and materials were disposed.

Wolstein Building Waste Facility:

Room 1120, in this facility, is a counting room that also contains a chemical hood. Room 1119 contains a walk-in chemical hood and a liquid process/storage area, and Room 1118 is used for solid process/storage activities. The liquid process/storage area and solid process/storage areas are used for short-term storage only.

Room 1120 has also been developed as a combined chemical and RAM emergency response center. It contains a liquid scintillation counter and computer that provides access to our OnSite web database and safety data sheets in the event of radioactive/ chemical spills.

IODINATION EQUIPMENT

Special hoods, air pumps and activated charcoal-filter exhausts are placed in laboratories that conduct iodinations. Four iodination hoods are in storage. Their locations are as follows:

WRB 1119 - Radiation Waste Facility Storage (1)
DOA 990 – Storage (2)
Bishop S629C – Storage (1)

ANIMAL RESOURCE CENTERS

Conventional animal care facilities are in the following buildings: Robbins, Wearn, Wickenden, Metro Health Hospital, the Small Animal Imaging Research Center (SAIRC), and the Wolstein Research (WRB). These facilities are used by AUs to conduct animal studies with radioactive, chemical, and biological materials. A variety of animals (mice, rats, hamsters, rabbits, groundhogs, ferrets, and large animals such as sheep, dogs, and pigs) are housed in the Robbins building as needed. The Wearn, Wickenden, and Wolstein facilities predominantly house mice and rats. Contaminated items are stored in the ARC freezer in Robbins until disposal. Animals used in studies involving radioactive materials are not housed in the Wolstein facility. Robbins houses one irradiator behind the ultra-barrier that is currently not in use.

EQUIPMENT CALIBRATION

Annual calibration procedures consist of an electronic assessment of survey instruments, plus a measurement of their performance using calibrated isotope reference standards. Survey meters that require dose rate calibrations or repairs are not calibrated by the RSOF. These instruments are sent to an appropriate vendor by the AUs' laboratory. Instruments requiring simple repairs are repaired in-house.

The Packard Cobra II auto gamma counter is in the service building's radiation laboratory. The new Perkin Elmer Tricarb 4910 is in the radiation laboratory. The old LSC was moved to the WRB laboratory, while the WRB LSC was moved to the DOA990 office.

Quality control checks are conducted monthly for the EHS liquid scintillation and gamma counters in the radiation laboratory, DOA 990 and WRB 1119. The continuous air monitor (CAM) in DOA 990 is out of service until further need arises. All iodination air pumps are out of service. Air flow meters are annually calibrated, so calibration of iodination pumps can be done when needed. The LSCs in the radiation safety laboratory, WRB 1120 and in DOA 990 are on service contracts and maintained.

RADIATION SAFETY PROGRAM

RADIOACTIVE MATERIALS RECEIVED & DISPOSED

PURCHASE OF RADIOACTIVE MATERIALS

AUs and their approved designees purchase radioactive material. All radioactive isotope purchases must be approved by the RSOF before the order is processed through purchasing. AUs must be approved for the isotope and the quantity of isotope ordered. The activity, when added to the AUs' existing inventory, cannot exceed the AUs' approved possession limit for that isotope. Replacement shipments, trial kits and free samples also must be approved by the RSOF. All deliveries are sent to shipping and receiving for RSOF inspection and clearance before delivery to the AUs' laboratories.

TRANSFER OF RADIOACTIVE MATERIALS

The RSOF reviews and approves the transfer of all RAM internally (on campus) and externally (off campus) to, or from, an AU. Before initiating a transfer, either the internal or external transfer form must be completed and forwarded to the RSOF for approval. There were 85 isotope transfers approved this year.

ISOTOPE	ORDERS		TRANSFERS	
	#	mCi	#	mCi
¹³⁷ Cs	1	0.0001	0	0
⁶⁴ Cu	1	10	0	0
⁶⁸ Ga	0	0	21	494.51
⁶⁸ Ge	2	0.9206	1	0.09
¹⁴ C	3	0.1001	0	0
¹²⁴ I	8	15.947	0	0
¹³¹ I	1	20	0	0
¹⁷⁷ Lu	4	255	10	140.21
¹⁸ F	2	10	48	384
³ H	2	54.250	1	0.6782
³² P	10	44.264	3	0.666
⁸⁹ Zr	1	3	0	0
³⁵ S	1	2.165	0	0
Total	35	1381	85	1415

RECEIPT OF RADIOACTIVE MATERIALS

Every package of radioactive material is inspected by the RSOF for contamination, dose rates and evidence of damage or breakage. If a package is contaminated or has dose rates greater than 10 mR/hr at one meter or 200 mR/hr at the surface, the package is held by the RSOF, and the laboratory is contacted. An inspection sticker and the RAM package receipt form is placed on the package to confirm that inspection has been completed by the RSOF. The campus mail group delivers packages to most laboratories. Laboratories located across Adelbert Road or Cornell Road use direct pickup. Direct pickup by a laboratory designee alleviates the need to

complete the bill of lading since the package is carried to the laboratory and not transported in a vehicle. The AU or designee is required to survey all radioactive material packages upon receipt for contamination and evidence of damage or breakage.

Radioisotope use, for biomedical research, results in frequent movement of radioactive materials to and from the campus. The broad scope license requires that shipments be surveyed within three hours of arrival. In the past year, 120 isotope shipments were inspected and approved by the RSOF upon receipt on the campus. A few shipments/transfers off campus were also made by laboratories. The RSOF assisted these laboratories by making sure that paperwork was properly prepared and proper labeling was used on the packages.

DISPOSAL OF RADIOACTIVE MATERIALS

Exclusive of decay of isotope in laboratories and minor inventory changes, isotopes were removed from laboratories by either 73 isotope waste pickups by the RSOF staff, or by 5 AU-directed disposals into the sanitary sewers. The following table presents a breakdown by isotope of radioactive materials entering and leaving laboratories.

RADIOACTIVE MATERIALS	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Orders	35	32	43	86	131	137	164	193	241
mCi	1381	97.97	206	335	444	363	383	578	732
Pickups	73	31	53	100	106	44	176	306	250
Sewer Disposals	5	15	14	35	37	21	53	69	50
Transfers	85	53	27	63	110	85	123	77	61
mCi	1415	299.4	220	471	227	641	462	173	814

SEALED SOURCES

CWRU's sealed source inventory contains 75 sealed sources. Of these, 71 sealed sources are required to be inventoried every six months. Four sealed sources require six-month leak tests as stated in our ODH license. This includes 4 gamma sources.

There are three high-dose irradiators and one low-dose irradiator on campus. One low-dose irradiator and one of the high-dose irradiators are not in use. There are two active high-dose irradiators. These irradiators are the only radioactive material sources that could produce significant external dose hazards should their shielding be compromised.

See the APPENDIX for a list of sealed sources on campus. These sources are not included in the general summary reports for radioactive materials. This fiscal year, no source was changed to inventory due to decay, two sources were disposed by Ecology Services, and no new sources were received. The RSOF has actively encouraged AUs to dispose of sealed sources for which there is no anticipated use.

INVENTORY	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Sealed Sources	75	77	78	84	82	86	94	93	93
Exempt	71	73	73	78	76	79	89	88	88
Irradiator	3	3	3	3	3	3	3	3	3
Neutron	0	0	0	0	0	1	1	1	1

IRRADIATORS

Four licensed low-to-high activity radiation sources are possessed for biomedical and other research. These include three high dose irradiators that contain ^{137}Cs sources, and one low ^{60}Co dose irradiator (out of service). Currently, two high dose irradiators are in use and the third is out of service. The ^{60}Co irradiator is now considered low dose. There were 31 irradiator users.

The number of Individual workers authorized to use irradiators are shown in the following table.

IRRADIATOR	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Total Workers	31	22	22	19	20	26	34	30	38
Total Active Irradiators	2	2	2	2	2	2	2	2	2

RADIATION SURVEY METER CALIBRATIONS

CWRU's ODH Broad Scope license requires annual calibration of portable survey meters. Properly calibrated meters are necessary for laboratories to perform accurate radiation surveys. AUs are responsible for the annual calibration, maintenance, and repair of their survey instruments. Count rate calibrations on survey instruments and minor repairs are provided by the RSOF as a free service. The EHS provided in-house services that generated \$11,600 in cost savings over the fiscal year in lieu of using outside vendors.

CALIBRATION/ SERVICE	COST PER SERVICE	COST SAVINGS
58 meters	\$200/meter	\$11,600
12 Rad Eye meters	\$200/meter	\$2,400
1 pump	\$100/pump	\$150
0 thyroid assays	\$100/assay	\$0
4 pre-filter changes	\$100/ set of 4/quarterly	\$400
	TOTAL COST	\$14,550

The RSOF calibrated 70 survey meters in the last fiscal year. There was 1 meter added to service. Certificates of calibration are kept in the RSOF for all meters in service at the University. Records for all meters include instrument efficiencies for isotopes used in laboratories. The DOA pre-filters are on a 90-day change out schedule. EHS no longer changes the pre-filters. Facilities Services does this now. Both fan units for the walk-in hood have not been changed since they do not run unless the walk-in hood is used. The HEPA filters for the walk-in hoods are two double filter units located in DOA radiation area. There are two single filter units for the chemical hood and decay area (located above the DOA office). The fan for the compactor has been repaired. Currently, there are two pre-filters and two HEPA filters that are regularly changed for two units.

The Bioassay Program is Inactive since 2021. There were no pumps calibrated for use in iodination hood and thus no thyroid assays were done. The CAM system is not in service and has not been calibrated.

CALIBRATION/ SERVICE	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Meter Calibration	70	75	81	73	88	95	91	115	112

METERS IN USE	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Hi-Q	1	1	1	1	1	1	2	2	1
Inovision	2	2	0	1	1	1	2	1	1
Ludlum	45	50	52	45	58	63	61	81	87
RPI Mini Monitor	3	4	4	2	4	6	10	13	8
Technical	0	0	1	1	1	1	1	1	1
Victoreen	3	0	4	2	3	2	4	6	4
WB Johnson	5	6	7	6	6	6	7	10	10
Fluke Biomedical	0	0	0	1	1	1	1	1	1
Research Product	1	1	1	2	1	1	1	1	1
Rad Eye	12	12	11	12	12	12	2	2	0

METER CALIBRATION BY MONTH	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
7/2022	10	12	16	10	13	24	12	18	17
8/2022	6	4	17	20	17	12	8	12	10
9/2022	5	25	13	9	15	9	7	8	6
10/2022	26	14	11	10	2	4	5	7	6
11/2022	6	4	3	0	5	4	4	6	1
12/2022	4	2	8	10	5	6	8	8	12
1/2023	1	2	5	1	0	1	0	7	9
2/2023	5	8	5	5	8	0	0	12	15
3/2023	4	2	1	1	1	23	8	10	13
4/2023	1	1	2	2	13	4	17	8	10
5/2023	5	0	1	2	8	7	9	7	12
6/2023	1	1	1	2	1	1	7	12	1

RAM SECURITY

RAM and potentially hazardous chemicals must be secured against unauthorized access or removal when unattended. All refrigerators, freezers or other storage units with RAM labels that are in unsecured areas must either have a security lock to limit access to the refrigerator or freezer or must contain a secured and labeled lock box within the storage unit. Access to isotope inventory must also be controlled when no authorized individual is in the area and constant surveillance cannot be maintained. Security checks by the RSOF are conducted on a monthly basis after normal working hours to ensure that radioactive materials are properly secured. All buildings underwent radiation security inspections each month. Only minor violations of required security procedures were found. Involved AUs were notified, corrective actions recommended, and remediation was monitored at the next inspection.

RAM SECURITY CHECKS	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Violations	6	3	7	2	15	10	10	7	13

PERSONNEL MONITORING

Personal radiation dosimeters are issued through the RSOF to radiation workers and personnel who have the potential to receive a measurable radiation dose while working at the University.

All laboratory workers, visitors to the laboratory, maintenance workers and contractors working in a laboratory are candidates for inclusion in the dosimetry program. Other personnel may request dosimeters, which are provided by the RSOF. Radiation workers who are issued dosimeters must complete the new radiation worker training class and fill out an occupational exposure history form. Dosimeters and area monitors are to be returned promptly at the end of each cycle of use so that the RSOF can take timely action consistent with implementation of ALARA in the event any significant exposure to radiation is detected by the dosimeter. ODH will be notified when exposure limits are exceeded.

The contract for dosimetry was renewed with Landauer, Inc., which provides radiation monitoring services. The date of the contract was extended to 6/2024.

PREGNANT WORKER PROGRAM

Any radiation worker who is, or thinks she may be, pregnant is advised to complete a declaration of pregnancy form found on the EHS website <https://case.edu/ehs/> under the 'radiation safety' link and send it to the RSOF. Counseling is provided and an additional dosimeter is issued to the worker that is read every month. This additional fetal dosimeter is worn to conservatively measure any dose to the developing baby. No women declared pregnancy.

NEUTRON USERS

For experiments and procedures involving the use of neutron sources, personnel monitors sensitive to neutron radiation must be worn. These can be obtained from the RSOF. There were 2 neutron dosimeters used in the Surgical Training and Research Laboratory (STAR) during the fiscal year.

USERS OF RGE/ X-RAY

The RSOF provides special dosimeters for individuals carrying out experiments and procedures involving the use of RGE/X-ray (X-ray), such as fluoroscopy and X-ray diffractometers. The 4 fluoroscopy users had collar badges. We ceased the badging of fluoroscopy observers and chose to use area monitors for the STAR Facility as of 2019.

Although only 20 percent of the workers currently monitored are required to wear dosimeters to comply with the terms of the CWRU's broad scope license or RGE programs, the use of dosimeters is encouraged as it provides an excellent method for early detection of activities that might be dangerous to individual workers.

PERSONNEL MONITORING	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Pregnant Workers	0	1	0	1	1	1	0	0	0
Neutron	2	2	2	2	2	2	2	2	2
RGE/ X-ray	25	25	25	175	76	251	32	25	37
Dental	47	47	51	38	35	41	27	37	28
General	340	342	399	325	284	347	485	460	473

CWRU uses Luxel badges, which are state-of-the-art detection technology for personnel dosimetry. Luxel badges can measure minimum detectable limits of 1.0 mRem. ODH regulations require that all monitored workers be advised annually of their occupational dose exposure. All workers were sent a copy of their prior calendar year's dose report in 2022.

RADIATION GENERATING EQUIPMENT

Machines that produce ionizing radiation (RGE) require safety labeling using appropriate warning indicator systems augmented by testing for radiation leakage during operation. Machines must be always locked, except under operator surveillance, to prevent unintentional exposures. Analytical research units include X-ray diffraction. As of 8/2015, X-ray registration is no longer required for electron microscopes. There are also X-ray units in use for healthcare and diagnostic research. There are currently nine AUs of RGE with equipment in 56 laboratories. RGE is inventoried semi-annually and surveyed annually for leakage. Investigators in charge of RGE, not the RSOF, are required to provide site-specific training programs for workers using this equipment. The EHS provides general safety classes for individuals using RGE.

RADIATION- GENERATING UNITS (Not In Use)	22/ 23	21/ 22	20/ 21	19/ 20	18/ 19	17/ 18	16/ 17	15/ 16	14/ 15
Diagnostic units Disposed	0	0	25	0	0	0	0	2	0
Diagnostic units Purchased	0	0	0	0	0	0	0	1	3

The ODH has changed the radiation generating units' classification. There was 1 unit purchased and 1 unit disposed of for 2022-2023. The table below reflects that change.

RADIATION GENERATING EQUIPMENT (IN USE)	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Closed Beam Analytical	5	5	5	5	6	6	6	6	6
Dental Computer Tomography (CT)	2	2	2	5	5	2	2	2	1
Photoelectron Spectrometer (No longer under ODH)	1	1	1	4	0	0	16	16	10
Fluoroscopy	1	1	1	2	2	2	2	2	3
Hand-held Dental	8	8	8	8	13	4	3	2	3
Hand-held Dental (Inoperable)	1	1	1	1	1	0	1	1	0
Intraoral	55	55	55	73	72	30	30	28	27
Panoral (Only)	1	1	1	1	1	1	1	1	1
Cabinet System exclude admittance	2	2	2	3	3	3	3	3	3
Tube Only (Inoperable)	11	11	11	9	0	0	9	9	12
TOTAL TUBES	87	87	87	112	103	49	71	71	74

RADIOACTIVE MATERIAL RELEASES

SEWER EXPOSURE CONTROL and MONITORING

State and federal regulations permit CWRU to dispose of low levels of RAM into the sanitary sewers. CWRU RSOF requires semiannual reports on RAM that is discharged into the sanitary

sewer system. CWRU's sewer releases were in compliance with both federal and state regulations. The report for July through December 2022 was filed by 12/31/2022 and the report for January through June 2023 was filed by 6/30/2023. Fourteen AUs in storage mode or using only sealed sources were exempt from completing this form. One hundred percent compliance with sewer disposal regulations was achieved for both reporting periods.

AIR EXPOSURE CONTROL & MONITORING

During the 2022 calendar year, RAM released into the air were less than 10 percent of the maximum levels set by the EPA. Therefore, CWRU had no reports to file and the University was in compliance with the air effluent releases stipulated by the EPA Clean Air Act, the NRC and the ODH.

Regarding airborne exposure control, the primary concern is to safeguard against exposure to airborne radioactive iodine that is used for protein iodination experiments. To control exposures, the RSOF requires that reactions involving use of volatile radioactive iodine isotopes be performed in an iodination hood that is housed in a chemical hood. The charcoal-filtered exhaust from the iodination hoods typically reduces radioactive material emissions by approximately 90 percent. Experiments requiring use of large amounts of iodine in especially volatile form are routinely carried out in closed systems to prevent airborne release of radioactive iodine. There were no experiments requiring the use of volatile iodine conducted this fiscal year. This program had been inactive since 2021.

BIOASSAY PROGRAM

Bioassays are required for employees who may receive an internal, measurable radiation dose. Bioassay procedures include, but are not limited to, thyroid screening and urinalysis. The RSOF can perform bioassays for radioactive iodine (thyroid scan) and tritium uptake (urinalysis). Bioassay records are retained in the RSOF and are available for review by the assayed individuals. The Bioassay Program has been inactive since 2021.

RADIOACTIVE IODINE

During 2022-2023, there were no active iodination laboratories. The RSO maintains an inventory of four iodination hoods to be deployed when needed. A bioassay is required when more than one mCi of radioactive iodine is used in volatile form. The RSOF must be notified prior to:

- Handling more than 1.0mCi of volatile radioactive iodine.
- The following must be completed prior to the procedure:
 - Performance of a baseline bioassay for anyone involved in the procedure that does not have a baseline radioactive iodine bioassay on file.
 - Arrangements for monitoring of effluent releases to the atmosphere during the first iodination procedure using a new protocol to measure and mitigate any release to the environment.

After an iodination procedure, individuals involved in the procedure must contact the RSOF and arrange for a bioassay to be completed by the end of the next business day. There were no iodination procedures performed this fiscal year. No workers exceeded 10 percent of the ODH limits.

IODINATION PROCEDURES	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Total	0	0	0	0	1	0	0	0	0

¹²⁵ I BIOASSAYS	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
RSOF Staff	0	0	16	16	16	16	16	16	16
Additional	0	0	0	0	2	0	0	0	0
Total	0	0	16	16	18	16	16	16	16

TRITIUM

Urine bioassays must be carried out for individuals using more than 10mCi of tritium, with a baseline bioassay required prior to experiment. There were no urine bioassays required during this fiscal year.

RADIOACTIVE MATERIALS INCIDENTS

EMERGENCY RESPONSE

Emergency response procedures have been developed and approved by the RSOF and RSC for spills, releases or loss of RAM, small fires, large fires, internalized contamination, and medical emergencies. The goal during any emergency response is to protect people first and property second. The RSO or designee provides instruction, assistance, and supervision of clean up as required. The RSO is authorized to act independently and take prompt remedial action in situations involving RAM that present imminent danger or threat to personnel, property, or the community at large.

INCIDENT/ SPILL RESPONSE

MAJOR INCIDENT/ SPILL

This is a spill that involves personnel contamination or results in contamination outside of the intended work area that cannot be easily and effectively contained and cleaned up.

MINOR INCIDENT/ SPILL

This is a spill that does not involve personnel contamination and that remains inside the intended work area; one that can be easily and effectively contained and cleaned up without assistance from the RSOF. It also includes events that trigger irradiator alarms, most of which are caused by mechanical failures and installation of new high security equipment.

There were two major incidents and twelve minor incidents documented over the past year.

INCIDENTS	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Major	2	0	0	0	0	0	0	0	0
Minor	12	15	19	7	11	20	21	22	30

TOTAL	14	15	19	7	11	20	21	22	30
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DATE	INCIDENT	CONTAMINATION	ROOT CAUSE	FOLLOW UP
6/254/2023	Minor Incident	IRR Comm Loss	RMS system and cameras down	System working. New dispatchers attended Dispatcher Training to make them more familiar with procedures and address questions.
5/3/2023	Minor Incident	IRR Piezo Alarm	Piezo alarm continually going off.	Alarm reset and stopped.
4/26/2023	Major Incident	RAM Package wrong location	3H package delivered by new FedEx to wrong CWRU location.	Complaint submitted to FedEx. RSOF was timely notified of unopened RAM package.
1/12/2023	Minor Incident	IRR Tamper Alarm	Animal cart bumped into equipment.	2 nd time Reviewing proper procedure with staff. Staff member required to complete retraining.
1/11/2023	Minor Incident	IRR Motion Alarm	Took too long entering room	Reviewed proper procedure with staff.
12/6/2022	Minor Incident	IRR Motion Alarm	Took too long entering the room	Reviewed proper procedure with staff.
12/2/2022	Minor Incident	IRR Survey Meter went off	IRR survey meter alarmed.	Survey meter replaced.
11/26/2022	Minor Incident	IRR Comm Loss Alert	Areas in comm loss for 3 days	Made adjustment to the computer system and computer worked as normal.
10/24/2023	Minor Incident	DOA 990 Alarm	Unlocked door before turning of DOA 990 alarm	Reviewed proper procedure. Noted prompt response by Police/Security
10/7/2022	Minor Incident	IRR Tamper Alarm	Security officer was not aware of testing in IRR when the alarm went off and called .	Reviewed proper procedure with dispatch.
9/21/2022	Minor Incident	IRR Comm Loss Alert	IRR alert of comm loss in all areas for 3 days	Security vendor reviewed system. The computer was rebooted and worked as normal.
8/26/2023	Minor Incident	RAM Contamination	14C contaminated jars lids found in RAM fridge during decommissioning.	Deconned and surveyed fridge door shelves and disposed of contaminated lids and cleaning materials.
8/22/2022	Minor Incident	Security Alarm	Forget to turn off DOA 990 alarm before unlocking the door to RAM waste room.	Reminder to disable alarm before unlocking the door.
8/15/2022	Major Incident	RAM Package	RAM package delivered to UH loading dock and stored in locked room for 4 weeks.	Orders using external vendors must utilize the CWRU Peoplesoft process to eliminate these errors. Requisition and PO number are separate for RAM material and non-Ram equipment. RAM packages will not be accepted with incorrect recipient name and/or address.

EHS WEBSITE & NEWSLETTER

The EHS home website (<https://case.edu/ehs/>) provides integrated web-based access to EHS services. Information on training classes, online retraining and safety manuals is available at this site. All information is updated on a regular basis.

The EHS newsletter is filled with articles that are designed to keep the campus community abreast of safety issues and concerns. It covers the latest government regulations, addresses various concerns that are found during laboratory inspections and provides answers to questions frequently asked by laboratory personnel. An articles that was submitted during this year included:

- Correct Process to Order a Radioactive Isotope

LASER SAFETY PROGRAM

There are 253 lasers/laser systems in our database for the campus used by 43 laser PIs in 21 buildings (38 Active, 5 Storage). The lasers of greatest concern are those labeled Class 3B and Class 4. There are 26 3B/4 PIs with a total of 146 Class 3B/4 lasers, as well as 17-3R PIs with a total of 104 lasers in other classes 1, 2, and 3A/3R.. There are 51 class 3B/4 enclosed laser systems that are considered eye-safe (class 1) under normal use that decrease the hazard to the user. Forty-three audits of laser systems were performed during this fiscal year. There were no laser incidents reported this year.

ULTRAVIOLET (UV) SAFETY PROGRAM

As noted by an Occupational Safety and Health Administration (OSHA) director, "OSHA has written two standards that cover employee exposure to radiation: Nonionizing Radiation (29 CFR 1910.97) and Ionizing Radiation (29 CFR 1910.1096). The non-ionizing radiation standard only covers the radio frequency region, including microwaves. The ionizing radiation standard covers alpha, beta, gamma, and X-rays; neutrons; high-speed electrons and protons; and other atomic particles; but does not include sound or radio waves, or visible, infrared, or ultraviolet light. Therefore, there are no OSHA-mandated employee exposure limits for ultraviolet radiation."

CLEARANCES/ RELOCATION PROGRAM

The RSOF requires at least three weeks' notice to decommission laboratories. An orchestrated effort between the RSOF, the safety services division of EHS, facilities services and AUs facilitates these operations. There were 596 pieces of equipment and 27 rooms that were cleared in this reporting period.

WASTE MANAGEMENT

RADIOACTIVE WASTE FACILITY

Our radiation waste facility decay-in-storage licensing with the ODH specifies that we must dispose of any interim generated waste as soon as practical when a waste site is open. The CWRU Radioactive Waste Facility (RWF) is used to segregate waste streams and prepare the waste for disposal. The different waste streams include aqueous waste, sharps, animals, scintillation vials, and dry solid waste.

³²P solid waste is held for decay (for at least 10 half-lives) in the radioactive waste facility. The waste is surveyed and subsequently sent to Medwaste Ohio, a commercial disposal facility for incineration. Currently, only the outside of waste bags is surveyed (with approval from ODH) followed by immediate placement into a burn box. This simplifies handling by staff and provides for compliant and economical disposal of these materials. This procedure has greatly decreased hazard exposures to RSOF personnel handling radioactive waste at CWRU. Reducing the volume of waste to be disposed remains a continuing aim of the waste program. As part of the waste minimization program, isotope users are encouraged to reduce the volume of waste generated in the laboratory by minimizing the use of extraneous paper products. Short-lived, non-sewer (hazardous waste) is held for decay, resurveyed after ten half-lives, and disposed by Chemtron, a commercial hazardous waste disposal company. ³⁵S and ¹²⁵I are no longer held for decay but are shipped along with the long-lived solid waste. Ecology Services, a commercial radioactive materials waste hauler, dispose long-lived solid waste (greater than 60-day half-life) and scintillation vials.

Non-hazardous aqueous waste is no longer held for decay. This waste is picked up from laboratories by the RSOF staff and immediate sewer disposal and is carried out in the radioactive waste facility since the isotope activities are significantly below our established regulatory limits as per OAC 3701:1-38-12 Appendix C. A sewer disposal log is kept in the EHS offices. Total sewer disposals are reported semi-annually to the Northeast Ohio Regional Sewer District (NEORSO).

COLLECTION AND DISPOSAL OF ANIMAL REMAINS AND BIOHAZARDOUS WASTE

The RSOF maintains two -20°C freezers (BRB B05A) for storage of radioactive animal remains and waste. One is located at the ARC and the other in Wolstein 1118. Radioactive wastes are bagged and labeled in yellow bags in the same manner as dry solid waste. All waste placed in the freezer must be logged on the animal disposal sheet on the cold room door. A log sheet of animals disposed in this manner is also kept for inventory purposes by the laboratories generating the waste.

Animal waste is placed in the ARC (BRB B05A) for disposal by the RSOF. Radioactive animal waste includes cage bedding, carcasses, viscera, excrement, serum, blood or other animal tissue containing radioactive materials. All waste is tagged. All animal waste is disposed of by the RSOF.

WASTE GENERATED IN JULY 1, 2022 - JUNE 30, 2023

	GENERATED 7/1/2022 6/30/2023	DISPOSED: MEDWASTE OHIO	DISPOSED: SEWER	DISPOSED: CHEMICAL SAFETY	DISPOSED: Ecology Services	IN STORAGE AS OF 6/30/2022
Short-Lived Dry	1	0	0	0	0	6
Long-Lived Dry	2	0	0	0	2	0
Scintillation Vials	4	0	0	0	4	0
Animals	0	0	0	0	0	0
Long-Lived Sewer	22	0	22	0	0	0
Long-Lived Non-Sewer	0	0	0	0	0	0
Short-Lived Sewer	0	0	0	0	0	0
Short-Lived Non-Sewer	0	0	0	0	0	0

All values in the dry waste, vial and animal categories denote the number of 55-gallon drums. All values for the liquid waste categories are in gallons. The single asterisk (*) demarcates the number of drums generated prior to 7/1/2022, kept for decay in storage and disposed during the period of 7/1/2022-6/30/2023. During this fiscal year, all long-lived hazardous aqueous waste was disposed.

Ecology Services animal waste cost = \$22/lb. for 10-pound barrel = \$220 per 10-pound barrel
Ecology Services dry waste cost = \$470 per 55-gallon drum

The cost of disposal for one box of biomedical waste at Medwaste Ohio is \$25 per container (average of 2 containers per 55-gallon drum). There was 1 drum of decay-in-storage dry waste surveyed and disposed of during 2022-2023. Thus, the indirect savings to researchers due to the decay in storage program was \$470.

WASTE GENERATION	22/23	21/22	20/21	19/20	18/19	17/18	16/17	15/16	14/15
Short-Lived Dry	1	3	5	4	6	18	9	11	10
Long-Lived Dry	2	2	2	6	8	6	5	9	6
Scintillation Vials	4	2	2	6	6	6	12	9	10
Animals	0	0	0	0	0	0	1	0.25	1
Long-Lived Sewer	22	20	35	25	35	28	30	23.75	25
Long-Lived Non-Sewer	0	0	0	1	5	2	2	2	2
Short-Lived Sewer	0	5	10	20	30	25	21	18	20
Short-Lived Non-Sewer	0	0	0	1	1	2	0	4	5

The contract for radioactive waste disposal has been extended to 6/2024 with Ecology Services. This contract provides for disposal of all long-lived dry materials, scintillation vials and animal wastes.

RECYCLING PROGRAM

The RSOF occasionally obtains laboratory equipment in very good condition from AUs who have either left the University or ceased to use RAM. The equipment includes radioactive waste containers (lead and Lucite), shielding (lead and Lucite) and survey meters. This equipment is

offered to the AUs to conserve funds otherwise needed to buy new RAM handling equipment. This cost saving from these recycling efforts resulted in re-use of equipment that saved AUs and EHS more than \$1,000 during 2022-2023.

RADIATION SAFETY COMMITTEE AUDITS

The RSC audits are carried out in two different ways:

- Individual RSC members conduct performance audits on-site at the RSOF at various times throughout the year.
- A compliance inspection of RSOF records is conducted shortly after the end of each fiscal year by a team of RSC Members.

Performance audits of RSOF activities included the following areas:

AREA AUDITED	# OF INDIVIDUAL
FILES EXAMINED	
RAM Applications	10
Isotope Orders/ AU Possession Limits	10
RGE inventory/ training	10
Ancillary staff training	10
AU/ worker training	10
Radiation survey meters	10
Waste disposal facility	2
Shipping papers	10
RAM security checks	10
Bioassays	10
Semi-Annual mailings	10
Sealed sources	10
EHS Radiation Webpage	1
Irradiators	5
Room Surveys (Active/Decommissioned)	10
Compliance Reviews	10
Lasers	10
Licensing	10
Dosimetry	10
Incidents	10

These audits were conducted between October and December 2022 and between March and June 2023. This effort resulted in the review of more than 170 files in the program areas listed above.

RSC TRI-ANNUAL AUDITS FOR 2022-2023

RSC AUDIT COMMENT:

In October 2022, the RSC members conducted a trimester audit of the following components of the RSOF:

Active/Decommissioning Room Surveys
AU/Worker Training
Dosimetry Program
Incident Reports

Irradiator User Training/Irradiators
Laser Program
Licensing Status
Radiation Generating Equipment (RGE) Inventory & Training
Security checks
Sealed Source Leak Tests
Survey Meters
Valid RAM Applications
Waste Disposal Facilities

Each audit consisted of randomly selecting five to twenty files from the past year to ensure its contents were up-to-date, accurate and consistent with the database.

Active/Decommissioning Room Surveys

An audit was performed on October 13th, 2022, to validate active RAM use files and Decommissioned room files to verify that the laboratory was surveyed within the last six months as well as verification for any follow-up on non-compliance issues. Dr. Valadkhan examined ten (10) files and noted to update files that Dr. Jankowski has left the University.

RSOF RESPONSE:

The Jankowsky files were updated to reflect his departure from CWRU.

AU/Worker Training

Authorized users and worker training files were audited for up-to-date training on radiation safety procedures on October 13th, 2022. Dr. Valadkhan reported six workers that were over 90 days past training. She also noted that the SOP was valid only until the end of October 2022.

RSOF RESPONSE:

The 6 workers were notified, and the files were updated. The SOP was also reviewed and updated.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed on October 11th, 2022, to verify that AU laboratory workers were current in dose record and active radiation badges. Dr. Croninger audited the record and identified no deficiencies.

RSOF RESPONSE:

No response required.

Incident Reports

A review of monthly incident reports was performed by Dr. Zhenghong Lee on October 7th, 2022, for verification and documentation of follow-up by the RSOF. During this period there were a total of three (4) incidents reported. The incidents were effectively resolved in a timely manner.

RSOF RESPONSE:

No response required.

Irradiator User Training/Irradiators

An audit of the Irradiator Information Files was performed by Dr. Croniger to verify that the irradiators were audited by the RSOF within the past six months. The audit was performed on October 11th, 2022. Four Irradiators were active on campus and each file was up-to-date and compliant, Dr. Croniger noted no deficiencies. Dr. Croniger also identified six individuals that were overdue for user training. The RSOF was notified of these individuals.

RSOF RESPONSE:

The 6 workers were notified, and the files were updated.

Laser Program

The Laser program was audited by Dr. McCormick for accuracy regarding laser inspections, inventory, and status of personnel training on April 25th, 2022. Dr. McCormick noted 1 deficiency. The Lasers associated with the Flow Cytometry Core needed to be updated to Dr. Grimberg.

RSOF RESPONSE:

The laser equipment custodian was updated to Grimberg.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations on October 14th, 2022. Components of the audit include Broad-scope license, RGE license, Waste license, Radiation Manual, X-ray Manual, Laser Manual, Radiation Training, X-Ray Training, Radiation Online Training, UV online training and RSC guidelines. Dr. Thomas Gerken reviewed all license programs and noted that all licenses were current (no deficiencies).

RSOF RESPONSE:

No response required.

Radiation generating equipment (RGE) inventory and training

Quarterly inventory status and equipment surveys were examined by Dr. McCormick who examined 9 files on October 14th, 2022. Dr. McCormick noted one individual in the dental unit that needed laser training, and two inoperable units reported. The RSOF was alerted to these deficiencies.

RSOF RESPONSE:

The individual was notified to complete Xray training, and the two units were inventoried during the Xray inspection.

Security checks

Verification and documentation of radioisotope security checks were performed on October 27th, 2022. Dr. Duval reported one deficiency in signage in Wood 470/464 during this period.

RSOF RESPONSE:

The AU was notified to submit a signage request to replace the old sign.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited on October 11th, 2022. Ten (10) files were examined by Dr. Fisher who reported no deficiencies.

RSOF RESPONSE:

No response required.

Survey Meters

Compliant calibration of survey meters was audited on October 11th, 2022. Ten (10) files were examined by Dr. Fisher who noted one meter whose calibration date was past due. The RSOF was notified of this calibration need.

RSOF RESPONSE:

The one survey meter was collected and calibrated.

Valid Ram Applications

RAM applications were audited on October 7th, 2022, to verify that the applications were complete and valid. Dr. Lee audited ten (10) files and reported three (3) deficiencies. Files for Drs. Schmaier, Schiemann, and Dowlati were not in the file. The RSOF was notified of these deficiencies.

RSOF RESPONSE:

The files for the three AUs were being reviewed at the time of the audit and were refiled.

Waste Disposal Facilities

The waste disposal facilities (DOA990/Wolstein) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF on October 27th, 2022. Dr. Duval inspected the facilities and reported that all records of maintenance, housekeeping, records and waste storage and handling were all in compliance.

RSOF RESPONSE:

No response required.

In January/February 2023, the RSC members conducted a tri-annual audit of the following components of the RSOF:

- Active/Decommissioning Room Surveys
- Compliance
- Direct Package Pickup
- EHS Webpage
- Dosimetry Program
- Incident Reports
- Isotope Possession Limits
- Licensing Status
- Sealed Sources Leak Tests
- Security Checks
- Semi-Annual Mailings (Air/Sewer Inventory)
- Support Staff Training
- Waste Disposal Facilities

Each audit consisted of randomly selecting five to 20 files from the past year to ensure its contents were up-to-date, accurate and consistent with the database.

Active/Decommissioning Room Surveys

An audit was performed on January 27th, 2023 to validate active RAM use files and Decommissioned room files to verify that the laboratory was surveyed within the last six months as well as verification for any follow-up on non-compliance issues. Dr. Christine Duval examined 10 files and noted 1 deficiency. This was reported to the Radiation Safety office for follow-up.

RSOF RESPONSE:

The misfiled Room file was found and placed in the correct file drawer. Also, the database updated to note that the room was decommissioned.

Compliance

Compliance review audits were performed by Dr. Gerken on January 11th, 2023, to ensure that any non-compliance issues were appropriately resolved. Upon examination of ten (10) files Dr. Gerken noted no deficiencies of outdated compliance.

RSOF RESPONSE:

No response required.

Direct Package Pickup

Isotope orders received within the last 3 months destined for direct pickup were reviewed by Dr. Thomas Gerken on January 11th, 2023. Dr. Gerken audited ten (10) files to ensure that direct pickup was denoted in the files. Dr. Gerken noted one deficiency for pickup from Dr. Stamler's laboratory where no note of pickup was found. The RSOF was notified of this deficiency.

RSOF RESPONSE:

The deficiency was corrected on the Stamler package receipt.

EHS Website

The website for the RSOF was audited to ensure proper operation, access and current links were operational on February 8th, 2023. Dr. McCormick reports all links within the Radiation Website were operational.

RSOF RESPONSE:

No response required.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed on January 10th, 2023 to verify that AU laboratory workers were current in dose record and active radiation badges. Dr. Fisher audited the record and identified no deficiencies.

RSOF RESPONSE:

No response required.

Incident Reports

A review of monthly incident reports was performed by Dr. Saba Valadkhan on January 26th, 2023, for verification and documentation of follow-up by the RSOF. During this period there were 2 incidents reported. No deficiencies were reported by Dr. Valadkhan.

RSOF RESPONSE:

No response required.

Isotope Possession Limits

Dr. Colleen Croniger audited 10 files on January 17th, 2023, to verify that the amount of radioactive material (RAM) ordered was within the possession limits of the AU and that all orders placed were in the Helix Database. Dr. Croniger noted no deficiencies.

RSOF RESPONSE:

No response required.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations on January 27th 2023. Components of the audit include Broad-scope license, RGE license, Waste license, Radiation Manual, X-ray Manual, Laser Manual, Radiation Training, X-Ray Training, Radiation Online Training, UV online training and RSC guidelines. Dr. Christine Duval reviewed all license programs and noted that all licenses were current (no deficiencies).

RSOF RESPONSE:

No response required.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited on January 17th, 2023. Ten (10) files were examined by Dr. Croniger who reported no deficiencies.

RSOF RESPONSE:

No response required.

Security checks

Verification and documentation of radioisotope security checks were performed on January 24th, 2023. Dr. Zhenghong Lee noted no deficiencies.

RSOF RESPONSE:

No response required.

Semi-Annual Mailings (Air/Sewer Inventory)

An audit of the air/sewer disposal inventory was on January 26th, 2023 by Dr. Saba Valadkhan. Ten (10) files were reviewed by Dr. Valadkhan who one deficiency for Dr. Tingwei Mu's laboratory. The RSOF was notified of this deficiency.

RSOF RESPONSE:

The inventory was collected from Tingwei Mu and the database was updated.

Support Staff Training

An audit was conducted to verify the training status of personnel encompassing ancillary segments of the radiation safety program including Animal Resource Center (ARC), Shipping & Receiving, Custodial, Security and Plant Security on January 10th, 2023. Dr. Fisher examined ten (10) files and reported 10 deficiencies in past due training for ancillary staff. The RSOF was notified of these deficiencies for follow-up.

RSOF RESPONSE:

The past-due support staff was contacted and the database was updated.

Waste Disposal Facilities

The waste disposal facilities (DOA990/Wolstein 1118) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF on January 24th, 2023. Dr. Lee inspected the facilities and reported that all records of maintenance, housekeeping, records and waste storage and handling were all in compliance.

RSOF RESPONSE:

No response required.

In April 2023, the RSC members did conduct a tri-annual audit of the RSOF. The Annual audit was performed as scheduled in person on campus with proper PPE and social distancing measures enacted during the process.

AU/Worker Training
Compliance Reviews
Dosimetry Program
EHS Website
Incident Reports
Irradiator Information Review
Laser Program
Licensing Status
RGE inventory and training
Security Checks

Support Staff Training
Survey Meters
Valid RAM Applications
Waste Disposal Facilities

Each audit consisted of randomly selecting 5 to 20 files from the past year to ensure its contents were up-to-date, accurate and consistent with the database.

AU/Worker Training

Authorized users and worker training files were audited for up-to-date training on radiation safety procedures on April 28th, 2023. Dr. Croniger reported one (1) deficiency. Dr. Croniger also noted that the SOP should be updated for this survey to reflect that no retraining paper copies are in the charts, the revised procedure is obtaining a printout of the AU/workers training date, and then checking 10 files for overdue dates and looking for correspondence confirming the worker was contacted.

RSOF RESPONSE:

The worker was contacted and the training was updated in the database. The SOP was revised to clarify the steps to complete the audit process.

Compliance

Compliance review audits were performed by Dr. Saba Valadkhan on April 13th, 2023, to ensure that any non-compliance issues were appropriately resolved. Upon examination of ten (10) files Dr. Valadkhan noted one (1) deficiency of outdated compliance. The RSOF was notified of this deficiency.

RSOF RESPONSE:

The one noted compliance review was completed and the database was updated.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed on April 21st, 2023 to verify that AU laboratory workers were current in dose record and active radiation badges. Dr. Thomas Gerken audited ten (10) records and reported ten (10) users that failed to pick up a badge. These workers were notified and the RSOF was notified.

RSOF RESPONSE:

Most of the workers were promptly notified and came to collect their badge. Two workers were archived.

EHS Website

The website for the RSOF was audited to ensure proper operation, access and current links were operational on April 13th, 2023. Dr. Valadkhan reports all links within the Radiation Website were operational.

RSOF RESPONSE:

No response required.

Incident Reports

A review of monthly incident reports was performed by Dr. Zhenghong Lee on April 5th, 2023 for verification and documentation of follow-up by the RSOF. During this period there were no incidents reported.

RSOF RESPONSE:

No response required.

Irradiator Information Review

An audit of the Irradiator Information Files was performed by Dr. McCormick on April 28th, 2023 to verify that the irradiators were audited by the RSOF in the last quarter. Four Irradiators were active on campus and each file was up-to-date and compliant.

RSOF RESPONSE:

No response required.

Laser Program

The Laser program was audited by Dr. Christine Duval for accuracy regarding laser inspections, inventory, and status of personnel training on April 27th, 2023. Ten (10) files were audited. Five (5) deficiencies in inspection were noted and the RSOF was notified of the responsible PI to contact for follow up on worker training.

RSOF RESPONSE:

The five laser PIs were contacted concerning worker training, which must be updated every two years instead of annually.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations on April 5th, 2022 by Dr. Zhenghong Lee. Components of the audit include Broad-scope license, RGE license, Waste license, Radiation Manual, X-ray Manual, Laser Manual, Radiation

Training, X-Ray Training, Radiation Online Training, UV online training and RSC guidelines. Dr. Lee reviewed all license programs and noted that all licenses were current (no deficiencies).

RSOF RESPONSE:

No response required.

Radiation Generating equipment (RGE) inventory and training

Inventory status and equipment surveys were examined by Dr. Valadkhan on April 13th, 2023 who examined 10 files for RGE status. Dr. Valadkhan noted two (2) workers who were non-compliant for training. The RSOF was informed of these deficiencies.

RSOF RESPONSE:

The two misfiled records were found.

Security checks

Verification and documentation of radioisotope security checks were performed on April 28th, 2023. Dr. McCormick reports no security checks during this period.

RSOF RESPONSE:

No response required.

Support Staff Training

An audit was conducted to verify the training status of personnel encompassing ancillary segments of the radiation safety program including Animal Resource Center (ARC), Shipping & Receiving, Custodial, Security and Plant Security on April 28th, 2023. Dr. McCormick examined ten (10) files and reported 10 deficiencies for overdue training. The RSOF was notified of these deficiencies.

RSOF RESPONSE:

The Support Staff were trained in groups in May 2023 and the database was updated.

Survey Meters

Compliant calibration of survey meters was audited on April 7th, 2023. Ten (10) files were examined by Dr. Gerken who noted two (2) meters whose calibration date was past due or were not in the inventory. The RSOF was notified of these meters.

RSOF RESPONSE:

The two meters were collected for calibration and the database was updated to include them in the inventory.

Valid Ram Applications

RAM applications were audited on April 28th, 2023 to verify that the applications were complete and valid. Dr. Croniger audited ten (10) files and reported two (2) deficiencies. Dr. Croniger noted that all of the deficiencies were related to overdue surveys. The RSOF office was notified of these deficiencies for follow up.

RSOF RESPONSE:

Corrected both reports to reflect the current status in the database.

Waste Disposal Facilities

The waste disposal facilities (DOA990; Wolstein 1118, 1119) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF on April 27th, 2023. Dr. Duval inspected the facilities and reported that all records of maintenance, housekeeping, records and waste storage and handling were all in compliance.

RSOF RESPONSE:

No response required.

Overall, this tri-annual part of the audit process was successful. Records were easily accessed and reviewed. The program was found to be efficient. Productive interaction among committee members and the RSOF staff during the audit process expedites the procedure. All corrections to the files and the Onsite database were made following each trimester audit.

ANNUAL RADIATION SAFETY PROGRAM AUDIT REPORT

The RSC conducted its annual audit of the RSOF in June 2023. The committee reviewed the performance of 20 components of the RSOF. Please note that surveys for October, January/February, April, and the annual audit were performed as scheduled in person on campus. The RSC members are to be commended for their participation and response to the duties of the committee. The areas audited were:

- Ancillary Staff Training
- AU and Worker Training
- Bioassays (Inactive)
- Compliance Review
- Isotope Orders, AU Possession Limits, and the database
- Dosimetry Program
- Incident Reports

- Irradiator Program Review
- Laser Program Review
- Licensing Status
- Radioisotope Security Checks
- Radiation Generating Equipment Inventory and Training
- Radiation Survey Meters
- Room Surveys
- EHS Radiation Webpage
- Sealed Sources
- Direct Pickup & Package Receipt
- Semi-Annual Mailings (air/sewer inventory)
- Valid RAM Application
- Waste Disposal Facilities (DOA990, Wolstein) & RSOF Laboratory

The results of this audit are summarized in this report as follows:

Ancillary Staff Training

An annual audit was conducted to verify the training status of Ancillary users and worker training files for a period from July 1st, 2022 - June 13th, 2023. The audit was conducted to verify the training status of personnel encompassing ancillary segments of the radiation safety program including Animal Resource Center (ARC), Shipping & Receiving, Custodial, Security and Plant Security. Dr. Fisher examined fifty (50) files and noted 50 individuals were overdue for training. The RSOF office contacted those individuals overdue for training.

RSOF RESPONSE:

The overdue workers were notified via email and phone calls to determine if they were still at CWRU. Those that had left were archived in the database, while the others did retrain.

AU and Worker Training

An annual audit was conducted to verify the training status of Authorized users and worker training files for a period from July 1st, 2022 - June 30th, 2023. Dr. Gerken reported twenty-seven (27) workers in three classes were overdue. The RSOF was notified of the overdue training and performed follow-up contact.

RSOF RESPONSE:

The overdue workers were notified via email and phone calls to determine if they were still at CWRU. Those that had left were archived in the database, while the others did retrain.

Bioassays

This program is currently inactive since 7/2021 as there have been use of >10mCi of ³H and/or 1mCi ¹²⁵I in the laboratories.

RSOF RESPONSE:

No response required.

Compliance

Compliance review audits were reviewed for the period July 1st, 2022 - June 30th, 2023 to ensure that any non-compliance issues were appropriately resolved. Upon examination of 50 files, Dr. Croniger noted no files that needed to be reviewed/updated.

RSOF RESPONSE:

No response required.

Direct Package Pickup

An audit was performed to cover the period of July 1st, 2022 - June 30th, 2023 to verify that package receipts were completed with each transfer of material from site to site. Dr. McCormick audited 3 files and identified no deficiencies.

RSOF RESPONSE:

No response required.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed to verify that AU laboratory workers were current in dose record and active radiation badges for the period July 1st, 2022 - June 30th, 2023. Dr. McCormick audited 50 records and reported 18 missing files, with 5 for laser only. The RSOF was informed of these deficiencies.

RSOF RESPONSE:

No radiation badge was required for the 18 workers; therefore, no dose history was needed in these files.

EHS Webpage

Dr. Duval inspected the operation of the EHS web pages for the radiation safety section on June 21st, 2023. Dr. Duval examined all the radiation safety web sites within the web pages and associated links and reported no deficiencies.

RSOF RESPONSE:

No response required.

Incident Reports

A review of yearly incident reports for the period July 1st, 2022 - June 30th, 2023 was performed by Dr. Christine Duval for verification and documentation of follow-up by the RSOF. During this period there were 15 incidents reported. Dr. Duval reports that all incidents were resolved satisfactorily.

RSOF RESPONSE:

No response required.

Irradiator Information Review

An audit of the Irradiator Information Files was performed by Dr. Valadkhan to verify that the irradiators were audited by the RSOF from July 1st, 2022-June 30th, 2023. Four Irradiators were active on campus and each file was up-to-date and compliant.

RSOF RESPONSE:

No response required.

Isotope Orders, AU possession limits and the Database

Dr. McCormick audited eighteen (18) files to verify that the amount of radioactive material (RAM) ordered was within the possession limits of the AU and that all orders placed were in the Database covering the period July 1st 2022 - June 22nd, 2023. Dr. McCormick noted one file missing for Dr. Monreal. The RSOF was notified of this missing file.

RSOF RESPONSE:

As a new Authorized User, a file was created for Monreal, and the AU was notified to update information for ordering privileges.

Laser Program

The Laser program was audited by Dr. Saba Valadkhan for accuracy regarding laser inspections, inventory, and status of personnel training in the period July 1st, 2022- June 30th, 2023. Dr. Valadkhan audited 47 folders, any deficiencies were noted and the RSOF was notified of the responsible PI to contact.

RSOF RESPONSE:

Several laser inspections that were past due were completed within the month and filed promptly. Notifications were also sent to workers for training and the database was updated.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations during the period July 1st, 2022-June 30th, 2023. Components of the audit include Broad-scope license, RGE license, Waste license, Radiation Manual, X-ray Manual, Laser Manual, Radiation Training, X-Ray Training, Radiation Online Training, UV online training and RSC guidelines were reviewed by Dr. Duval, and all license programs and licenses were current.

RSOF RESPONSE:

No response required.

Radiation generating equipment (RGE) inventory and training

Quarterly inventory status and equipment surveys were examined by Dr. Valadkhan who examined 29 files for the period July 1st, 2022 - June 22nd, 2023. Dr. Valadkhan noted no non-compliant devices.

RSOF RESPONSE:

No response required.

Room Surveys

An audit was performed to validate active RAM use files and Decommissioned room files for the period July 1st, 2022 - June 2nd, 2023 to verify that the laboratory was surveyed within the last six months as well as verification for any follow-up on non-compliance issues. Dr. Croniger examined thirty-six (36) files and noted seventeen (17) rooms that had been de-commissioned.

RSOF RESPONSE:

No response required.

Radioisotope security checks

Verification and documentation of radioisotope security checks were performed for the period July 1st, 2022 - June 30th, 2023. Dr. Lee audited the security checks and noted that all security checks were in order.

RSOF RESPONSE:

No response required.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited for the period of July 1st, 2022 - June 30th, 2023. Fifty (50) files were examined by Dr. Gerken who reported multiple out of date, or overdue tests. The RSOF was notified of these deficiencies.

RSOF RESPONSE:

The overdue sealed sources were inventoried and/or leak-tested and the database was updated. Also, misfiled reports were corrected and organized.

Semi-Annual Mailings (Air/Sewer Inventory)

An annual audit of the air/sewer disposal inventory was performed for the period July 1st, 2022 - June 30th, 2023. Thirty-five (35) files were reviewed by Dr. Gerken who noted no deficiencies in Active PIs or inactive PIs.

RSOF RESPONSE:

No response required.

Survey Meters

Compliant calibration of survey meters was audited for the period July 1st, 2022 - June 22nd, 2023. Thirty-six (36) files were examined by Dr. Croniger who noted eight (8) meters were overdue for calibration. The RSOF was informed of the status of these meters.

RSOF RESPONSE:

Of the 8 overdue meters, 4 were inactive, and 4 were sent notifications and the database was updated to reflect current status.

Valid Ram Applications

RAM applications were audited for the period July 1st, 2022 - June 30th, 2023 to verify that the applications were complete and valid. Dr. Lee audited twenty-six (26) files and reported no deficiencies.

RSOF RESPONSE:

No response required.

Waste Disposal Facilities

The waste disposal facilities (DOA990, Wolstein 1118, 1119) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF for the period July 1st, 2022-June 30th, 2023. Dr. Zhenghong Lee inspected the facilities for Wolstein and the

RSOF laboratory and reported all other records of maintenance, housekeeping, records and waste storage and handling were in compliance.

RSOF RESPONSE:

No response required.

SUMMARY

No major problems exist in the RSOF program and the RSOF staff is functioning on a very competent level.

RSOF RESPONSE:

The RSOF thanks the RSC for its careful audit of safety activities over the past year. Deficiencies uncovered during the audit were referred to the RSOF auditor for increased scrutiny during the coming year.

EHS INTERNAL AUDITS

Three layers of audits are utilized by the RSOF on an ongoing basis to ensure that the radiation safety programs and procedures are working smoothly. In addition to audits conducted by the RSOF Staff and RSC, the assistant RSO conducts quality control reviews of all programs and records and assists with resolution. Full audit results of the program are available in the EHS office.

Sealed Source	RAM Security Checks	Bioassays
Shipping Papers	Semi-Annual Mailings	Dosimetry
Valid RAM Applications	RGE Inventory/ Training	Survey Meters
Isotope Orders/ AU Possession Limits	Ancillary Training	Compliances
AU/ Worker Training	Licensing	EHS Radiation Webpage
Waste Disposal Facility	Incidents	Laser Program
Active/Decommissioned Room Surveys	Irradiator	

Corrections to the files were made promptly. In response to internal audit findings, radiation safety continues to improve its procedures and programs.

This report was prepared by Felice T. Porter on 10/11/2023. It covers fiscal years 7/1/2022-6/30/2023.

APPENDIX

AUTHORIZED USERS WITH STATUS CHANGE DURING FISCAL 2022-2023

RADIATION ACTIVE

Benjamin Monreal (7/20/2022) Joseph Luna (12/7/2022)

STORAGE MODE

None

RADIATION INACTIVE

Michael Martens (8/29/2022) Cathleen Carlin (8/29/2022) William Merrick (9/19/2022) Jonathan Karn (12/13/2022)

DEPARTED

Chris Dealwis (8/5/2022) Donny Licatalosi (9/16/2022) Eckhard Jankowsky (12/20/2022)

X-RAY AUTHORIZED POSSESSOR LIST

<u>AP NAME</u>	<u>CONTACT PERSON</u>	<u>UNITS</u>
Corbin Covault	Corbin Covault	1
Syed Ali	Susan Opsitnick	61
Zhenghong Lee	Chris Flask	3
Suparna Mahalaha	Aeysha Kisner	4
Jeffrey Pigott	Jeffrey Pigott	5
Anna Samia	Anna Samia	1
Steve Schomisch	Steve Schomisch	1
Lei Zhu	Lei Zhu	2
Andrew Shoffstall	Andrew Shoffstall	1

LASER USERS

Ozan Akkus (1)	Eric Baer (3)	Harihara Baskaran (2)	James Basilion (2)
Jesse Berezovsky (14)	Walter Boron (2)	Clemens Burda (3)	Carlos Crespo (6)
Alan Diehl (2)	Mohammed Draz (1)	Diana Driscoll (16)	Dominique Durand (2)
Steven Eppell (10)	Roger French (3)	Robert Gao (3)	Jeffrey Garvin (1)
Stanton Gerson (1)	Brian Grimberg (10)	Alex Huang (2)	Hatsuo Ishida (5)
Michael Jenkins (15)	Jonathan Karn (1)	Kathleen Kash (17)	Chirag Kharangate (8)
Lydia Kisley (10)	Michael Martens (14)	Thomas McCormick (1)	James McGuffin Cawley (5)
Claudia Mizutani (2)	Michael Moffitt (3)	Svetlana Morozova (8)	Andre Paes (2)
Valentin Rodionov (1)	Andrew Rollins (8)	RSOF (1)	Britton Sauerbrei (1)
Daniel Scherson (17)	Bryan Schmidt (6)	Alp Sehirlioglu (6)	Andrew Shoffstall (2)
Scott Sieg (3)	Kenneth D. Singer (18)	Jonathan Stamler (1)	Giuseppe Strangi (13)
Carlos Subauste (1)	Gary Wnek (2)	Gabriella Wolff (1)	Peter Zimmerman (1)
Christian Zorman (5)			

Heidi Martin (Storage) (1) Ben Strowbridge (Storage) (1)

Jeffrey Capadona (Inactive)	Hillel Chiel (Inactive)	Agata Exner (Inactive)	Minh Lam (Inactive)
Michael Martens (Inactive)	Edward Medof (Inactive)	Benjamin Monreal (Inactive)	Paul Park (Inactive)
John Protasiewicz (Inactive)	Rajesh Ramachandran (Inactive)	Charles Rosenblatt (16)	Anirban SenGupta (Inactive)
Lei Zhu (Inactive)			

Eckhard Jankowsky (Departed)