CASE WESTERN RESERVE UNIVERSITY DEPARTMENT OF ENVIRONMENTAL HEALTH & SAFETY (EHS) RADIATION SAFETY ANNUAL REPORT 2011-2012

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INTRODUCTION

This report is submitted to the President and designated members of the Senior Administration of the University, as required by the Radiation Safety Committee (RSC) Operating Guidelines and Case Western Reserve University's State of Ohio (Nuclear Regulatory Commission Agreement State) Broadscope 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. Its contents cover the period from July 1, 2011 through June 30, 2012.

SUMMARY

DEPARTMENT STRENGTHS

The RSOF has a staff with broad and diverse backgrounds that can address and resolve a wide range of issues faced in Radiation Safety at Case Western Reserve University (CASE). The RSOF has developed programs that meet or exceed regulatory requirements. This program proactively anticipates new safety requirements by promulgation of new programs. Success of these programs 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 2011-2012

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 Radiation Safety Program generated in-house savings accrued from meter calibration, recycling, and decay-in-storage programs amounting to more than \$27,103 in 2011/2012 through its services to the research community at Case Western Reserve University.
- EHS will continue its efforts to improve both safety awareness and effective performance of its University
 programs. Success in these programs is measured in terms of both the number of accidents and violations
 found during safety inspections and the degree to which the RSOF and the Radiation Safety Committee
 jointly resolve problems arising in its Safety Programs through quick action that meet regulatory
 requirements through providing solutions that facilitate programmatic advancement within a safe working
 environment.
- The RSOF and the Radiation Safety Committee have continued to work together to ensure that individual investigators outdated Radiation Safety protocols are updated and adjusted to meet the current activities of each individual laboratory.
- The RSOF has enthusiastically participated in the restructuring of EHS operation aimed at address of emerging programmatic needs, improved compliance, streamlining of operations, and increase productivity.
- Several technology upgrades were made to better meet programmatic needs.
- Departmental personnel participated in outside training to update and sharpen skills and refresh needed background.

RADIATION SAFETY GOALS FOR 2012-2013

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 Case Western Reserve University Safety Programs on the surrounding community through educational and programmatic interaction with local partners and emergency responders. Specific efforts currently address:

- · Continued incorporation of new integrated Radiation Safety forms into the OnSite computer database.
- · Continuous review and updating of all Radiation Safety, X-Ray Safety, and Laser Safety Manuals
- Implementation of Radiation Safety trainings on OnSite.
- · Revision of X-Ray/Laser Safety training
- Implementation of updated radioactive materials use refresher trainings online
- · Adjustment programs to operate efficiently following the reorganization of EHS
- · Completion of the Rebranding of the Department from DOES to EHS
- Creation of a link to the UH Fluoroscopy Program manual/training updates
- Incorporation of the Laser Safety and X-Ray Safety Programs into Onsite database

OHIO DEPARTMENT OF HEALTH (ODH) LICENSE

Case Western Reserve University has one Ohio Department of Health (ODH) Broadscope license. The license covers possession and use of both nuclear accelerator-produced radioactive material (NARM) and naturally occurring radioactive material (NORM) for experimental purposes. It also provides for the licensed use of four (4) irradiators. A Broadscope License inspection was last conducted by ODH on October 14-15, 2009. No issues of non-compliance requiring a written response were noted during this inspection.

The University has one ODH Radiation Generating Equipment (RGE) registration. The registration covers the receipt, possession, use, storage, and disposal of all radiation-generating sources including dental x-ray machines, x-ray diffraction units, fluoroscopy units, and electron microscopes. The Radiation-Generating Equipment (RGE) Partial Inspection was conducted on April 26, 2012. One issue of non-compliance concerning utilization of a radiation expert to conduct an area radiation survey upon installation of a dental CT unit was noted. The issue was corrected within the allotted time and corrective action report was submitted and accepted.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2015	Broadscope License
09-M-06944-12	May 31, 2014	Radiation-Generating
		Equipment Registration

DECOMMISSIONING FUNDING PLAN

The Broadscope License and the Decommissioning Funding Plan became effective 2/25/2010. The University is required to maintain a Standby Letter of Credit to cover possible costs if the University's Broadscope License is required to undergo rapid decommissioning. The expiration date for the Standby Letter of Credit is 2/28/2013. Funds required for this letter of credit depend on the kind and amounts of radioactive materials maintained in active use or waste by the University. Experimental procedures using more sensitive methods increasingly require less radioactive materials. There were no significant changes in cost for the Decommissioning Funding. Therefore, following ODH guidelines, the cost estimate was increased by 16%. The Standby Letter of Credit carried by the University is now \$333,406, consistent with the above changes. This document covers all possible decommissioning costs for radioactive materials located at the University at the time of the last submission of the University Broadscope License to the State.

RADIOACTIVE MATERIAL USE AND STORAGE LOCATIONS

Radioactive material is located at the following facilities:

- Main campus of Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH
- University Hospitals (UH), 2065 Adelbert Road, Cleveland, OH
- Wolstein Research Building, 2103 Cornell Road, Cleveland, OH

Radioactive material is received and/or stored at the following sites:

- Shipping and Receiving, 2232 Circle Drive, Cleveland, OH
- Wolstein Research Building, 2103 Cornell Road, Cleveland, OH

PURPOSE FOR RADIOACTIVE MATERIAL (RAM) USE

The majority of isotope use 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. Five (5) licensed low to high activity radiation sources are currently used for biomedical and other research. These include an ²⁴¹Am-Be neutron source and four high dose irradiators that contain ⁶⁰Co or ¹³⁷Cs sources and one low dose irradiator charged with ¹⁹²Ir. Currently, two irradiators are active and two are out of service. The low dose irradiator is currently out of service. There were 48 irradiator users. Of these, 6 were new users and 5 voluntarily had access removed.

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

IRRADIATOR	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Total Workers	48	47	52	68	55	45	28	10	5	2
Total Irradiators	4	4	4	4	4	4	4	3	3	3

RADIATION SAFETY PROGRAM - RESPONSIBLE PARTIES

RADIATION SAFETY COMMITTEE (RSC)

The Radiation Safety Committee sets policy for use of radioactive materials for the University Community. 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) Broadscope License. Radiation Safety Committee members are chosen from diverse disciplines to provide comprehensive expertise. The Committee reviews all applications for use of radioactive materials.

The 2011-2012 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. Anthony Berdis Dept. of Pharmacology HG Wood 276A Term Expires: 11/8/2013 Chairperson: 12/31/2007 Resigned – 6/2012	Dr. Jeffery Coller Dept. of RNA Center HG Wood 113 Term Expires: 11/8/2013	Dr. William Schlemann Dept. of Medicine WRB 2404 Term Expires: 1/10/2015
Colleen Croniger Dept. of Nutrition BRB 925 Term Expires: 5/1/2013	Dr. Lax Devireddy Dept. of Pathology Wolstein 6524 Term Expires: 11/8/2013	Dr. Thomas McCormick Dept. of Dermatology BRB 530 Term Expires: 11/8/2014 Chairperson: 6/1/2012
Dr. W. David Sedwick Radiation Safety Officer (RSO) Dept. of Medicine EHS - Service Building, 1 st Floor	Dr. Saba Valadkhan Dept. of RNA Center Research Tower 100-8 Term Expires: 11/8/2013 Dr. Monica Montano Dept. of Pharmacology HG Wood 367 Term Expired 9/1/2011	Dr. Eckhard Jankowsky Dept. of Biochemistry HG Wood 137 Term Expires: 1/3/2014

EX-OFFICIO MEMBERS

Dr. Charles Hart EHS Executive Director EHS, Service Bldg., 1 st Fl. Resigned – 12/2011	Felice T. Porter Asst. Dir./Asst. RSO Quality Assurance Specialist EHS Service Bldg., 1 st Fl.
Bruce DeMeza Asst. RSO University Hospitals Case Medical Center Bishop S621	R. Michael Sramkoski Senior Research Associate & Laser Specialist Comprehensive Cancer Center WRB 3542
Richard Jamieson Vice President of Campus Svcs. Adelbert Hall 205	

SUPPORT STAFF

Shirley Mele	Gwendolyn Cox-Johnson
Office Supervisor	Department Assistant
Service Bldg., 1 st Floor	Service Bldg., 1 st Floor
Laid off - 6/2012	

The Radiation Safety Committee acts as an advisory and enforcement body to ensure that radioactive materials are safely used in accordance with ALARA (As Low As Reasonably Achievable) 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 Case Western Reserve University 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 seven occasions during the 2011-2012 fiscal years to review applications for radioisotope use and action on other business. Four 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 Administration.

APPLICATIONS	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
New AU	7	3	9	5	7	14	11	8	3	8
Additional Isotopes	7	5	5	1	7	7	6	10	2	13
Radioisotope use in Animals	5	3	5	2	5	6	5	7	4	4
Sealed Sources	2	1	1	1	1	1	6	1	1	2
AU Reactivation	1	0	0	0	0	0	1	0	1	0
Possession Limit Increase	0	1	0	0	0	1	0	1	0	0
AU Protocol Update	10	12	0	0	Ö	0	0	3	0	0
TOTAL APPROVALS	32	25	20	9	20	29	29	30	11	27

Major topics acted upon or discussed by the RSC:

- Radiation Safety Waste Bid Contract and Dosimetry Bid Contract have been renewed.
- PETNET has relocated from UH to CCF
- · Radiation Safety new hire selected
- There were 13 Radiation incidents in 2011
- SAIRC now has only 2 Authorized Users (Muzic and Wang). Personnel and rooms for Z. Lee were placed under Dr. Wang during Dr. Lee's suspension.
- · Revised transfer form and process for short-lived isotopes working well.
- Berdis presented Montano with a gift in acknowledgment for her contribution and dedication for 9 years of service on the RSC.
- Jamieson reports that Chuck Hart resigned as Executive Director of EHS and will begin new teaching role at Kent State University.
- Berdis thanked RSC for completing Quarterly Audits
- Laser Exposure incident reported on Feb 2012 and is under investigation. No eye damage was noted however better work practices when working with lasers was discussed and report was filed.
- Berdis introduced new RSC member William Schiemann.
- Jamieson reported on a mock Tabletop Exercise regarding Homeland Security in April 2012 that included radioactive materials issues addressed by members of the RSOF. A follow-up exercise was scheduled for July 2012.

- Laser Safety Officer reported 2nd Laser exposure incident. No permanent eye damage was found. Better
 work practice recommendations made by the RSOF were discussed and a report on the incident was filed.
- UH new Senior Diagnostic Medical Physicist, Dave Jordan, assisted CASE in testing one of its new CT machines after installation.
- The Ohio Department of Health Safety Culture Policy statement was discussed.
- Radiation Safety Incident in the DOA 990 Processing Area occurred on May 2012 that was addressed and resolved
- Berdis, RSC Chairman, left CASE for new position at CSU in June 2012.
- Thomas McCormick replaced Berdis as Chairman of the RSC.
- The CASE WARN system was updated and is now called the RAVE system.
- · Laser Safety Officer presented monthly program summary
- Sedwick, Nikstenas, & Kulasekere attended a Weapons of Mass Destruction Radiation Awareness and Response Workshop on June 20-21, 2012.
- Jamieson reported that Shirley Mele (EHS Administrative Manager) was laid off as part of an administrative restructuring on June 2012. Two new technology positions were approved and created for a Fire Safety Specialist I and Biological Safety Officer who will collaborate with the RSOF program
- The RSC Annual Audit for June was distributed.
- Two researchers for the Wang group from CCF attended Safety Awareness Training in preparation for a new study involving imaging of radioactive tracer compounds in monkeys that will be conducted under the auspices of CWRU investigators.

SENIOR MANAGEMENT

The Radiation Safety Program monitors, inspects, and audits radiation materials, radiation generating equipment and source use by AUs and their personnel. Senior management oversight and support of radiation safety-related activities is ensured by attendance of the Vice President for Campus Services at all RSC meetings. The RSC conducts independent audits of the Radiation Safety Program. Radiation Safety Office (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.

RSOF AND AUTHORIZED USERS (AUs)

The AU and RSOF share responsibility for safety. The AU is directly responsible for safe use of radioactive materials 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 Case Western Reserve University's license. The audit program includes routine unannounced inspections of each AU's laboratory.

ADMINISTRATIVE CONTROLS

Administrative controls are established and approved by the Radiation Safety Committee for laboratories where radioactive material (RAM) 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 Ohio Department of Health. 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 move of 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 radioactive materials
- Unapproved transfer of radioactive materials

There were no major severity violations accessed. Of the 22 moderate violations listed below, 11 were the result of unsecured RAM found during after-hours security checks and routine compliance reviews. Eleven (11) were assessed to laboratories that had three or more minor violations during one compliance review by Radiation Safety during routine audits. Documented follow up and resolutions were completed for all major & moderate violations.

VIOLATIONS	11/12	10/11	09/10	08/09	07/08	06/07
Minor	112	64	53	103	83	57
Moderate	22	37	76	27	43	11
Major	0	2	0	0	0	1
Total	134	103	129	130	106	69

The Assistant RSO, the RSOF staff, and RSO have updated and revised most of the Departments manuals, training, licenses, certificates, and standard operating procedures in 2011-2012.

AU CATEGORIES:

RADIATION ACTIVE (RA)

AUs who actively use RAM are "Radiation Active". Laboratories of these AUs are inspected by the RSOF three times per year. Audits are more frequent if there are particular concerns in a laboratory. A listing of AUs and their radioactive materials can be found in the Appendix.

RADIATION INACTIVE (RI)

These AUs do not currently use RAM and do not possess radioactive materials. AUs in storage mode for more than two years were placed in Radiation Inactive mode this fiscal year.

RADIATION ACTIVE (STORAGE MODE) - RA (SM)

AUs who did not actively use RAM for a period of at least six months and no more than two years, but who wished to maintain their RAM inventory are, by their request, placed in storage mode status this fiscal year.

DEPARTED (D)

AUs who no longer carry out research at Case Western Reserve University and whose laboratories have been decommissioned for radioactive material use are placed in the Departed category this fiscal year.

AUs	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04
RA	89	87	87	91	92	112	124	116	123
RI	7	4	13	1	14	8	12	2	7
SM	13	16	3	4	5	6	4	9	8
D	1	2	3	6	8	12	11	12	12
Total in Program	102	103	90	95	97	118	128	125	131

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 AU Possession Limits, relative to NRC/ODH Registration Limit.

AU RADIOISOTOPE INVENTORY

The Radioisotope Inventory Report (see APPENDIX) lists researchers along with the amount of radioactive material each is authorized to use, each AU's 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 (3) Department Assistant (1) Student (1) Asst. Director/Asst. RSO/Quality Assurance Specialist (0.5) Department Administrator (0.5)

Supervisor (1)

The new Executive Director, Dr. Charles (Chuck) Hart, resigned in December 2011 after one year of service. Kumudu Kulasekere, Radiation Safety Specialist, was hired in August 2012.

Training and education are central to our Department's aim to develop diverse skills among our personnel that are required for response 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 2011-2012 included RCRA Selected Hazardous Waste Training, Security Awareness Training, 8-Hour HAZWOPER Refresher Training, BWC Hazard Communication, BWC Nonviolent Strategies for Staff Working Directly with the Public, Radiation Technician, BWC Effective Safety Teams, Response to an Improvised Nuclear Device, Hazardous Materials Transportation Security Awareness, X-Ray Safety Awareness, & FBI Radiological Awareness and Response Workshop.

One member of the EHS Staff is responsible for maintaining the EHS website that houses all on-line departmental training programs and schedules, safety manuals, safety newsletters, MSDSs, and safety information resources. The website is an essential resource for the campus community that requires continuous updating. This individual also monitors and backs up all departmental databases.

LIAISON PROGRAM

The Liaison Program requires RSOF personnel to visit University laboratories on a routine basis to offer safety advice and to answer safety questions. This program has helped to foster a service oriented relationship between the RSOF Staff and the research community and has improved follow up on inquiries and safety concerns. Staff members are assigned to various buildings and are responsible for maintaining contact with designated laboratories.

EMAIL HOT-LINE

Since implementing the 'hotline', the number of inquiries and safety concerns raised by Case Western Reserve University personnel has averaged fifteen (15) 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 "As Low As Reasonably Achievable" (ALARA). The RSOF provides training for all personnel that use RAM or Radiation Generating Equipment (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 Authorized User 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 RADIATION LABORATORY WORKER

Personnel listed under an AU who work in RAM laboratories but have only minor incidental contact with radioactive material or have to service radioactive laboratories or classrooms where RAM is used.

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, Animal Resource Center, 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 under the supervision 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 that has met the requirements for unescorted room access, including background & fingerprint check and radiation safety, site-specific, & laboratory safety training.

TRAINING

The RSOF documents 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 Case Western Reserve University safety philosophy. Training is audited on a monthly basis by the Assistant RSO to ensure compliance.

TYPE	NEW CLASSES	NEW USERS	ONLINE RETRAINING
Radiation Safety	30	279	405
X-Ray	17	72	O
Laser	13	89	32
RTK (Right to Know)	53	382	0
Irradiator (site specific)	6	48	0

New isotope user training classes are offered at least three 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 University Hospitals CASE Medical Center) in addition to the general X-Ray and site-specific trainings. Right-To-Know Fluoroscopy 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 which is offered on-line.

All non-laboratory personnel are required to attend Hazard Communication & Ancillary Radiation training, which now incorporates the Custodial, Plant, ARC, Shipping, Security departments, and Contractors. Employees who do not complete training are restricted from working in areas where radioactive materials are used.

TRAINING	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Radiation	279	186	279	223	240	297	284	284	283	322
Online Retraining	405	311	215	418	430	695	724	775	793	754
X-Ray	72	86	52	97	96	64	51	74	45	84
Ancillary	382	146	345	403	382	402	413	356	448	540
Laser	89	38	48	66	41	56	31	116	0	0
Laser Online	32	42	35	28	15	10	11	0	0	0
Irradiator	48	47	52	56	10	14	50	0	0	0

FACILITIES AND EQUIPMENT

Case Western Reserve University 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 Case Western Reserve University for the use of licensed material include:

AW Smith Bingham Biomedical Research Bishop Bolwell DeGrace 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

LABORATORIES

There are 267 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	180
X-Ray	46
Laser	41

Radiation Safety Office (RSOF)

Facilities and equipment used by the RSOF to support laboratory inspection or isotope storage are located in the Service Building (1st Floor), Medical School (Rm. DOA990), and the Wolstein Building (Rms. 1118, 1119, & 1120).

Up-to-date hardware is crucial to ensure efficient and quick access to records in the RSOF. A Smart Board System augments the in-house training program, and allows our trainers to directly demonstrate the use of on-line database and training materials. It also provides direct access to library services and campus maps during staff meetings, and emergency incident exercises or responses.

The University no longer offers the Legato backup service. All EHS personal computers (PCs) are being backed up onto a terabyte array. The Carbonite backup service is currently used for two EHS Servers (EHS, onsite-server). The web server (Aurora) itself is backed up, and additionally the files are copied locally on magnetic storage and periodically backed up onto optical storage discs.

The following maintenance was accomplished this fiscal year:

Hardware Maintenance

- Repaired about 12 workstation hardware problems
- Purchased and set up 4 new computers
- Repaired approximately 30 other hardware issues (workstations, phones, printers)
- Fixed approximately 40 IT issues in the office

Software Maintenance

- Rolled out major new training system
- Repaired about 200 workstation software problems
- Developed automated data validation software
- Website updates
- Fixed approximately 170 IT issues in the office

The Department of Environmental Health & Safety has transitioned to the use of Employee ID numbers in lieu of Social Security Numbers in its training program since 2008.

RSOF Laboratory:

The RSOF is located in the Service Building on the 1st Floor at 2220 Circle Drive. The laboratory in the RSOF is equipped with a Packard Model 1900C Liquid Scintillation Counter (duplicate machines are located in both Radioactive Waste Facilities), and a Packard 5000 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 multichannel analyzer with a sodium iodide detector. These instruments are used for bioassays and the quantification of air samples for EPA audits, as well as for identification of unknown isotopes found during radiation inspections. The RSOF laboratory also houses a chemical hood, survey meters, decontamination supplies, and essential analytical and calibration equipment.

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 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 5-gallon carboys and placed in spill trays to contain leakage. Radioactive animal carcasses are kept in a designated freezer in the ARC until they are disposed.

Wolstein Building Waste Facility:

This facility has a counting room (Rm. 1120) that contains a chemical hood, a liquid process/ storage area (Rm. 1119) that contains a walk-in chemical hood, and solid process/ storage area (Rm. 1118) for disposal activities. The liquid process/ storage area and solid process/ storage area are used for short-term storage only. All waste is transferred to the DOA990 facility for decay in storage and disposal. This area maintains negative pressure relative to surrounding building spaces.

One room (1120) in this Facility has been developed as a combined Chemical and Radioactive Materials Emergency Response Center. It contains spill supplies, a liquid scintillation counter, survey meters for both count and dose rates, and a computer that provides access to our Helix web database and MSDS in the event of radioactive/ chemical spills.

IODINATION EQUIPMENT

Special hoods, air pumps and activated charcoal-filter exhaust are placed in laboratories that conduct iodinations. Currently no laboratories are performing iodinations. All five iodination hoods are in storage. Their locations are as follows:

WRB 1119 - Radiation Waste Facility Storage (1) DOA 990 - Storage (4)

ANIMAL RESOURCE CENTER (ARC)

Conventional animal care/use facilities are located in the Robbins Building, Wearn Building, Metrohealth Hospital, 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 & large animals such as sheep, dogs, and pigs) are housed in the Robbins facility 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 facility during in 2009 which added an Ultra Barrier Facility. One irradiator behind the Ultra Barrier is not in current use but is being considered for re-commissioning in the program.

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 AU's laboratory. Instruments requiring simple repairs are repaired in-house.

Packard Auto Gamma Minaxi 500 Counter calibrations are conducted monthly for the EHS Radiation Laboratory and as needed for the LSCs in Radiation Laboratory, DOA 990 and WRB 1119. The continuous air monitor (CAM) in DOA 990 is currently out of service. 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 the Purchasing Department.

AUs must be approved for the isotope and the quantity of isotope ordered. The activity, when added to the AU's existing inventory, cannot exceed the AU's 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 Area for RSOF inspection and clearance before delivery to the AUs' laboratories.

TRANSFER OF RADIOACTIVE MATERIALS

The RSOF reviews and approves the transfer of all radioactive material 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 151 isotope transfers approved this year, for a total of 543 mCi.

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 placed on the package confirm that inspection has been completed by the RSOF. The Campus mail group delivers packages to most laboratories. Laboratories located across Adelbert Rd or Cornell Rd 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 Broadscope License requires that shipments be surveyed within three hours of arrival. In the past year, 331 isotope shipments (totaling 760 mCi) were inspected and approved by the RSOF after receipt on the campus. A few shipments/transfers off campus were made by laboratories. The RSOF assisted these laboratories by making sure that paperwork was properly prepared and proper labeling was used. There was one 68Ge sealed source transferred to UH. There were also three shipments off campus, which included 3H, 137Cs, 14C, & 60Co.

DISPOSAL OF RADIOACTIVE MATERIALS

Exclusive of decay of isotope in laboratories and minor inventory changes, isotopes were removed from laboratories by either 236 isotope waste pickups by RSOF staff (102 mCi) or by

90 AU-directed disposals into the sanitary sewers (25 mCi). The following table presents a breakdown by isotope of radioactive materials entering and leaving laboratories.

ISOTOPE	ORDERS		WASTE PICKUPS		SEWER DISPOSALS		TRANSFERS	
	#	mCi	#	mCi	#	mCi	#	mCi
²⁶ AI	0	0	0	0	2	0	0	0
¹¹ C	0	0	0	0	0	0	28	66.3000
¹⁴ C	12	3.071	39	2.285	13	1.714	6	1.351
⁵¹ Cr	0	0	0	0	1	0.008	0	0
¹³⁷ Cs	0	0	2	0.026	0	0	0	0
¹⁸ F	0	0	0	0	0	0	73	464.200
⁵⁹ Fe	2	2.0	6	0.257	6	1.035	0	0
³ H	33	21.712	77	16.277	27	8.954	10	2.272
124	1	0.590	0	0	0	0	0	0
125	6	0.3326	1	0.009	3	0.015	7	0.772
⁵⁴ Mn	0	0	0	0	1	0.072	0	0
²² Na	2	0.300	0	0	1	0.010	0	0
⁶³ Ni	0	0	0	0	1	3.643	0	0
³² P	251	648.960	89	58.413	27	4.664	27	8.382
³³ P	8	2.347	9	0.991	2	0.027	0	0
³⁵ S	16	80.752	13	23.995	6	4.593	0	0
Total	331	760.065	236	102.253	90	24.735	151	543.277

RADIOACTIVE MATERIALS	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
ļ										
Orders	331	358	311	428	832	776	933	1036	1310	1594
mCi	760	662	655	714	1692	1212	1332	1428	1470	1570
Pickups	236	275	417	556	548	506	634	725	796	1064
mCi	102	162	187	218	355	383	304	503	327	61
Sewer Disposals	90	59	89	76	90	98	119	98	148	160
mCi	25	11	24	5	14	14	12	12	17	18
Transfers	151	119	84	98	33	240	124	66	31	0
mCi	543	802	426	324	40	1234	273	149	21	0

SEALED SOURCES

Case Western Reserve University's sealed source inventory contains 142 sealed sources. Of these, 134 sealed sources are required to be inventoried every six months. One (1) of the 142 sealed sources is a low-dose irradiator. The low-dose irradiator is not currently in use. Eight (8) sealed sources require six-month leak tests, as stated in our ODH license. This includes 7 gamma sources and 1 neutron source. Four (4) sources are high-level dose irradiators, and one (1) is used to irradiate material with neutrons. There are currently two active Irradiators and two that are in storage. These 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, five (5) sealed sources were disposed, one sealed source was transferred, and one (1) new source was received. The low-dose irradiator is currently not in use.

INVENTORY	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Sealed Sources	142	147	213	211	213	207	168	204	204	171
Exempt	134	138	203	201	190	188	154	183	186	158
Irradiator	4	4	4	5	4	4	4	3	3	3
Neutron	1	1	1	1	1	1	1	1	1	1

RADIATION SURVEY METER CALIBRATIONS

Case Western Reserve University's ODH Broadscope 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 \$12,225 in cost saving over the fiscal year in lieu of using outside vendors.

CALIBRATION/ SERVICE	COST PER SERVICE	COST SAVINGS
136 meters	\$80/meter	\$10,880
0 pumps	\$70/pump	\$0
19 thyroid assays	\$55/assay	\$1,045
16 pre-filter changes	\$75/ set of 4/quarterly	\$300
	TOTAL COST SAVINGS	\$12,225

There are 219 survey meters on campus. The RSOF calibrated 136 of these meters in the last fiscal year. There were 12 meters removed from service. In service meter calibrations totaled 124. 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 changed every 90 days. Both fan units for the walk-in hood have been changed. The fan for compactor needs to be repair and a facilities request has been made. Currently, there are four filters that must be periodically changed for two units:

- Two single filter units for the chemical hood and decay area (located above the DOA office)
- One double filter unit for the walk-in hood (located in DOA Radiation Area)

No operational pumps for radioactive materials were calibrated for use in the iodination hoods.

CALIBRATION/ SERVICE	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Meter Calibration	136	121	142	172	170	157	188	233	245	250

METERS IN USE	TOTAL
Hi-Q	1
Inovision	2
Ludium	93
RPI Mini Monitor	15
Technical	1
Victoreen	9
WB Johnson	15

METER CALIBRATION BY MONTH	TOTAL
7/2011	10
8/2011	14
9/2011	1
10/2011	8
11/2011	21
12/2011	7
1/2012	10
2/2012	14
3/2012	7
4/2012	13
5/2012	15
6/2012	16

RAM SECURITY

Radioactive materials 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. Over the last year a trend toward fewer RAM security violations continued.

RAM	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04
SECURITY									
CHECKS									
Violations	17	24	71	19	37	54	74	89	104

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 7/1/2011 to 6/31/2013 with two 1-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. Two women declared their pregnancy. During 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 four 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 radiation generating (x-ray) equipment, such as fluoroscopy and X-Ray difractometers. The four Fluoroscopy users had collar badges.

Although only 20% of the workers currently monitored are required to wear dosimeters to comply with the terms of the Case Western Reserve University Broadscope License or Radiation generating equipment programs, the use of dosimeters is encouraged because it provides an excellent method for early detection of activities that might be dangerous to individual workers.

PERSONNEL MONITORING	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Pregnant Workers	2	2	1	1	2	2	6	6	13	15
Neutron	4	4	4	4	4	0	0	0	0	0
RGE/ X-Ray	30	28	45	103	70	38	60	201	160	180
Dental	47	34	28	28	28	28	28	28	28	28
General	456	448	518	698	665	705	905	1005	970	1030

Case Western Reserve University uses Luxel badges, which are considered to be state-of-theart 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 2012.

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 electron microscopes, X-Ray diffraction and particle

accelerators. There are also X-Ray units in use for health care & diagnostic research. There are currently 17 Authorized Possessors with equipment in 46 laboratories. Radiation-generating equipment is inventoried quarterly 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)	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Diagnostic units Disposed	4	3	3	3	4	4	7	3	2	1
Diagnostic units Purchased	4	3	3	3	3	4	11	2	1	1

The ODH has changed the Radiation Generating Units classification. One hand-held Dental unit was added this year. The table below reflects that change.

RADIATION GENERATING EQUIPMENT (IN USE)	11/12	10/11	09/10
Closed Beam Analytical	6	6	6
Computer Tomography	2	1	1
Electron Microscope/ Photoelectron Spectrometer	11	11	11
Enclosed System	4	4	4
Fluoroscopy	2	3	3
Hand-held Dental	2	1	1
Intraoral	27	27	27
Open Beam Analytical	1	1	1
Panoral	1	1	1
Particle Accelerator	1	1	1
RADIATION GENERATING EQUIPMENT (IN-OPERABLE)			
Closed Beam Analytical	3	3	3
Electron Microscope/ Photoelectron Spectrometer	2	2	2
Tube Only	26	26	26
TOTAL TUBES	88	87	87

RADIOACTIVE MATERIAL RELEASES

SEWER EXPOSURE CONTROL & MONITORING

State and Federal regulations permit Case Western Reserve University to dispose of low levels of radioactive materials into the sanitary sewers. The Northeast Ohio Regional Sewer District (NEORSD) requires semiannual reports on radioactive material discharged to the sanitary sewer system. Case Western Reserve University's sewer releases were in compliance with both Federal and State regulations. The report for July through December 2011 was filed by January 31, 2012 and the report for January through June 2012 was filed by August 8, 2012. 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 2011 calendar year, radioactive material releases to the air were less than 10% of the maximum levels set by the EPA. Therefore, Case Western Reserve University 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%. Experiments requiring use of large amounts of iodine in especially volatile form are routinely carried out in closed systems to prevent airborne release of radioactive iodine. There were no experiments requiring the use of volatile iodine conducted this fiscal year.

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 2011-2012, there were no active iodination laboratories. The RSO maintains an inventory of five 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 1.0 mCi of volatile radioactive iodine. The following must be completed prior to the
 procedure.
- Performance of a baseline bioassay for anyone involved in the procedure that does not have a baseline radioactive iodine bioassay on file.
- Arrangements for monitoring of effluent releases to the atmosphere during the first iodination procedure
 using a new protocol to measure and mitigate any release to the environment.

After an iodination procedure, individuals involved in the procedure must contact the RSOF and arrange for a bioassay to be completed by the end of the next business day. Bioassays were completed for the RSOF staff involved in radioactive waste handling. There were no iodination procedures performed this fiscal year. No workers exceeded 10% of the ODH limits. This chart highlights the sustained decrease in iodination procedures in University laboratories.

IODINATION PROCEDURES	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Total	0	0	0	0	0	6	6	7	11	20

125	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
BIOASSAYS		ļ								
RSOF Staff	19	24	24	44	44	32	64	67	64	40
Additional	0	0	0	0	0	0	7	10	13	20
Total	19	24	24	44	44	32	71	77	77	60

TRITIUM

Urine bioassays must be carried out for individuals using more than 10 mCi 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.

Seven (7) minor incidents documented over the past year.

INCIDENTS	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Major	0	0	0	0	1	2	0	1	1	5
Міпог	7	18	17	20	6	7	0	4	8	5
TOTAL	7	18	17	20	7	9	0	5	9	10

DATE	INCIDENT	CONTAMINATION	ROOT CAUSE	FOLLOW UP
5/4/2012	Minor Incident	DOA 990 CO2 Dump and Alarm	During return from a waste pickup, the DOA 990 RAM waste alarm sounded and discharged all the CO2 into the facility. No one was injured and no inventory lost. The Fire department and HAZMAT were called.	The Fire Marshall determined the incident to be a malfunction of the Fire Suppression System due to extreme heat in the DOA Facility. The Fire suppression system and HVAC system will be updated. Safety Drills will be performed twice/year.
4/13/2012	Minor Incident	Power Outage	During a power outage, Irradiator access was hampered.	RSOF contacted Security and the reader was reset. Area was secured.
10/13/2011	Minor Incident	Irradiator Unauthorized Entry	Problem with the Biometric Reader. Irradiator Manager contacted Security to deactivate the reader before contacting RSOF. Without an escort, Security accessed the room to repair the reader. Neither person was authorized to do this.	Both persons were contacted and informed that they must notify RSOF Irradiator Safety Staff to deactivate the reader or escort for access to Irradiator rooms. The door was secured and the Biometric reader functional.
9/9/2011	Minor Incident	RAM Unsecured	WRB 1119 Liquid Waste Storage Room door found open and the lights on.	RAM Waste Manager was notified, door properly latched, & Facilities checked the door-locking mechanism
9/2/2011	Minor Incident	RAM Unsecured	DOA 990 RAM Waste Facility back right door found to be unsecured.	RAM Waste Manager was notified, door properly latched, & Facilities oiled the doorlocking mechanism so that it no longer sticks.
7/21/2011	Minor Incident	Unauthorized Move	RSOF was not notified of relocation of laboratories in Wood Building. No RAM was moved, only equipment.	AU avouched the incident and its correction. RSOF picked up all waste, decommissioned old laboratory space, posted new laboratory spaces, & received new maps of the areas from the AU.
7/11/2011	Minor Incident	Improper PPE	AU wearing flip-flops with a laboratory coat in the laboratory	AU avouched the incident and its correction. AU switched to more appropriate shoes while working in the laboratory

EHS WEB SITE & NEWSLETTER

The updated EHS home web site (https://case.edu/ehs/) provides integrated web-based access to EHS services. Information on training classes, on-line 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

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:

- Dosimetry
- What should we know about Radon?
- Recording Survey Results in DPM
- Disposal of Radioactive Liquids
- Do you have to wear that badge?
- Security of Radioactive Materials
- Three New EHS Members!

LASER SAFETY PROGRAM

The Laser Safety Program and related training has progressed well since its inception in September 2004. A standard operating procedure has been incorporated into the Physical Safety Manual that is provided to all laser users.

There are a total of 89 lasers on the campus for 37 Laser Pls in 12 buildings. There are currently 132 active users of lasers in 41 laboratories. This includes 16 laboratories in the class 1-3A groups and 25 laboratories in the class 3B-4 groups. There were 8 active users that do not have to retrain due to eye-safe laser use. The lasers of greatest concern are those labeled Class 3B and Class 4. There are 37 Class 4 lasers (17 active and 20 inactive), 22 Class 3B lasers (18 active and 4 inactive), and 22 lasers in the other classes of 1, 2, and 3A.

There are 17 class 3B/4 enclosed laser systems that are considered eye-safe under normal use thus decreasing the hazard to the user. These 17 lasers were incorporated into confocal systems, thus they are no longer counted as separate lasers. Twenty-six (26) audits were performed during this fiscal year. There were 5 laser laboratories found during chemical inspections. Upon further investigation, these laboratories were noted as being inactive and the old Laser labels were removed from the door. This fiscal year 2 current Laser Pl's went Inactive.

There were two Laser incidents reported. One was a laser beam exposure and one was a possible scattered laser light exposure. Both incidents were investigated and were documented as no damage found after eye exams.

The Laser safety training Power Point for new users was updated February 2012 and the Laser online retraining Power Point update is in progress. A question pool is being generated and the presentation should be incorporated into the campus Black Board system by the end of the calendar year. The Onsite database has 80 percent of the laser inventory incorporated. An online Laser Awareness training for classes of 1, 2, and 3A users is in progress and will address eye safe laser and laser system use on campus.

ULTRA VIOLET (UV) SAFETY PROGRAM

With increased use of UV equipment on campus, a program for UV Safety has been implemented. A UV safety PowerPoint presentation has been placed on the EHS website. UV users are being identified through laboratory inspections and new employee orientations and training.

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 the AU facilitates these operations. There were 20 clearances required for 58 pieces of equipment. A total of 4 relocations and 11 terminations were completed over the past year.

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 Case Western Reserve University 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 Stericycle (formally BFI), 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 Case Western Reserve University. 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 Chemical Analytics, 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 ADCO Services, a commercial radioactive 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 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 & DISPOSAL OF ANIMAL REMAINS AND BIOHAZARDOUS WASTE

The RSOF maintains two –20°C freezer for storage of radioactive animal remains and waste. One is located at the Animal Resource Center (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 by the RSOF.

WASTE GENERATED IN JULY 1, 2011 - JUNE 30, 2012

	GENERATED 7/1/2011- 6/30/2012	DISPOSED: HAZ, WASTE SVCS.	DISPOSED: SEWER	DISPOSED: CHEMICAL SAFETY	DISPOSED: ADCO	IN STORAGE AS OF 6/30/2012
Short-Lived Dry	25	22*	0	6	1	27
Long-Lived Dry	10	0	0	0	3	0
Scintillation Vials	В	0	0	0	7	0
Animals	0.35	0	0	0	0	0.6
Long-Lived Sewer	17	0	17	0	0	0
Long-Lived Non-Sewer	55	0	0	0	40	2
Short-Lived Sewer	18.5	0	18.5	0	0	0
Short-Lived Non-Sewer	1	0	0	0	1	0

All values in the dry waste, vial, and animal categories denote the number of 55-gallon drums. All values for the liquid waste categories are in gallons. The single asterisk (*) denotes the number of drums generated prior to July 1, 2011, kept for decay in storage, and disposed during the period of July 1, 2011–June 30, 2012. During this fiscal year, all long-lived hazardous aqueous waste was disposed.

ADCO animal waste cost = \$22.5/lb. for 10 pound barrel = \$225 per 10 pound barrel ADCO dry waste cost = \$500 per 55-gallon drum

The cost of disposal for one drum of biomedical waste at Hazardous Waste Services (Stericycle) is \$51 per drum. There were 22 drums of dry waste surveyed and disposed during 2011-2012 fiscal year at a cost of \$1,122. Without the decay in storage program, it would cost \$500 to send one 55-gallon drum of decay in storage (DIS) dry waste and it would cost \$225 per 10 lb. drum of animal waste through ADCO services. Therefore, in the absence of decay in storage, the cost to dispose of the waste drums through ADCO would have been \$11,000. Thus, the indirect savings to researchers due to the decay in storage program was \$9,878.

WASTE GENERATION	11/12	10/11	09/10	08/09	07/08	06/07	05/06	04/05	03/04	02/03
Short-Lived Dry	25	25	87	95	91	85	72	66	63	66
Long-Lived Dry	10	11	25	50	35	20	25	28	31	26
Scintillation Vials	8	7	12	30	25	30	47	44	45	39
Animals	0.35	0,25	0	1	2	4	3	2	1	3
Long-Lived Sewer	17	11.5	60	50	38	35	46	55	60	50
Long-Lived Non-Sewer	55	91	120	80	20	5	15	5	0	0
Short-Lived Sewer	18.5	21.5	65	50	140	135	125	115	80	76
Short-Lived Non-Sewer	1	3	10	20	25	30	20	35	75	85

The contract for radioactive waste disposal has been renewed for 11/1/2010 to 6/30/2013 with two 1-year renewal options with ADCO Services. This contract provides for disposal of all long-lived dry materials, scintillation vials, & animal wastes.

RECYCLING PROGRAM

The RSOF occasionally obtains laboratory equipment, in very good condition, from AU's 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 AU's if and when their funds do not allow them to buy new radioactive materials handling equipment. This cost-saving recycling program resulted in re-use of equipment that saved AUs & EHS more than \$5,000 during 2011-2012 in lieu of waste disposal.

RADIATION SAFETY COMMITTEE AUDITS

Radiation Safety Committee (RSC) audits are carried out in two different ways:

- Performance audits are conducted on-site at the Radiation Safety Office (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 Limits	10
RGE inventory/ training	10
Ancillary staff training	10
AU/ worker training	10
Radiation survey meters	10
Waste disposal facility	2
Shipping papers	10
RAM security checks	10
Bioassays	10
Semi-Annual mailings	10
Sealed sources	10
Web site Accuracy	1
Irradiators	5
Room Surveys (Active/Decommissioned)	10
Compliance Reviews	10
Lasers	10
Licensing	10
Dosimetry	10
Incidents	10

These audits were conducted between October and December 2011 and between March and June 2012. This effort resulted in the review of more than 170 files, in the program areas listed above.

RSC TRI-ANNUAL AUDITS FOR 2011-2012

RSC AUDIT COMMENT:

In November 2011 the Radiation Safety Committee Members, conducted a tri-annual audit of the following components of the Radiation Safety Office:

- AU and Worker Training
- Compliance Review
- Dosimetry Program
- Isotope Possession Limits
- Incident Reports
- Irradiator Program
- Laser Program
- Licensing Status
- Security Checks
- · Radiation Generating Equipment Inventory and Training

- Sealed Source
- · Support Staff Training
- Valid RAM Application
- Waste Disposal Facilities (DOA990/Wolstein) and RSOF Laboratory

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

AU AND WORKER TRAINING

Ten (10) files were examined to verify the training dates of AU and workers during this quarter. Four (4) deficiencies regarding training were noted.

RSOF RESPONSE

The two Authorized Users and two Radiation workers were contacted and trained in October 2011.

COMPLIANCE REVIEW

Ten (10) files were examined to verify that AU laboratories were audited within the last six months and that any non-compliant issues were appropriately followed up. No deficiencies were noted.

RSOF RESPONSE

No response required.

DOSIMETRY PROGRAM

Ten (10) files were randomly examined. No deficiencies were reported.

RSOF RESPONSE

No response required.

ISOTOPE POSSESSION LIMITS

Ten (10) files were examined to verify that the amount of RAM ordered is within AU possession limits and that the orders are in the new database. No deficiencies were reported.

RSOF RESPONSE

No response required.

INCIDENT REPORTS

There were nineteen (19) incidents reported since February 2011. No injuries or damage were reported in any of these incidents. All incidents were effectively resolved in a timely manner.

RSOF RESPONSE

No response required.

IRRADIATOR PROGRAM

Irradiator information files were examined to verify that the irradiators were audited by the RSOF within the last six months. No deficiencies were reported with respect to training of personnel. No deficiencies were noted with respect to last date of audit. However, two (2) deficiencies were noted with respect to matches between "USER LOG" and "USER LIST".

RSOF RESPONSE

There was one person on the Irradiator list that had access temporarily suspended due to training lapse. The person was trained and reinstated.

LASER PROGRAM

Information was reviewed for accuracy regarding laser inspections, inventory, and current training. Ten (10) files were audited. All files were noted for one or more deficiencies. These deficiencies range from no inventory on file to rooms not properly demarcated. The auditor indicated that reviewing this program is very difficult due to lack of synchronization between files and database.

RSOF RESPONSE

The Laser user files were updated to include the list of workers and the inventory. All remaining Laser user files were reviewed and updated with current information that coordinates with the Laser database. Work on the database is in progress.

LICENSING STATUS

An audit was conducted to verify the status of the radiation licensing status of the radiation safety office. Components of this audit include the following: Broadscope License, RGE License, Waste License, Radiation Manual, X-ray Manual, and Radiation Training, X-Ray training, Radiation Online Retraining, and RSC Guidelines. All licenses are active and accurate.

RSOF RESPONSE

No response required.

SECURITY CHECKS

Reports were reviewed for verification and documentation of radioisotope security checks. Ten (10) files were examined, and no deficiencies were noted.

RSOF RESPONSE

No response required.

RADIATION GENERATING EQUIPMENT INVENTORY AND TRAINING

Ten (10) files were examined. No deficiencies were found in any of the files examined.

RSOF RESPONSE

No response required.

SEALED SOURCE

Ten (10) files were randomly screened for verification that the sealed source had been tested for leaks. No deficiencies were reported for files examined.

RSOF RESPONSE

No response required.

SUPPORT STAFF TRAINING

Ten (10) files were randomly screened for verification of training. No deficiencies were reported.

RSOF RESPONSE

No response required.

VALID RAM APPLICATION

Ten (10) files were randomly audited to verify that they were valid, complete and current. One (1) file was found to be deficient (RAD room not designated).

RSOF RESPONSE

The laboratory locations have been added to the Onsite database and designated as Radiation rooms for the Authorized User.

WASTE DISPOSAL FACILITIES (DOA990/WOLSTEIN) AND RSOF LABORATORY

The Waste Disposal facilities and Laboratories of the RSOF were inspected to ensure safe operation and adequacy of amenities. All records of the Facilities Maintenance and General Housekeeping, Record Maintenance, and Waste Storage and Handling were audited and found to be compliant, adequate, orderly, and secure.

RSOF RESPONSE

No response required.

RSC AUDIT COMMENT:

In March 2012 the Radiation Safety Committee Members, conducted a tri-annual audit of the following components of the Radiation Safety Office:

- Survey Meters
- EHS Website (Radiation Safety)
- Bioassavs
- Direct Package Pickup
- Active/Decommissioning Survey

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

SURVEY METERS

Ten (10) files were randomly audited. One deficiency was denoted on RSOF 10643 (wrong calibration date on tag).

RSOF RESPONSE

The calibration date on the form was corrected to match the tag.

EHS WEBSITE (RADIATION SAFETY)

Ten (10) links on the Radiation Safety Office Web Page were reviewed for being up-to-date for training, forms, and information related to safety. One (1) deficiency was reported - Laser Safety program is overdue (1/6/2011).

RSOF RESPONSE

The Laser Safety Manual was reviewed and revised and the EHS Radiation website was updated to reflect the current revision date.

BIOASSAYS

No deficiencies were reported as no orders of >1 mCi of ¹²⁵l or >10 mCi ³H were ordered over the past six (6) months.

RSOF RESPONSE

No response required.

DIRECT PACKAGE PICKUP

Ten (10) files were examined for accuracy in shipping papers over the past quarter. One (1) deficiency was noted in which there is no indication that the AU picked up the isotope.

RSOF RESPONSE

The package receipt was corrected to reflect a direct pick up for the AU.

ACTIVE/DECOMMISSIONING SURVEY

Ten (10) files were randomly audited. No deficiencies were noted. However, the auditor noted that the audit procedures need to be revised due to the unavailability of data in the new computer database.

RSOF RESPONSE:

The Onsite database has now been populated with the active and decommissioned room surveys for efficient review. The RSOF is in the process of preparing a database report that provides a list of commissioned and decommissioned rooms.

RSC AUDIT COMMENT:

The RSC conducted a third trimester audit during May 2012. Each audit consisted of randomly selecting five (5) to twenty (20) files in the past year to ensure items were up-to-date, accurate, and matched the database. The following components of the Radiation Safety Office were audited:

- Irradiator
- Laser
- Support Staff Training
- AU/Worker Training

- Isotope Orders/Possession Limits
- RGE Inventory/Training
- Sealed Sources
- Licensing
- · Security Checks
- Incidents
- Dosimetry
- Waste Facility
- Valid RAM Application
- Compliance Review

IRRADIATOR

A Quarterly audit of the Irradiator Information Files was performed by Dr. Jankowsky in May 2012 to verify that the irradiators were audited by the RSOF within the past six months, and that any compliance issues were appropriately followed up and pending issues corrected. Four radiators were active on campus and each file was up-to-date and compliant. Dr. Jankowsky noted 7 deficiencies in Irradiator User Training for tests that were past due. The RSOF was notified of the deficiencies.

RSOF RESPONSE

The tests, for each irradiator worker, was found in their files and updated in the stand alone database.

LASER

The laser program was audited by Dr. Jankowsky for accuracy regarding laser inspections, inventory and status of personnel training. Ten (10) files were audited in the quarterly audit, May 2012. Dr. Jankowsky noted 6 deficiencies within the audited files corresponding to inventory lists and/or personnel training. The RSOF was notified of the deficiencies. Dr. Jankowsky further noted that the Operating Procedure is in need of updating.

RSOF RESPONSE

The Laser user files were updated to include the list of workers and the inventory. All remaining Laser user files were reviewed and updated with current information that coordinates with the Laser database. Work on the database is in progress for this part of the program.

SUPPORT STAFF TRAINING

A quarterly 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 Services. Ancillary workers were surveyed for May 2012. Dr. Devireddy examined 10 files and noted no deficiencies.

RSOF RESPONSE

No response required.

AU/WORKER TRAINING

Authorized users and worker training files were audited for a quarterly audit in May 2012. Dr. Devireddy examined10 records of workers that were overdue for radiation safety training and verified notices have been sent to overdue personnel. Dr. Devireddy noted one deficiency for an AU who never trained and a file cannot be found for this individual.

RSOF RESPONSE

Reminder notices were sent to all personnel that were overdue for training. Review of response the notices showed that some individuals had left the University and others were no longer Radiation workers. These database inaccuracies were corrected.

ISOTOPE ORDERS/POSSESSION LIMITS

Dr. Berdis audited 10 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 for the quarterly audit in May, 2012. Dr. Berdis reported no deficiencies in this paperwork.

RSOF RESPONSE

No response required.

RGE INVENTORY/TRAINING

Quarterly inventory status and equipment surveys were examined by Dr. Croniger who examined 10 files for the May 2012 quarterly audit. Dr. Croniger noted 3 deficiencies in quarterly inventory reports. RSOF was notified of the deficiencies.

RSOF RESPONSE

The inventories were updated and several workers were determined to no longer be x-ray users.

SEALED SOURCES

Files verifying that sealed sources had been leak tested were audited for the quarterly audit, May 2012. Ten (10) files were examined by Dr. Croniger who reported one deficiency for the report period. A physical inventory sheet for one AU was missing. The RSOF reported the original form was misplaced and a replacement form was generated.

RSOF RESPONSE

The original source sheet was misplaced. The source sheet was placed in the correct file.

LICENSING

A quarterly audit was conducted to verify the licensing status of all ODH licenses and registrations during the May 2012 audit. Components of the audit include: Broadscope license, RGE license, RSC member status, RSC guidelines and Radiation Safety space and equipment. Dr. Schiemann reviewed all license programs and reported no deficiencies. All licenses are active and accurate.

RSOF RESPONSE

No response required.

SECURITY CHECKS

Verification and documentation of radioisotope security checks were performed for the quarterly audit, May 2012. Dr. Schiemann reports that 3 security checks were generated during this period. Unlocked RAM storage accounted for all of these security checks. All incidents were noted to be resolved in an efficient and timely manner.

RSOF RESPONSE

No response required.

INCIDENTS

A review of monthly incident reports for the Quarterly Audit, May 2012 was performed by Dr. Coller for verification and documentation of follow-up by the RSOF. During this period there was 1 incident reported, a power outage. This incident was effectively resolved in a timely manner.

RSOF RESPONSE

No response required.

DOSIMETRY

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 Quarterly Audit May, 2012. Dr. Valadkhan audited 10 records and reported no deficiencies within the active personnel files.

RSOF RESPONSE

No response required.

WASTE FACILITY

The waste disposal facilities (DOA990/Wolstein) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF for the quarterly audit in May 2012. 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.

VALID RAM APPLICATIONS

RAM applications were audited for the quarter on May 2012 to verify that the applications were complete and valid. Dr. McCormick audited 10 files and reported 4 deficiencies. Deficiencies were due to three instances where the Inventory list did not match the decay list and one instance where personnel list did not match. Dr. McCormick further noted that the standard operating procedure needed to be updated for this survey to account for accuracy and to update language in the forms. The RSOF was notified of the deficiencies.

RSOF RESPONSE

The RAM Quarterly Audit forms were updated to reflect to the Onsite database from the Helix database. Information is still being entered into the Onsite database as part of the database change over from Helix to Onsite and should be more accurate during the next Audit.

COMPLIANCE REVIEW

Compliance review audits were performed to ensure that any non-compliance issues were appropriately resolved. Upon examination of 10 files for the Quarterly audit on May 2012, Dr. McCormick noted no deficiencies.

RSOF RESPONSE

No response required.

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

ANNUAL RADIATION SAFETY PROGRAM AUDIT REPORT

The Radiation Safety Committee conducted its annual audit of the Radiation Safety Office the first week in June 2012. Members of the RSC conducted the audit. The committee reviewed the performance of 20 components of the RSOF. The areas were:

- 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
- Radiation Website
- Room Surveys
- Seal Source /Leak Test
- Shipping Papers
- Semi-Annual Mailings (air/sewer inventory)
- Valid RAM Application
- Water Disposal Facilities (DOA990, Wolstein) & RSOF Laboratory

The Results of this audit are summarized in this report as follows.

ANCILLARY STAFF TRAINING

RSC AUDIT COMMENT:

An annual 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 Services. Ancillary workers were surveyed from July 1, 2011-June 30, 2012. Dr. Devireddy examined 50 files and noted one deficiency from a worker that did not pass the test. This worker has been notified.

RSOF RESPONSE:

The worker re-tested and passed with 95%.

AU AND WORKER TRAINING

RSC AUDIT COMMENT:

Authorized users and worker training files were audited for a period from July 1, 2011-June 30, 2012. Dr. Devireddy examined 50 records and noted 16 workers that were overdue for radiation safety training. Dr. Devireddy further noted a lack of training information for an AU (PI name not on file). Overdue workers were notified of their training status.

RSOF RESPONSE:

The overdue workers were contacted. Many updated their training promptly. Some had either left CASE or were no longer working in a Radiation Laboratory. The database was updated to reflect these changes.

BIOASSAYS

RSC AUDIT COMMENT:

An audit was performed to verify completion of bioassays for laboratories using >10mCi of ³H and/or 1mCi ¹²⁵I during the period July 1, 2011-June 30, 2012. No shipments exceeding these doses of each respective isotope were made; therefore, Dr. Jankowsky noted no bioassays had been performed for this period.

RSOF RESPONSE

No response required.

COMPLIANCE REVIEW

RSC AUDIT COMMENT:

Compliance review audits were performed to ensure that any non-compliance issues were appropriately resolved. Upon examination of 50 files Dr. McCormick noted that 7 files indicated Overdue Training issues, 3 files indicated delinquent Room Surveys, two files indicated other (summer) personnel training updates and two files indicated Laboratory Map changes were needed. Overdue personnel for training were notified, as were the PI of all other laboratories with noted deficiencies.

RSOF RESPONSE

Most compliance reviews have various minor deficiencies that are corrected during and after the review. These deficiencies include past due training, past due meter calibration, as well as other incomplete room surveys. Laboratories very rarely have repeat deficiencies. All noted deficiencies are corrected in a timely fashion and are noted at the next compliance review.

ISOTOPE ORDERS, AU POSSESSION LIMITS, AND THE HELIX DATABASE

RSC AUDIT COMMENT:

Dr. Coller audited 50 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. Of the files audited only one file was not found in the Helix database. This order had been cancelled by the RSOF and was therefore not in Helix.

RSOF RESPONSE:

The canceled order was corrected in the database.

DOSIMETRY PROGRAM

RSC AUDIT COMMENT:

An audit of Current Dose records held by the RSOF was performed to verify that AU laboratory workers were current in dose record and active radiation badges for the period July 1, 2011–June 30, 2012. Dr. Valadkhan audited 50 records and reported 25 individuals were deficient for badges. In addition, 2 workers were found to have no records within the active personnel files. Individuals without badges were notified of the deficiency and the PI of workers not appearing in the active record was notified.

RSOF RESPONSE

This database was audited by the RSOF following Dr. Valadkhan's review. Many of the personnel that did not have badges were not working with radioactive material currently or they were only working with 3H or 14C. Current dosimetry records were placed in the active worker's files.

INCIDENT REPORTS

RSC AUDIT COMMENT:

A review of monthly incident reports From July 1, 2011-June30, 2012 was performed by Dr. Coller for verification and documentation of follow-up by the RSOF. During this period there were a total of 4 incidents reported. All incidents were effectively resolved in a timely manner.

RSOF RESPONSE

No response required.

IRRADIATOR INFORMATION REVIEW

An audit of the Irradiator Information Files was performed by Dr. Jankowsky to verify that the irradiators were audited by the RSOF within the past six months, and that any compliance

issues were appropriately followed up and pending issues corrected. Four radiators were active on campus and each file was up-to-date and compliant.

RSOF RESPONSE

No response required.

LASER PROGRAM REVIEW

The laser program was audited by Dr. Jankowsky for accuracy regarding laser inspections, inventory and status of personnel training. Thirty-eight (38) files were audited. Laboratories that contained no files for equipment indicated 9 deficiencies and laboratories that had personnel that had not been trained indicated 5 deficiencies. Improved compliance in the laser program is noted, however further improvement is necessary.

RSOF RESPONSE:

The Laser Program is a new program that continues to improve through review of equipment inventory and personnel training for currency and accuracy.

LICENSING STATUS

RSC AUDIT COMMENT:

An audit was conducted to verify the licensing status of all ODH licenses and registrations during the period July 1, 2011-June 30, 2012. Components of the audit include: Broadscope license, RGE license, Waste license, and Radiation Manual, X-ray Manual, Radiation Training, X-Ray Training, Radiation Online Training and RSC guidelines. Dr. Schiemann reviewed all license programs and reported no deficiencies. All licenses are active and accurate.

RSOF RESPONSE

No response required.

RADIOISOTOPE SECURITY CHECKS

RSC AUDIT COMMENT:

Verification and documentation of radioisotope security checks were performed for the period July 1, 2011- June 30, 2012. Dr. Schiemann reports that 16 security checks were generated during this period. Unlocked RAM storage accounted for 12 of these security checks, incorrect posting generated 3 security checks and one un-armed alarm system generated a security check. All incidents were noted to be resolved in an efficient and timely manner.

RSOF RESPONSE:

No response required.

RADIATION GENERATING EQUIPMENT INVENTORY AND TRAINING

RSC AUDIT COMMENT:

Quarterly inventory status and equipment surveys were examined by Dr. Croniger who examined 47 files for the period July 1, 2011- June 30, 2012. Dr. Croniger noted no deficiencies in quarterly inventory reports and one (1) deficiency in an equipment survey for Dr. Lee (Bolwell B164). Dr. Lee was notified to provide the equipment survey.

RSOF RESPONSE:

The misplaced survey was place in the proper file.

RADIATION SURVEY METERS

RSC AUDIT COMMENT:

Compliant calibration of survey meters was audited for the period July 1, 2011- June 30, 2012. Fifty (50) files were examined by Dr. Croniger who noted only one (1) meter that was out of service.

RSOF RESPONSE:

The broken survey meter was taken out of service. The database has been updated.

EHS WEBPAGE (RADIATION SAFETY)

The website for the RSOF was audited to ensure proper operation, access and current links were operational. Dr. Devireddy reports that the Homepage, Training pages and links as well as the Forms and Manuals pages were all operational.

RSOF RESPONSE

No response required.

ROOM SURVEYS (ACTIVE/DECOMMISSION)

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. Schiemann examined 50 files and noted no deficiencies.

RSOF RESPONSE

No response required.

SEALED SOURCE LEAK TEST

RSC AUDIT COMMENT:

Files verifying that sealed sources had been leak tested were audited for the period of July 1, 2011- June 30, 2012. Forty-nine (49) files were examined by Dr. Croniger who reported no deficiencies for the report period.

RSOF RESPONSE:

No response required.

SHIPPING PAPERS

RSC AUDIT COMMENTS:

An annual audit of shipping papers was performed to verify that paperwork is completed for each transfer of radioactive material for the period July 1, 2011- June 30, 2012. Dr. Coller examined 32 files and found no deficiencies among paperwork verifying transfers.

RSOF RESPONSE:

No response required.

SEMI-ANNUAL MAILINGS (AIR/ SEWER INVENTORY)

RSC AUDIT COMMENT:

An annual audit of the air/sewer disposal inventory was performed for the period July 1, 2011-June 30, 2012. Forty-seven (47) files were reviewed by Dr. Valadkhan who noted 4 deficiencies. Records were not found for two investigators and two records were out of date (overdue). The PIs were informed to submit their inventories.

RSOF RESPONSE:

One newly approved researcher had not yet received a mailing. One researcher response had been misfiled. The remaining two researchers were in Storage Mode and a letter was placed in their file.

VALID RAM APPLICATION

RSC AUDIT COMMENT:

RAM applications were audited for the period July 1, 2011- June 30, 2012 to verify that the applications were complete and valid. Dr. McCormick audited 46 files and reported no deficiencies. One application was missing due to the PI in the process of becoming an 'inactive' user (Storage Mode).

RSOF RESPONSE:

The Authorized User has gone from Storage Mode to Inactive Status.

WASTE DISPOSAL FACILITIES (DOA990/WOLSTEIN) & RSOF LABORATORY

RSC AUDIT COMMENT:

The waste disposal facilities (DOA990/Wolstein) and RSOF Laboratory were inspected to ensure safe operation and maintenance as required by RSOF for the period July 1, 2011- June 30, 2012. 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.

SUMMARY

RSC AUDIT COMMENT:

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 Radiation Safety Committee, 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 Room Surveys (Active/ Decommissioned) RAM Security Checks Semi-Annual Mailings RGE Inventory/ Training Ancillary Training Licensing Incidents Irradiator Bioassays
Dosimetry
Survey Meters
Compliances
Website Accuracy
Liaison Program
Laser Program

INTERNAL AUDITS

Update of RAM applications – Audits of RAM applications revealed applications that were more than ten (10) years old. These applications have been flagged for updated to be consistent with existing application requirements. AUs are now required to update protocols that are more than 10 years old and every 5 years thereafter. There are currently twenty-three (23) applications that require updating. Nine (9) RAM Applications were updated this fiscal year. During the 7/2012-6/2011 fiscal year twelve (12) RAM Applications were updated.

Continuous Air Monitoring (CAM) Audit – 125I air monitoring has been checked since 1992 using the CAM. The total 125I release has been 0.00uCi since 9/2007. In 10/2008, the filter change out for the CAM was decreased from two times per month to once per month due to the decease of 125I air monitoring for the DOA 990 waste room. The CAM was turned off on 9/2009 due to no 125I releases to the environment in the DOA 990 waste area. The CAM is currently being repaired and upgraded for use in the DOA 990 waste facility in late 2012.

Bioassay Audit – The Bioassay Program is audited monthly to document the use of any volatile or non-volatile 125I. 125I Bioassays are completed quarterly to correspond with badge exchange. The frequency for 125I bioassays decreased for the Radiation Safety Staff from monthly to quarterly since there has been no documented use of volatile 125I by researchers on the CASE campus and no documented 125I releases to the environment in the DOA 990 waste area since 9/2007. There have been no documented 125I uptakes by the Radiation Safety staff as evidenced by monthly bioassay records that have been kept by our office for the past 20 years. In the event that volatile 125I experiments resume, the monthly bioassay frequency and the twice per month change-out of the filter in DOA would be reinstated.

Clearances Audit – Radiation equipment clearances are done on an as needed basis. Eighteen (18) clearances were completed this fiscal year for items that were relocated or disposed.

Incidents Audit – There were seventeen (17) radiation incidents for 2011 and two (2) radiation incidents recorded for the 2012 as of June 30, 2012. The incidents occurred in the following buildings: BRB (5), WRB (4), Bishop (3), Wood (3), DOA (2), Lerner (1), & Robbins (1). The incident types are as follows: Unapproved package (5), Alarm (2), Bad Sewer Disposal (2), Unsecured door (2), Unauthorized move (2), Improper waste (1), Unapproved transfer (1), PPE deficiency (1), Unauthorized access (1), Power outage (1), & CO2 Dump (1).

RAM Package Receipt Audit – There were thirty-one (31) direct pickups of RAM Packages this fiscal year. The direct pickups were taken to the following buildings: WRB (10), Millis (5), & AW Smith (1).

Sealed Sources Audit – All 139 source files were reviewed for a total of 30 Authorized Users. Inspection frequency includes 6-month leak tests (8) and 6-month inventories (131). The sealed source types include: LSC (28), Homemade Source (24), Button (22), Rod (21), Disc (21), Survey meter (12), & Detector (11).

Decommissioned Room Surveys Audit – There were 161 decommissioned room surveys audited. Each decommissioned room file was entered in the Onsite database along with the date of commissioning and decommissioning.

Active Room	Surveys	Audit -	There '	were 14	45 act	ive r	room	survey	s audited	d. Each	active	room
file was enter	red in the	Onsite	databa	se alor	ng with	n the	date	of cor	nmission	and the	respo	nsible
AUs.					-						•	

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 Thornton-Porter on 9/2/2012 and reviewed by Dr. David Sedwick. It covers fiscal years 7/1/2011-6/30/2012.

APPENDIX

AUTHORIZED USERS WITH STATUS CHANGE DURING FISCAL 2011-2012

RADIATION ACTIVE

Eben Alsberg (1/2012) Zhenghong Lee (1/2012) Faramarz Ismail-Beigi (5/2012) Vincent Monnier (5/2012) Robert Salomon (8/2011) David Wald (11/2011) Thomas Gerken (1/2012) Eric Arts (7/2011) Robert Petersen (4/2012) Timothy Nilsen (5/2011) Jonathan Stamler (5/2012) Junran Zhang (1/2012)

STORAGE MODE

Joseph Lamanna (8/2011) Marian Harter (1/2012) Paul MacDonald (1/2012)

RADIATION INACTIVE

James Kazura (8/2011) Helene Bernstein (3/2012) Kumar Alagramam (4/2012) Marian Harter (4/2012) Michael Maguire (10/2011) Clark Distelhorst (3/2012) Edward Greenfield (4/2012)

DEPARTED

Shunichi Murakami (4/2012)

X-RAY AUTHORIZED POSSESSOR LIST

LASER USERS

Iwan Alexander Mary Barkley

Jesse Berezovsky

Robert Brown

Clemens Burda

Paul Carey

Patty Conrad

Kevin Cooper (Inactive)

Corbin Covault (Inactive)

Carlos Crespo

David Dean

Diana Driscoll

James Drake

Dominique Durand

Steven Eppell Philip Feng

Roger French

Maryann Fitzmaurice (Inactive)

Alex Huang Yoshikazu Imanishi

Hatsuo Ishida

James Jacobberger

Alexander Jamieson

Eckhard Jankowsky

Jaikrishnan R. Kadambi

Yasuhiro Kamotani

Kathleen Kash

Melissa Knothe Tate

Jack Koenig LaShanda Korley (Inactive)

Jay Adin Mann

Roger Marchant Heidi Martin

Thomas McCormick

Edward Medof

Claudia Mizutani

Wyatt Newman

Nancy Oleinick Roger Quinn

Sayed Qutubuddin (Inactive) Rajesh Ramachandran

Andrew Rollins

Charles Rosenblatt

John Ruhl

Shasta Sabo

Daniel Scherson

David Schiraldi

David Schwam

W. David Sedwick (Inactive)

Alp Sehirlioglu

Jie Shan

Kenneth D. Singer

Benjamin Strowbridge

Dustin Tyler



Environmental Health & Safety Organizational Chart

