CASE WESTERN RESERVE UNIVERSITY DEPARTMENT OF ENVIRONMENTAL HEALTH & SAFETY RADIATION SAFETY ANNUAL REPORT 2018-2019

W. David Sedwick, Director/ RSO Felice T. Porter, Assistant Director/Assistant RSO

TABLE OF CONTENTS

INTRODUCTION	3
SUMMARY	3
RADIATION SAFETY ACCOMPLISHMENTS FOR 2018-2019	3
RADIATION SAFETY GOALS FOR 2019-2020	3
OHIO DEPARTMENT OF HEALTH LICENSE	4
RADIATION SAFETY PROGRAM-RESPONSIBLE PARTIES	6
ADMINISTRATIVE CONTROLS	10
RADIATION SAFETY OFFICE	12
RADIATION SAFETY PROGRAM	17
RADIATION SAFETY COMMITTEE AUDITS	29
APPENDIX	· 47
Authorized User Inventory List	1
Sealed Sources	11
X-Ray Devices	111
• Lasers	IV
Organizational Chart	· · · · · · · · · · · · · · · · · · ·

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 (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 7/1/2018 – 6/30/2019.

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. 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 2018-2019

Over the past year, the Radiation Safety division of EHS continued to improve the effectiveness of the Radiation Safety program. Notable new accomplishments included:

- The 63rd Health Physics Society Annual Meeting met in Cleveland this summer from July 15 to July 20, 2018. The main sessions were held downtown at the Huntington Convention Center, but a number of our surrounding institutions played key roles as seminar hosts and as education centers for particular program subjects. Specifically, personnel from CWRU and University Hospitals (UH) assisted in coordinating meetings or served as lecturers. EHS staff members attended the national meeting, acquainted themselves with new instrumentation useful to CWRU's Radiation Safety Program and attended a variety of informative seminars. Some of our staff members were directly involved in organizing the venue for some of the major seminars.
- Implemented Waste facility clean out of old sources, shielding and broken equipment and reorganization of the waste Facility.
- Successfully switched online training systems from Blackboard to Canvas
- Seamlessly changed website interface from Blackboard to Canvas
- Generated in-house savings accrued from meter calibration, recycling and decay-in-storage programs amounting to more than \$19,030 in 2018-2019 through its services to the research community at CWRU.

RADIATION SAFETY GOALS FOR 2019-2020

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 on the surrounding community through educational and programmatic interaction with local partners and emergency responders. Specific efforts currently address:

- Dosimetry: reduce quantity of unreturned badges
- X-ray program: maintain new survey/inventory schedule and make sure that all old units are properly disposed or transferred.
- Waste program: visit waste disposal sites which were not visited during the bid process;
- Training: incorporate more safety related and day-to-day regulations from experience-based knowledge to augment theoretical information
- Laser program: train backup specialist to conduct laser audits and laser training; update laser safety manual to new laser signage
- Sealed Source program: continue to spread cost for sealed source disposal for several years
- Packages: establish a better relationship with purchasing
- Irradiators: reduce the number of alarms caused by User operational errors.
- Clearances: facilitate average of one clearance per day
- Meter calibrations: Attend class on how to calibrate Rad Eye meters for dose and efficiency
- Develop necessary radiation safety and radiation generating equipment (RGE) programs and evaluate their impact for the dental school in its new location/campus
- Meet with Cleveland Clinic radioactive materials (RAM) program leaders to examine new joint program interfaces that may arise in the new medical school.
- Jointly consider including a Cleveland Clinic program representative on the CWRU Radiation Safety Committee to coincide with opening of new Facilities at Cleveland Clinic location.
- Ensure that all Radiation Safety programs and procedures are ready for ODH inspection that is inspected in the Fall of 2019.
- Complete an update of Radiation License renewal edits.
- Examine and evaluate status of joint program relationships with University Hospitals (UH) radiation safety
 with special emphasis on dual user relationships and responsibilities. Arrange meetings with UH radiation
 safety personnel to review these issues.

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 radioactive material (RAM) and naturally occurring RAM for experimental purposes. It also allows for the licensed use of four irradiators. A Broad Scope license site visit was last conducted by ODH on 5/22/2017.

The University has two ODH RGE registrations. The registration covers the receipt, possession, use, storage and disposal of radiation generating equipment including dental X-ray machines, X-ray diffraction units, and fluoroscopy units. The last ODH RGE (X-ray) inspection was conducted on 8/8/2017.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2020	Broad Scope License
09-M-06944-12	May 31, 2020	Radiation-Generating
,		Equipment Registration (All)
06-E-06944-020	May 31, 2020	Radiation-Generating
		Equipment Registration
		(Mobile Units)

DECOMMISSIONING FUNDING PLAN

The Broad Scope license and the decommissioning funding plan became effective 2/25/2010. The University was required to maintain a standby letter of credit to cover possible costs if the University's Broad Scope license is required to undergo rapid decommissioning. The expiration date for the standby letter of credit was 2/28/2016. Funds required for this letter of credit

depended on the kind and amounts of RAM maintained in active use or waste by the University. Experimental procedures now use more sensitive methods that increasingly require less RAM. The University now operates under an agreement with ODH that requires no letter of credit but is dependent on the University 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 is located at the following facilities:

- Main campus of Case Western Reserve University, 10900 Euclid Avenue, Cleveland, Ohio
- · University Hospitals (UH), 2065 Adelbert Road, Cleveland, Ohio
- · Wolstein Research Building (WRB), 2103 Cornell Road, Cleveland, Ohio
- Health Education Campus (HEC) Dental Clinic, 9601 Chester Ave., Cleveland, OH 44106
- Health Education Campus (HEC) Main Bldg, 9501 Euclid Ave., Cleveland, OH 44106

RAM is received and/or stored at the following sites:

- · Shipping and receiving, 2232 Circle Drive, Cleveland, Ohio
- Wolstein Research Building, 2103 Cornell Road, Cleveland, Ohio
- Health Education Campus (HEC) Dental Clinic, 9601 Chester Ave., Cleveland, OH 44106
- Health Education Campus (HEC) Main Bldg, 9501 Euclid Ave., Cleveland, OH 44106

PURPOSE FOR RAM USE

The majority of isotope used at the University is for biomedical research. The most typical isotopes used are ¹⁴C, ³H, 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.

RADIATION SAFETY PROGRAM - RESPONSIBLE PARTIES

RADIATION SAFETY COMMITTEE

The RSC sets policy for the use of RAM for the University Committee. Members of this Committee are appointed by the president of the University and have responsibility for monitoring and enforcing compliance with the University's Radiation Safety Program as outlined in the University's Ohio Department of Health (ODH) Broad Scope license. Radiation Safety Committee members are chosen from diverse disciplines to provide comprehensive expertise. The Committee reviews all applications for use of RAM.

The 2018-2019 Radiation Safety Committee 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	Dr. W. David Sedwick
Dept. of Dermatology	Radiation Safety Officer (RSO)
BRB 530	Dept. of Medicine
LC - 4926	EHS - Service Building,
Term Expires: 10/15/2020	First Floor
Chairperson Term Expires:	LC = 7227
10/15/2020	Term Expires: 10/15/2020
Dr. Colleen Croniger	Dr. Eckhard Jankowsky
Dept. of Nutrition	Dept. of RNA Center
BRB 925	HG Wood 137
LC - 4954	LC - 4973
Term Expires: 10/1/2022	Term Expires: 10/1/2022
Dr. William Schiemann	Dr. Saba Valadkhan
Dept. of Comprehensive Cancer Ctr	Dept. of Molecular & Microbiology
WRB 2131	HG Wood 210A
LC - 7284	LC - 4960
Term Expires: 10/15/2020	Term Expires: 10/1/2022
Dr. Tomoaki Ogino	Dr. Donny Licatalosi
Dept. of Molecular & Microbiology	Dept. of RNA Center
HG Wood 207F	HG Wood 106
LC - 4960	LC - 4973
Term Expires: 10/17/2021	Term Expires: 10/17/2021
Dr. Suhrim Fisher	
Animal Resource Center	
BRB RB5P	
LC - 4925	
Term Expires: 10/15/2020	

EX-OFFICIO MEMBERS

Richard Jamieson	Felice T. Porter
Vice President	EHS Asst. Dir./Asst. RSO
Dept. of Campus Services	Quality Assurance Specialist
Administration	Service Bldg.,
Adelbert Hall 229	First Floor
LC - 7173	LC - 7227
Bruce DeMeza	R. Michael Sramkoski
University Hospitals Asst. RSO	Senior Research Associate &
Bishop S621	Laser Specialist
LC - BSH 5056	Comprehensive Cancer Ctr
	WRB 3405
	LC - 7285

Joseph Nikstenas EHS Laser Safety Officer & Safety Specialist Service Bldg. First Floor LC - 7227

Marc Rubin
EHS Senior Director
Service Bldg.
First Floor
LC - 7227

SUPPORT STAFF

The Radiation Safety Committee acts as an advisory and enforcement body to ensure that all RAM are 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:

- 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 Committee met on 10 occasions during the 2018-2019 fiscal years to review applications for radioisotope use and action on other business. Two RSC meetings were cancelled 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.

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

Major topics acted upon or discussed by the RSC:

- RSC Quoram Meeting to approve with conditions 2 applications: one New and one Updated. (7/2018)
- New Perkin Elmer Liquid Scintillation Counter (LSC) installed in the Radiation Safety Laboratory as a replacement for the old LSC that had sustained water damage in DOA office. (9/2018)
- The Annual Health Physics Society (HPS) Conference was held in Cleveland, OH from 7/15-20/2018 with more than 950 registrants from all over the world. The EHS Radiation Staff along with the local chapter was

involved in every aspect of preparation, proctoring, and logistics for the seminars and training sessions. Several CWRU and EHS facilities were used for training. EHS Staff also attended several sessions and classes. (9/2018)

- Old stored radioactive waste was disposed including Unused exit signs from the Maltz Center and other decayed sealed sources. (9/2018)
- Renewal of RAM applications are required every 5 years. Several have updated RAM applications for approval by the RSC. (9/2018)
- Richard Jamieson, Senior Administration, reported a new academic school year with 1400 students in the
 Freshman year. HEC and Dental Clinic planning continues. Transportation shuttles, bikes, and walking
 paths will be used. The CWRU Maltz Performing Arts Center Plan is going well. UH may buy back half of
 WRB by department. Some departments will be relocated back to BRB. Dental/Nursing research
 departments may be relocated to Wood. The Dental/Nursing buildings will not be demolished. (9/2018)
- Thomas McCormick, RSC Chairman, thanked the members for their continued commitment in completing the Quarterly/Annual Audits. (9/2018)
- Felice Porter, ARSO, introduced EHS Radiation Safety Department Assistant, Naomi Boles. (10/2018)
- W. David Sedwick (RSO), and Felice Porter (ARSO) presented the Annual Report to the RSC and thanked the Radiation Safety staff and Committee members for their commitment. The RSO explained the importance of the RSC audits and the annual report. The RSC Annual report is sent to the CWRU President and is reviewed by ODH as part of inspection. The ODH Inspection was completed, license was reviewed and the follow-up done. There have been no major accidents and fewer alarms. (10/2018)
- During clearances, radioactive equipment, lasers, and x-ray units must be cleared before relocation or departure. (10/2018)
- There were two incidents of radiation materials order by department credit cards. The CWRU Radiation License requires that these sources be approved through our purchasing process. Both departments and researchers were contacted and instructed in the correct procedure for future radioactive materials purchases. (10/2018)
- The Quarterly Irradiator Checks were completed with no concerns. (10/2018)
- A researcher requested that a Radon Test be done for the Rockefeller Sub-Basement. The results are filed in RSOF and were less than 25% of the trigger level. (10/2018)
- The request for a new Gamma Counter was approved. (10/2018)
- Laser Summary was provided by Joseph Nikstenas. (11/2018)
- Felice Porter attended the University Hospital Radiation Safety Committee quarterly meeting. ODH have inspected their outlying hospitals and facilities. The main campus hospital will be inspected during December 2018. (11.2018)
- The RSC completed the Quarterly audits in October 2018. (11.2018)
- There have been no high badge readings for the year and only one fetal badge declaration. (10/2018)
- The RSC Annual Report is completed and has been sent to the CWRU President. (11/2018)
- Richard Jamieson, Senior Administration, stated that security measures are being reviewed due to shooting of a CWRU student. (11/2018)
- Completed quarterly Human Resources review of Irradiator information. (1/2019)
- HEC & Dental Clinic activation meeting are in progress. (1/2019)
- RSOF has requested a list of new equipment for the Dental School before the move to the new HEC Dental Clinic. (1/2019)
- Laser Safety Officer will follow-up on the new laser laboratory that needs to utilized curtains as barriers.
 (2/2019)
- Two Radiation Staff attended the Health Physics Society Conference in San Diego, CA. (2/2019)
- There is a new freezer in the Animal Resource Center with a lock to hold radioactive carcasses. (2/2019)
- The RSC completed the Quarterly audits in February 2019. (2/2019)
- Introduced new EHS Staff members to RSC: Naomi Boles, Gayle Starling Melvin, Debra Nunn, Kaden Wortman, and Lawrence Bo Wyszynski. (4/2019)Laser Officer followed up on new laser laboratory and found the room to be curtained adequately. 'Laser in Use' sign was functional. (4/2019)
- New Pulser machine for calibration was received along with the new Gamma Counter for the Radiation Safety Laboratory. (4/2019)
- We contacted ODH for an inspector review of an analytical x-ray unit that was received from a Dental practice. The researcher will not be authorized to use this equipment until we are sure of state-approved safety procedure for use. (4/2019)
- The RSO sent correspondence to the Facilities Director and Assistant Director concerning two Facilities
 workers that documented information on Ancillary Radiation training logs that would be interpreted as
 inappropriate disrespect of authority. Response was requested and received as documentation of our
 follow-up of this incident for authorities. (4/2019)

- Old Dental School has begun the move to the new HEC Dental Clinic. (4/2019)
- Analytical X-Ray unit in Engineering laboratory has been inspected by the ODH inspector for classification. (6/2019)
- HEC Dental Clinic is moved in but is not open for patients. (6/2019)
- Irradiator security equipment upgrade went well. (6/2019)
- Radiation Staff member, Yelena Neyman, celebrated her 25th anniversary at CWRU. (6/2019)

SENIOR MANAGEMENT

The Radiation Safety Program monitors, inspects and audits RGE and source 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 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 Radiation Safety Programs. In the absence of Richard Jamieson, Marc Rubin, EHS Senior Director provides administrative representation.

RSOF AND AUTHORIZED USERS (AUs)

The AU and 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 AUs' 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 Radiation Safety Office

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, 17 were the result of unsecured RAM found during after-hours security checks and routine compliance reviews. Two laboratories were assessed a moderate violation that had three or more minor violations during three compliance reviews by Radiation Safety during routine audits. Documented follow up and resolutions were completed for all major & moderate violations.

VIOLATIONS	18/19	17/18	16/17	15/16	14/15
Minor	38	43	70	78	81
Moderate	17	13	11	10	13
Major	0	0	0	0	0
Total	55	56	81	88	94

The assistant RSO, the RSOF staff and the RSO have updated and revised most of the department manuals, training, licenses, certificates and standard operating procedures in 2018-2019.

AU CATEGORIES:

RADIATION ACTIVE

AUs who actively use RAM are "radiation active" (RA). 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

These AUs do not currently use or possess RAM.

RADIATION ACTIVE STORAGE MODE

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	18/	17/	16/	15/	14/
	19	18	17	16	15
RA	47	49	50	54	62
SM	18	20	15	20	8
RI	2	7	5	5	3
D	3	5	5	2	6
Total in Program	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)

Specialist Positions (4)

Asst. Director/Asst. RSO/Quality Assurance Specialist (1)

Department Assistant (1) Student (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 2018-2019 included radiological instrument training, RCRA selected hazardous waste training, 8-hour HAZWOPER refresher training and hazardous materials transportation security awareness.

EHS staff are responsible for maintaining the EHS website that houses all online departmental training programs and schedules, safety manuals, safety newsletters, material 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 (does@case.edu 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 may 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. 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 that are trained include:

ΑU

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 and radiation safety, 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.

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 trainings. 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	18/19	17/18	16/17	15/16	14/15
Radiation	143	133	118	61	92
Online	398	342	349	563	615
Retraining					
X-ray	32	22	43	58	50
Ancillary	1561	710	741	619	279
Laser	66	59	40	46	41
Laser Online	40	68	22	67	27

Over 2,240 laboratory workers were trained through the Radiation Safety Program in 2018-2019, which is a high point over the last 5 years. This increase reflects an effort on the part of the RSOF to provide full training instead of ancillary training to all workers in 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	Biomedical Research
Bishop	Bolwell	DeGrace
Old Dental	Glennan	HG Wood
Lerner Tower	Kent Hale Smith	Med East/Robbins
Millis	Olin	Pathology
RBC	Rockefeller	Service
Wearn	West Quad (CCSB)	White
Wickenden	Wolstein Research	Wood Research Tower
HEC Main	HEC Dental	

LABORATORIES

There are 254 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	92
X-ray	58
Laser	104

Radiation Safety Office (RSOF)

Facilities and equipment used by the RSOF to support laboratory inspection or isotope storage are located 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 located 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 located 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 Environmental Protective 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, an MCA that was upgraded (2016) to a USB version, new software & computer, decontamination supplies and essential analytical and calibration equipment. Perkin Elmer 2470 automatic gamma counter (Wallac Wizard 2) acquired and in process of getting set up.

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. Also, 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 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. This area maintains negative pressure relative to surrounding building spaces.

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

<u>IODINATION</u> EQUIPMENT

Special hoods, air pumps and activated charcoal-filter exhausts are placed in laboratories that conduct iodinations. Four iodination hoods are in storage. In 2014, one iodination hood was loaned to an associate facility and in 2016, the hood was donated to the Scripps Research Institute. Their locations are as follows:

WRB 1119 - Radiation Waste Facility Storage (1) DOA 990 - Storage (3)

ANIMAL RESOURCE CENTER

Conventional animal care facilities are located in the Robbins Building, Wearn Building, MetroHealth Hospital, the Small Animal Imaging Research Center and the Wolstein Research Building. 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 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. A major renovation was completed in the Robbins during 2009 which included the addition of an ultra-barrier facility. One irradiator behind the ultra-barrier 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 Auto Gamma 5000 counter in the Service Building's radiation laboratory was replaced by a Packard Cobra II auto gamma counter in 2016. Due to a water leaking from the DOA990 ceiling, the LSC in DOA990 office sustained water damage and was replaced through the University insurance claim. The new Perkin Elmer Tricarb 4910 replaced the Packard 2100TR Liquid Scintillation Counter in 5/2018. The old LSC in the Radiation laboratory was moved to the WRB laboratory, while the WRB LSC was moved to DOA990 Office. The gamma counter calibrations are conducted monthly for the EHS radiation laboratory and as needed for the Liquid Scintillation Counters in the radiation laboratory, DOA 990 and WRB 1119. The continuous air monitor (CAM) and the connected air pump in DOA 990 are out of service and calibration is on hold. The LSCs in the radiation laboratory, WRB 1119 and in DOA 990 were serviced and cleaned.

RADIATION SAFETY PROGRAM

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 the 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 110 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 than 10 mR/hr at 1 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, 131 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 106 isotope waste pickups by the RSOF staff or by 37 AU-directed disposals into the sanitary sewers. The following table presents a breakdown by isotope of radioactive materials entering and leaving laboratories.

ISOTOPE	ORDERS		TRANSFERS	
	#	mCi	#	mCi
¹³³ Ba	1	0.001	0	0
¹¹ C	0	0	10	121.6
¹⁴ C	2	1.05	0	0
¹⁰⁹ Cd	1	0.001	0	0
⁵⁷ Co	2	0.002	0	0
⁶⁰ Co	1	0.001	0	0
¹³⁷ Cs	2	0.029	0	0
⁶⁴ Cu	0	0	0	0
¹⁸ F	0	0	31	168.93
⁶⁸ Ga	0	0	24	105.06
⁶⁸ Ge	0	0	0	0
³H	4	3.25	0	0
125	3	2.153	5	0.44
⁵⁴ Mn	1 _	0.001	0	0
²² Na	2	0.011	0	0
³² P	107	413.63	0	0
³³ P	1	0.34	0	0
²¹⁰ Po	0	0	0	0
³⁵ S	4	23.28	0	0
⁶⁵ Zn	1	0.001	0	0
Total	131	443.75	110	227.12

RADIOACTIVE MATERIALS	18/19	17/18	16/17	15/16	14/15
Orders	131	137	164	193	241
mCi	444	363	383	578	732
Pickups	106	44	176	306	250
Sewer Disposals	37	21	53	69	50
Transfers	110	85	123	77	61
mCi	227	641	462	173	814

SEALED SOURCES

CWRU's sealed source inventory contains 82 sealed sources. Of these, 76 sealed sources are required to be inventoried every six months. Six sealed sources require six-month leak tests as stated in our ODH license. This includes six gamma sources. The one neutron source (AmBe) was disposed by Ecology Services.

There are three high-dose irradiators and two low-dose irradiators on campus. Both of the low-dose irradiators 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, three sealed sources were returned to the manufacturer, one sealed source was shipped to another university, and thirteen sources were disposed by Ecology Services, and eleven new sources were received. The RSOF has actively encouraged AUs to dispose of sealed sources for which there is no anticipated use.

INVENTORY	18/19	17/18	16/17	15/16	14/15
Sealed Sources	82	86	94	93	93
Exempt	76	79	89	88	88
Irradiator	3	3	3	3	3
Neutron	0	1	1	1	1

IRRADIATORS

Six licensed low-to-high activity radiation sources are possessed for biomedical and other research. These include a ²⁴¹Am-Be neutron source (in waste storage), three high dose irradiators that contain ¹³⁷Cs sources, and two low dose irradiators when charged with ¹⁹²Ir and ⁶⁰Co (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 20 irradiator users. Of these, 3 were new users and 9 had access removed.

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

IRRADIATOR	18/19	17/18	16/17	15/16	14/15
Total Workers	20	26	34	30	38
Total Active Irradiators	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 \$10,100 in cost savings over the fiscal year in lieu of using outside vendors.

CALIBRATION/ SERVICE	COST PER SERVICE	COST SAVINGS
70 meters	\$90/meter	\$6,300
10 Rad Eye meters	\$200/meter	\$2,000
1 pumps	\$100/pump	\$100
17 thyroid assays	\$100/assay	\$1,700
4 pre-filter changes	\$92/ set of 4/quarterly	\$0
	TOTAL COST SAVINGS	\$10,100

The RSOF calibrated 88 survey meters in the last fiscal year. There were seven meters removed from 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.

This year, one pump for radioactive materials were calibrated for use in an iodination hood. The CAM system is not in service and have not been calibrated.

CALIBRATION/ SERVICE	18/19	17/18	16/17	15/16	14/15
Meter Calibration	88	95	91	115	112

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

METER CALIBRATION BY MONTH	18/19	17/18	16/17	15/16	14/15
7/2018	13	24	12	18	17
8/2018	17	12	8	12	10
9/2018	15	9	7	8	6
10/2018	2	4	5	7	6
11/2018	5	4	4	6	1
12/2018	5	6	8	8	12
1/2019	0	1	0	7	9
2/2019	8	0	0	12	15
3/2019	1	23	8	10	13
4/2019	13	4	17	8	10
5/2019	8	7	9	7	12
6/2019	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 located 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	18/19	17/18	16/17	15/16	14/15
Violations	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 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.

The contract for dosimetry was renewed with Landauer, Inc. which provides radiation monitoring services. The dates of the contract are for 7/1/2015 to 6/31/2018 with two one-year renewal options.

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. One woman did confirm her pregnancy and during her monitoring, no fetal doses above background radiation levels were detected.

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 two neutron dosimeter users 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 four fluoroscopy users had collar badges. This fiscal year, we issued 150 visitor badges to fluoroscopy observers.

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	18/19	17/18	16/17	15/16	14/15
MONITORING					

Pregnant Workers	1	1	0	0	0
Neutron	2	2	2	2	2
RGE/ X-ray	76	251	32	25	37
Dental	35	41	27	37	28
General	284	347	485	460	473

CWRU uses Luxel badges, which are considered to be 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 2018.

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. 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 health care and diagnostic research. There are currently 11 AUs of RGE with equipment in 19 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)	18/19	17/18	16/17	15/16	14/15
Diagnostic units Disposed	0	0	0	2	0
Diagnostic units Purchased	0	0	0	1	3

The ODH has changed the Radiation Generating Units classification. There were no units purchased or disposed of for 2018-2019. The table below reflects that change.

RADIATION GENERATING EQUIPMENT (IN USE)	18/19	17/18	16/17	15/16	14/15
Closed Beam Analytical	6	6	6	6	6
Dental Computer Tomography (CT)	5	2	2	2	1
Photoelectron Spectrometer (No longer under ODH)	0	0	16	16	10
Fluoroscopy	2	2	2	2	3
Hand-held Dental	13	4	3	2	3
Hand-held Dental (Inoperable)	1	0	1	1	0
Intraoral	72	30	30	28	27
Panoral (Only)	1	1	1	1	1
Cabinet System exclude admittance	3	3	3	3	3
Tube Only (Inoperable)	0	0	9	9	12
Radiographic (Mobile)	1	1	1	1	1
TOTAL TUBES	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. The Northeast Ohio Regional Sewer District 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 2018 was filed by 12/31/2018 and the report for January through June 2019 was filed by 6/30/2019. Twenty-two 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 2018 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.

With regard to 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 reduce 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 was one experiment requiring the use of volatile iodine conducted this fiscal year. This program had been inactive since 2014.

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.

RADIOACTIVE IODINE

During 2018-2019, there was one active iodination laboratories. The RSO maintains an inventory of four iodination hoods to be deployed when needed. A bioassay is required when more than 1 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:
 - o Performance of a baseline bioassay for anyone involved in the procedure that does not have a baseline radioactive iodine bioassay on file
 - o 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. Bioassays were completed for the RSOF staff involved in radioactive waste handling. There was one iodination procedure performed this fiscal year. No workers exceeded 10 percent of the ODH limits.

IODINATION PROCEDURES	18/19	17/18	16/17	15/16	14/15
Total	1	0	0	0	0

125	18/19	17/18	16/17	15/16	14/15
BIOASSAYS				ļ	
RSOF Staff	16	16	16	16	16
Additional	2	0	0	0	0
Total	18	16	16	16	16

<u>TRITIUM</u>

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 no major incidents and twenty minor incidents documented over the past year.

INCIDENTS	18/19	17/18	16/17	15/16	14/15
Major	0	0	0	0	0
Minor	11	20	21	22	30
TOTAL	11	20	21	22	30

DATE	INCIDENT	CONTAMINATION	ROOT CAUSE	FOLLOW UP
5/13/2019	Minor Incident	IRR Communication Loss	IRR Communication loss in Lenel	Contractor called to troubleshoot and no problems were found.
2/18/2019	Minor Incident	IRR Alarm	RFID Alarm was not clearing in Lenel.	Contractor was called to troubleshoot and sound button was reset.
12/18/2018	Minor Incident	IRR Computer	Power outage caused the computer to go down.	Contractor called to troubleshoot and no problems were found.
11/14/2018	Minor Incident	Ceiling water leak	DOA 990 Office Ceiling leak on LSC	LSC was unplugged and moved. LSC will be replaced through insurance.
10/31/2018	Minor Incident	IRR Alarm	Connection loss with RMS & not Linel	Connection back once Contractor done
10/26/2018	Minor Incident	Radon Test Inquiry	Radon Test requested for Rockefeller Basement	The results are filed in RSOF and were less than 25% of the trigger level.
10/23/2018	Minor Incident	Unsecured RAM	RAM was placed in a non-radiation refrigerator.	The RAM was stored in the RSOF refrigerator while the Authorized User purchased a lock for refrigerator.
10/11/2018	Minor Incident	Food in the laboratory	Refrigerator used for food placed next to locked RAM freezer.	The refrigerator was surveyed for contamination and the results were background. The refrigerator was moved out of the laboratory.
9/21/2018	Minor Incident	Unauthorized Sealed Sources Purchase	Notified that Researcher did not follow the proper CWRU purchase process for ordering gamma sealed check sources.	RSOF checked/documented the check sources and met with Authorized User & principal persons to review the proper purchase procedure for radioactive materials.
7/1/2018	Minor Incident	Unauthorized LSC Purchase	Notified that LSC in a non-Radiation Room	LSC & Sealed source placed under RSOF license until new Authorized User was approved. Also met with principal persons to review the proper purchase procedure for radioactive materials.
9/11/2018	Minor Incident	Door Alarm	DOA 990 Chem waste room door opened without turning off the alarm.	Reviewed proper procedure with staff.

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. Articles that were submitted during this year included:

- Radiation Therapy Basics Part II
- Radiation Therapy Basics-Part I
- Use Of Potassium Iodide
- 63rd Annual Health Physics Society Meeting
- Radiation Risks Associated with Medical Events

LASER SAFETY PROGRAM

There are a total of 210 lasers/laser systems in our database for the campus used by 39 laser PIs in 16 buildings (33 Active, 6 Storage). The lasers of greatest concern are those labeled Class 3B and Class 4. There are 25 3B/4 PIs with a total of 133 Class 3B/4 lasers, as well as 14 1-3R PIs with a total of 77 lasers in other classes 1, 2, and 3A/3R.

There are 31 class 3B/4 enclosed laser systems that are considered eye-safe under normal use that decrease the hazard to the user. Thirty-four audits of laser systems were performed during this fiscal year. There were no laser incidents reported this year.

ULTRA VIOLET (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 971 pieces of equipment and 49 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, beta plates 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 are 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. Long-lived solid waste (greater than 60-day half-life) and scintillation vials are disposed by Ecology Services, a commercial radioactive materials waste hauler.

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.

COLLECTION AND DISPOSAL OF ANIMAL REMAINS AND BIOHAZARDOUS WASTE

The RSOF maintains two -20°C freezers 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.

Any item that has come in contact with an etiologic agent is considered biohazardous. Etiologic agents include bacteria, viruses and parasites and must be disinfected or decayed to background before disposal. Infected 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. Additional information regarding etiological agents is placed on the tag. All animal waste is disposed of by the RSOF.

WASTE GENERATED IN JULY 1, 2018 - JUNE 30, 2019

	GENERATED 7/1/2018- 6/30/2019	DISPOSED: MEDWASTE OHIO	DISPOSED: SEWER	DISPOSED: CHEMICAL SAFETY	DISPOSED: Ecology Services	IN STORAGE AS OF 6/30/2019
Short-Lived Dry	6	0	0	0	4	2
Long-Lived Dry	8	0	0	0	8	0

Scintillation Vials	6	0	0	0	6	0	
Animals	00	0	0	0	0	0	
Long-Lived Sewer	35	0	35	0	0	0	
Long-Lived Non-Sewer	5	0	0	0	0	5	
Short-Lived Sewer	30	0	30	0	0	0	
Short-Lived Non-Sewer	1	0	0	0	0	1	

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 7/1/2018, kept for decay in storage and disposed during the period of 7/1/2018—6/30/2019. 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 were no drums of Decay-in-Storage dry waste surveyed and disposed of during 2018-2019. Thus, the indirect savings to researchers due to the decay in storage program was \$0.

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

The contract for radioactive waste disposal has been renewed for 6/2016 to 6/2019 with two one-year renewal options 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' 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 \$8,930 during 2018-2019.

RADIATION SAFETY COMMITTEE AUDITS

The RSC audits are carried out in two different ways:

- Performance audits are conducted on-site at the RSOF by individual RSC members 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 Webpage	1
Irradiators	5
Room Surveys (Active/Decommission	ned) 10
Compliance Reviews	10
Lasers	10
Licensing	10
Dosimetry	10
Incidents	10

These audits were conducted between October and December 2018 and between March and June 2019. This effort resulted in the review of more than 170 files in the program areas listed above.

RSC TRI-ANNUAL AUDITS FOR 2018-2019

RSC AUDIT COMMENT:

In October 2018, the RSC members conducted a bi-annual audit of the following components of the RSOF:

Active/Decommissioning Room Surveys Compliance Reviews Direct Package Pickup Dosimetry Program EHS Webpage Irradiator Program
Licensing Status
Radiation Generating Equipment (RGE) Inventory & Training
Sealed Source Leak Tests
Support Staff Training
Radiation Survey Meters
Valid RAM Applications
Waste Facility

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 10/22/2018 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. Licatalosi examined ten (10) files and noted no deficiencies.

RSOF RESPONSE:

No response required.

Compliance Reviews

Compliance review audits were performed by Dr. Croniger on 10/25/2018, to ensure that any non-compliance issues were appropriately resolved. Upon examination of ten (10) files Dr. Croniger noted no deficiencies of any files not in the database.

RSOF RESPONSE:

No response required.

Direct Package Pickup

Isotope orders received within the last 3 months destined for direct pickup were reviewed by Dr. Croniger on 10/25/2018. Dr. Croniger audited two (2) files to ensure that direct pickup was denoted in the files. No deficiencies were noted.

RSOF RESPONSE:

No response required.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed on 10/25/2018 to verify that AU laboratory workers were current in dose record and active radiation badges. Dr. Ogino audited ten (10) records and reported no deficiencies.

RSOF RESPONSE:

No response required.

EHS Webpage

Dr. Tomoaki Ogino inspected the operation of the EHS web pages for the radiation safety section. Dr. Licatalosi examined 10 random sites on 10/25/2018 within the web pages and associated links and reported no deficiencies.

RSOF RESPONSE:

No response required.

Irradiator User Training/Irradiators

An audit of the Irradiator Information Files was performed by Dr. Fisher to verify that the irradiators were audited by the RSOF within the past six months. The audit was performed on 10/22/2018. Four Irradiators were active on campus and each file was up-to-date and compliant, Dr. Fisher noted one entry where the user name was illegible, this was reported to the RSOF.

RSOF RESPONSE:

The User name was clarified and no further response required.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations on 10/22/2018. Components of the audit include: Broadscope 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. Fisher 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 10 files on 10/22/2018. Dr. McCormick noted three (3) instances of users in need of updated training. All records were updated successfully upon notification of the RSOF.

RSOF RESPONSE:

No further response was required.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited on 10/25/2018. Ten (10) files were examined by Dr. Licatalosi, who reported one (1) deficiency. The PI (Taylor) was not listed in the database. This was reported and the situation corrected by the RSOF.

RSOF RESPONSE:

The record is under RSOF in the database because the AU was not yet approved for 137Cs.

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 10/25/2018. Dr. Valadkhan reported two (2) deficiencies upon examination of ten (10) records. The RSOF was notified of the overdue workers and the workers were sent notices.

RSOF RESPONSE:

No further response was required.

Radiation Survey Meters

Compliant calibration of survey meters was audited on 10/29/2018. Ten (10) files were examined by Dr. Jankowsky who noted no meters that were overdue for calibration. Dr. Jankowsky further noted that two meters would soon be due for calibration.

RSOF RESPONSE:

No response required.

Valid Ram Applications

RAM applications were audited on 10/22/2018 to verify that the applications were complete and valid. Dr.McCormick audited ten (10) files and reported two (2) deficiencies where files needed updating. The RSOF was notified of these files and the files were subsequently completed for compliance.

RSOF RESPONSE:

No further response required.

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 10/25/2018. Dr. Valadkhan 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 2019, the RSC members conducted a tri-annual audit of the following components of the RSOF:

Active/Decommissioning Room Surveys
AU & Worker Training
Bioassays
Direct Package Pickup
EHS Webpage
Incident Reports
Irradiator Program
Isotope Possession Limits
Laser Program
Radiation Generating Equipment (RGE) Inventory & Training
Sealed Sources
Radioisotope Security Checks
Semi-annual Mailings
Survey Meters

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.

Active/Decommissioning Room Surveys

An audit was performed on 1/17/2019 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. Jankowsky examined 10 files and noted no deficiencies.

RSOF RESPONSE:

No response required.

AU and Worker Training

Authorized users and worker training files were audited on 1/29/2019 by Dr. Croniger, who examined ten (10) records and noted no workers that were overdue for training.

RSOF RESPONSE:

No response required.

<u>Bioassays</u>

An audit was performed to verify completion of bioassays for laboratories using 10mCi of 3H and/or 1mCi 125I on 1/25/2019. Dr. Schiemann noted that five (5) Bioassays had been performed for this period, with no deficiencies.

RSOF RESPONSE:

No response required.

Direct Package Pickup

Isotope orders received within the last 3 months destined for direct pickup were reviewed on 1/17/2019 by Dr. Ogino. Dr. Ogino audited five (5) files to ensure that direct pickup was denoted in the files. Dr. Ogino noted no deficiencies.

RSOF RESPONSE:

No response required.

EHS Website

The website for the RSOF was audited to ensure proper operation, access and current links were operational on 1/18/2019. Dr. McCormick reports no systems within the Radiation Website that were dysfunctional.

RSOF RESPONSE:

No response required.

Incident Reports

A review of monthly incident reports was performed on 1/18/2019 by Dr. McCormick for verification and documentation of follow-up by the RSOF. During this period there were a total of twenty (20) incidents reported. All 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. Licatalosi to verify that the irradiators were audited by the RSOF within the past six months; the audit was performed on 1/22/2019. Four Irradiators were active on campus and each file was up-to-date and compliant. Dr. Licatalosi noted four (4) authorized users were overdue for training. The RSOF notified the overdue workers.

RSOF RESPONSE:

The workers were notified to update all of their safety training, not just Radiation Safety, and were compliant. No further response was required.

Isotope Possession Limits

Dr. Valadkhan audited 10 files on 1/23/2019 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. Valadkhan noted no deficiencies in the audited records.

RSOF RESPONSE:

No response required.

Laser Program

The Laser program was audited by Dr. Schiemann for accuracy regarding laser inspections, inventory and status of personnel training on 1/25/2019. Five (5) files were audited. One (1) deficiency in inspection was noted and the RSOF was notified of the responsible PI to contact for follow up on worker training.

RSOF RESPONSE:

The inspection for the laser PI was completed and the equipment posted as damaged and non-functional.

Radiation Generating Equipment (RGE) inventory and training

Quarterly inventory status and equipment surveys were examined by Dr. Ogino who examined 10 files on 1/17/2019. Dr. Ogino noted three (3) instances of worker training overdue. The RSOF office issued notices to the workers for updated training.

RSOF RESPONSE:

For those that needed training, they were notified and completed the training. One person was not using the unit and therefore did not need to train.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited on 1/29/2019. Ten (10) files were examined by Dr. Croniger who reported that no deficiencies were noted.

RSOF RESPONSE:

No response required.

Radioisotope security checks

Verification and documentation of radioisotope security checks were performed on 1/17/2019. Dr. Fisher reports that one (1) security check during this period showed a deficiency. This follow up resolution is documented in the file email chain.

RSOF RESPONSE:

No response required.

Semi-Annual Mailings (Air/Sewer Inventory)

An audit of the air/sewer disposal inventory was on 1/17/2019 by Dr. Jankowsky. Ten (10) files were reviewed by Dr. Jankowsky who noted five (5) questionable status updates. The Assistant RSO was notified of these missing surveys.

RSOF RESPONSE:

Increased attention to these deficiencies was implemented. The five inventories were received and the database updated.

Radiation Survey Meters

Compliant calibration of survey meters was audited on 1/23/2019. Ten (10) files were examined by Dr. Valadkhan who noted three (3) meters that was overdue for calibration. The RSOF office followed up with the responsible PI for this meter.

RSOF RESPONSE:

The meters were marked as out of service.

In April 2019, the RSC members conducted a tri-annual audit of the following components of the RSOF:

AU/Worker Training
Compliance Reviews
Dosimetry
Incidents
Isotope Possession Limits
Lasers
Licensing
Security Checks
Semi-Annual Mailings
Support Staff Training
Valid RAM Applications
Waste Facility
EHS Radiation Webpage

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 5/2/2019. Dr. Jankowsky examined ten (10) records and noted 10 overdue workers.

RSOF RESPONSE:

The workers were notified and training was completed.

<u>Bioassays</u>

An audit was performed to verify completion of bioassays for laboratories using 10mCi of 3H and/or 1mCi 125I on 4/30/2019. Dr. Licatalosi noted that four (4) Bioassays had been performed for this period, with no deficiencies.

RSOF RESPONSE:

No response required.

Compliance Reviews

Compliance review audits were performed by Dr. Ogino on 4/24/2019, to ensure that any non-compliance issues were appropriately resolved. Upon examination of ten (10) files Dr. Ogino noted five (5) deficiencies of a file not in the database or with a late entry. The RSOF was notified of these occurrences and the files were corrected.

RSOF RESPONSE:

Increased attention to this filing deficiency was implemented. Note: At annual inspection, only 1 of 50 files exhibited this deficiency.

Dosimetry Program

An audit of Current Dose records held by the RSOF was performed on 4/26/2019 to verify that AU laboratory workers were current in dose record and active radiation badges. Dr. McCormick audited ten (10) records and reported no deficiencies in these files.

RSOF RESPONSE:

No response required.

Incident Reports

A review of incident reports on 4/30/2019 by Dr. Licatalosi was performed for verification and documentation of follow-up by the RSOF. During this period no deficiencies were reported.

RSOF RESPONSE:

No response required.

Isotope Possession Limits

Dr. Ogino audited 10 files on 4/24/2019 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. Ogino noted no deficiencies in the audited records.

RSOF RESPONSE:

No response required.

Laser Program

The Laser program was audited by Dr. Jankowsky for accuracy regarding laser inspections, inventory and status of personnel training on 5/2/2019. Five (5) files were audited. Three (3) deficiencies in inspection was noted and the RSOF was notified of the responsible PI to contact. The director of the Laser program notified the Principal Investigators regarding these deficiencies.

RSOF RESPONSE:

A number of lasers posed no risk and were reclassified to reduce the number of units in non-compliance.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations on 4/25/2019. Components of the audit include: Broadscope 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. Croniger reviewed all license programs and noted that all licenses were current.

RSOF RESPONSE:

No response required.

Security checks

Verification and documentation of radioisotope security checks were performed on 4/26/2019. Dr. McCormick reports that one (1) security check during this period showed a deficiency. The PI was notified by phone and email from the RSOF.

RSOF RESPONSE:

The response was received from the AU.

Semi-annual Mailings

Dr. Schiemann surveyed ten (10) files on 4/26/2019 to ensure that responses to the latest semi-annual mailing were in order. Dr. Schiemann reported no deficiencies.

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 4/24/2019. Dr. Fisher reported no deficiencies upon examination of ten (10) records.

RSOF RESPONSE:

The Ancillary Radiation personnel were training and entered in the database.

Valid Ram Applications

RAM applications were audited on 4/25/2019 to verify that the applications were complete and valid. Dr. Valadkhan audited ten (10) files and reported two (2) deficiencies where files needed

updating. The RSOF was notified of these files and the files were subsequently updated to be in compliance.

RSOF RESPONSE:

The training deficiencies were corrected and entered in the database.

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 4/26/2019. Dr. Schiemann 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 bi-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 helped expedite 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 the first week in June 2019. The committee reviewed the performance of 20 components of the RSOF. The areas were:

- Active/Decommissioning Room Surveys
- Ancillary Staff Training
- AU and Worker Training
- Bioassays
- 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
- EHS Radiation Webpage
- Seal 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:

Active/Decommissioning Room Surveys

An audit was performed 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. Ogino examined rooms for the period: 7/1/2018-6/30/2019. Fifty (50) files were examined and four (4) deficiencies were noted. The RSOF was informed of these and the deficiencies were corrected.

RSOF RESPONSE:

No response required.

Ancillary Staff Training

An annual audit was conducted to verify the training status of Ancillary Staff and worker training files for a period from 7/1/2018-6/30/2019. Dr. McCormick reported that 30 of 50 of the ancillary workers audited were overdue for training. The Radiation Safety Office notified overdue workers.

RSOF RESPONSE:

These Ancillary personnel will be trained as a group in 7/2019 and updated in the database.

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 7/1/2018-6/30/2019. Dr. Schiemann reported that 9 of 50 of the ancillary workers audited were overdue for training. The Radiation Safety Office notified overdue workers.

RSOF RESPONSE:

No further response required.

Bioassays

An audit was performed to verify completion of bioassays for laboratories using 10mCi of 3H and/or 1mCi 125l between 7/1/2018-6/30/2019. Dr. Fisher noted that two (2) bioassays had been performed for this period, with no deficiencies.

RSOF RESPONSE:

No response required.

Compliance

Compliance review audits were reviewed for the period 7/1/2018-6/30/2019 to ensure that any non-compliance issues were appropriately resolved. Upon examination of 50 files Dr. Jankowsky noted one (1) deficiency. The RSOF staff was informed of the missing file.

RSOF RESPONSE:

The misfiled compliance was found and filed correctly.

Direct Package Pickup

An audit was performed to cover the period of 7/1/2018-6/30/2019 to verify that package receipts were completed with each transfer of material from site to site. Dr. Fisher audited 15 files and identified no deficiencies in package receipts.

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 7/1/2018-6/30/2019. Dr. Croniger audited 50 records and reported four (4) individuals without dose record files, the RSOF was notified concerning the files and any workers identified with no badges were notified of the deficiency by the RSOF.

RSOF RESPONSE:

No further response required.

Incident Reports

A review of monthly incident reports From 7/1/2018-6/30/2019 was performed by Dr. Jankowsky for verification and documentation of follow-up by the RSOF. During this period there were a total of ten (10) incidents reported. All incidents were effectively resolved in a timely manner.

RSOF RESPONSE:

No response required.

Irradiator Program Review

A review of Irradiator Files from 7/1/2018-6/30/2019 was performed by Dr. Croniger for verification and documentation of follow-up by the RSOF. During this period there were a total of four (4) files reviewed. All files were complete with no deficiencies.

RSOF RESPONSE:

No response required.

Isotope Orders, AU possession limits and the Helix Database

Dr. McCormick audited 22 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 Helix Database covering the period 7/1/2018-6/30/2019. Dr. McCormick noted one (1) deficiency in the audited records. The RSOF was informed of the missing file.

RSOF RESPONSE:

The misplaced file was found and filed correctly.

Laser Program

The Laser program was audited by Dr. Croniger for accuracy regarding laser inspections, inventory and status of personnel training in the period 7/1/2018-6/30/2019. Thirty-six (36) files were audited. Numerous (overdue) deficiencies (15) were noted and the RSOF was notified of the responsible PI to contact.

RSOF RESPONSE:

The Laser PI was contacted and the deficiencies were corrected.

Licensing Status

An audit was conducted to verify the licensing status of all ODH licenses and registrations during the period 7/1/2018-6/30/2019. Components of the audit include: Broadscope 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. Valadkhan reviewed all license programs and noted that all licenses were current. She notes that the underground storage tank renewal was about to expire (6/30/2019).

RSOF RESPONSE:

No response required.

Radiation Generating Equipment (RGE) inventory and training

Quarterly inventory status and equipment surveys were examined by Dr. Schiemann who examined 16 files for the period 7/1/2018-6/30/2019. Dr. Schiemann noted no deficiencies in inventory reports and equipment surveys.

RSOF RESPONSE:

No response required.

Sealed Source Leak Tests

Files verifying that sealed sources had been leak tested were audited for the period of 7/1/2018-6/30/2019. Fifty (50) files were examined by Dr. Fisher who reported three (3) outdated files. The RSOF corrected these files.

RSOF RESPONSE:

No further response required.

Radioisotope security checks

Verification and documentation of radioisotope security checks were performed for the period 7/1/2018-6/30/2019. Dr. Valadkhan audited nine (9) security checks generated during this period. All incidents were noted to be resolved in an efficient and timely manner.

RSOF RESPONSE:

No response required.

Semi-Annual Mailings (Air/Sewer Inventory)

An annual audit of the air/sewer disposal inventory was performed for the period 7/1/2018-6/30/2019. Fifteen (15) files were reviewed by Dr. Licatalosi who noted no deficiencies.

RSOF RESPONSE:

No response required.

Radiation Survey Meters

Compliant calibration of survey meters was audited for the period 7/1/2018-6/30/2019. Fifty (50) files were examined by Dr. Ogino who noted two (2) meters that were due for calibration. The RSOF was notified of these calibration needs and the proper PIs were contacted.

RSOF RESPONSE:

No further response required.

EHS Website

An annual audit was conducted to verify the that the EHS Website links were working for the period from 7/1/2018-6/30/2019. Dr. Jankowsky reported that all links were working and there were no deficiencies.

RSOF RESPONSE:

No response required.

Valid Ram Applications

RAM applications were audited for the period 7/1/2018-6/30/2019 to verify that the applications were complete and valid. Dr. Ogino audited eleven (11) files and reported no deficiencies.

RSOF RESPONSE:

No response required.

Waste Disposal Facilities

The waste disposal facilities (DOA990/Wolstein) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF for the period 7/1/2018-6/30/2019. Dr. McCormick inspected the facilities for Wolstein and the RAOF laboratory and reported all other records of maintenance, housekeeping, records and waste storage and handling were in compliance. Dr. McCormick was unable to inspect DOA990 due to construction.

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 Isotope Orders/ AU Possession Limits AU/ Worker Training Waste Disposal Facility Active/Decommissioned Room Surveys RAM Security Checks Semi-Annual Mailings RGE Inventory/ Training Ancillary Training Licensing Incidents Irradiator

Bioassays
Dosimetry
Survey Meters
Compliances
EHS Radiation Webpage
Liaison Program
Laser Program

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 10/5/2019 and reviewed by Dr. David Sedwick. It covers fiscal years 7/1/2018-6/30/2019.

APPENDIX

AUTHORIZED USERS WITH STATUS CHANGE DURING FISCAL 2017-2018

RADIATION ACTIVE

Christine Duval (7/25/2018) Fu-Sen Liang (9/28/2018)

STORAGE MODE

Param Ramakrishnan (8/8/2018) Hua Lou (6/5/2019)

RADIATION INACTIVE

Faramarz Ismail Beigi (7/5/2018) Jennifer Dorth (7/16/2018)

DEPARTED

Michael Weiss (7/5/2018) Krzysztof Palczewski (9/27/2018) Xingjun Fan (9/27/2018)

X-RAY AUTHORIZED POSSESSOR LIST

AP NAME	CONTACT PERSON	UNITS
Gary Chottiner	Gary Chottiner	4
Chris Dealwis	Lucas Hoffman	0
Fady Faddoul	Susan Opsitnick	90
Edward Greenfield	Teresa Pizzuto	1
Mukesh Jain	Steve Schomisch	3
Zhenghong Lee	Chris Flask	3
Suparna Mahalaha	Angel Henderson	3
Stephanie Piatt	Nan Avishai	4
Anna Samia	Anna Samia	1
Daniel Scherson	Daniel Scherson	2
Lei Zhu	Lei Zhu	5

LASER USERS

Rigoberto Advincula (4)
Clemens Burda (3)
Steven Eppell (8)
Brian Grimberg (10)
James Jacobberger (10)
Lydia Kisley (1)
James McGuffin Cawley (1)
Andre Paes (1)
Charles Rosenblatt (14)
Kenneth D. Singer (18)
Christian Zorman (4)

Alan Diehl (Storage) (1) Edward Medof (Storage) (1)

Paul Carey (Inactive) Agata Exner (Inactive) Ben Strowbridge (Inactive) Ozan Akkus (1)
Carlos Crespo (8)
Philip Feng (5)
Alex Huang (2)
Michael Jenkins (9)
Michael Lederman (1)
Minh Lam (1)
John Protasiewicz (4)
Daniel Scherson (15)
Jonathan Stamler (1)

Liming Dai (2)
Roger French (1)
Yoshikazu Imanishi (4)
Kathleen Kash (13)
Soumyajit Mandal (1)
John Mieyal (1)
Rajesh Ramachandran (1)
Alp Sehirlioglu (1)
Giuseppe Strangi (4)

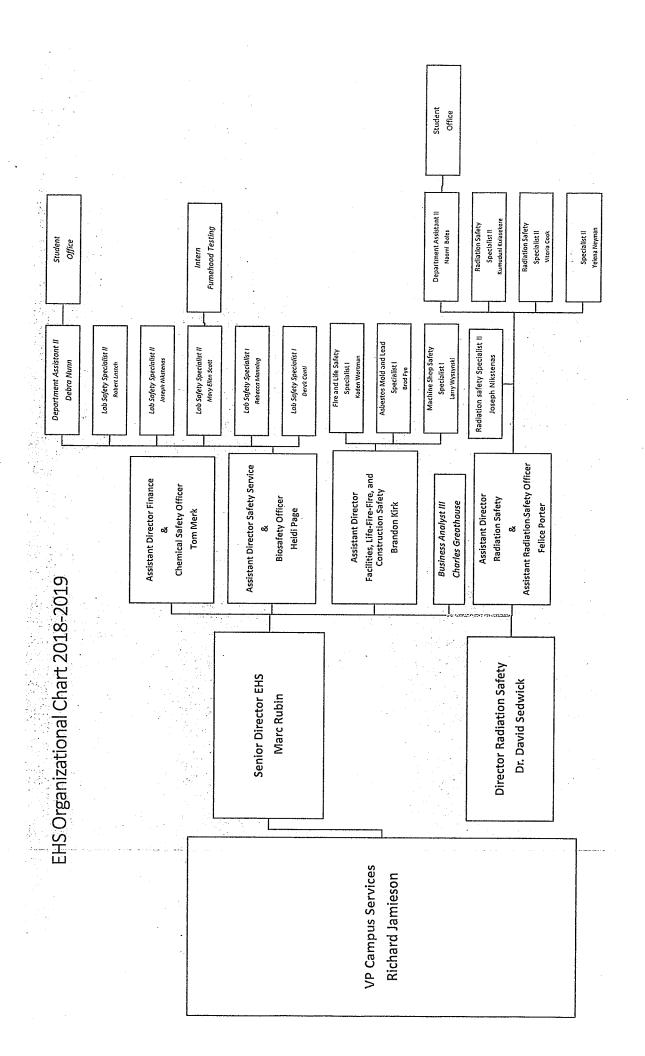
James Basilion (2)

Jesse Berezovsky (14)
Diana Driscoll (16)
Jeffrey Garvin (1)
Hatsuo Ishida (5)
Chirag Kharangate (11)
Michael Martens (13)
Claudia Mizutani (1)
Andrew Rollins (12)
Rafick Sekaly (1)
Nicole Ward (1)

Dominique Durand (Storage)(2) Wyatt Newman (Storage) (1)

Hillel Chiel (Inactive) Krzysztof Palczewski (Inactive) Heidi Martin (Storage) (1) Eckhard Jankowsky (Storage) (1)

Jeffrey Duerk (Inactive) Lei Zhu (Inactive)



and the second of the second o