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

PURPOSE FOR RAM USE

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

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.

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.

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)

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

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.

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

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. Thi

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 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 ¹²⁵I. 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.

proper The storage area contains racks for the 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.

<u>IODINATION EQUIPMENT</u>

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.

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

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

IRRADIATORS

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

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

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 RGEX-ray (X-ray), such as fluoroscopy and X-ray diffractometers. The 4

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

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	İ
Closed Beam Analytical	5	5	5	5	6	6	6	6	6	Ì
Dental Computer Tomography (CT)	2	2	2	5	5	2	2	2	1	Ì
Photoelectron Spectrometer (No longer	1	1	1	4	0	0	16		466	302.4

under ODH)

.48001

sewer system. CWRU's sewer releases were in compliance with both federal and state

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

125_|

TOTAL	14	15	19	7	11	20	21	22	30

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 (NEORSD).

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 Limi	ts 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 Webp ar.0DI	2

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.

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.

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.

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.

<u>Irradiator Information Review</u>

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:

RSOF RESPONSE:

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.

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 Pls or inactive Pls.

RSOF RESPONSE:

No response required.

Survey Meters

Compliant calibration of survey meters was audited for the period July 1st, 2022 - June 22nd,

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 Shipping Papers Valid RAM Applications RAM Security Checks Semi-Annual Mailings RGE Inv

Bioassays Dosimetry

APPENDIX