

**CASE WESTERN RESERVE UNIVERSITY
DEPARTMENT OF OCCUPATIONAL &
ENVIRONMENTAL SAFETY (DOES)
RADIATION SAFETY
ANNUAL REPORT 2006-2007**

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RADIATION SAFETY ANNUAL REPORT 2006-2007

TABLE OF CONTENTS

INTRODUCTION	3
OHIO DEPARTMENT OF HEALTH (ODH) LICENSE	4
RADIATION SAFETY PROGRAM-RESPONSIBLE PARTIES	6
ADMINISTRATIVE CONTROLS	9
RADIATION SAFETY OFFICE (RSOF)	12
RADIATION SAFETY PROGRAM	20
SUMMARY	35
RADIATION SAFETY COMMITTEE AUDITS	37
APPENDIX	56
Authorized Users	57
RGE/ X-Ray Users	58
Laser Users	59
Master Isotope List	I
Authorized User (AU) Inventory List	II
Sealed Sources	III
Organizational Chart	VI

RADIATION SAFETY ANNUAL REPORT 2006-2007

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 State of Ohio (Nuclear Regulatory Commission Agreement State) Broadscope License. This report summarizes the activities of the Radiation Safety Office (RSOF) of the Department of Occupational & Environmental Safety (DOES) at Case Western Reserve University. Its contents cover the period from July 1, 2006

RADIATION SAFETY ANNUAL REPORT 2006-2007

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.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2010	Broadscope License
09-M-06944-12	May 31, 2008	Radiation-Generating Equipment Registration
0849-34-07	December 31, 2007	South Carolina Radioactive Waste Transport Permit

RADIATION SAFETY ANNUAL REPORT 2006-2007

RADIATION SAFETY PROGRAM - RESPONSIBLE PARTIES

RADIATION SAFETY COMMITTEE (RSC)

The Radiation Safety Committee assists the President and the University by Program as outlined in its 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 2006-2007 Radiation Safety Committee membership and their affiliations are listed below. The President of the University must approve changes to the voting membership. 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. David Danielpour Dept. of Medicine Wolstein 3532 Term Expires: 12/31/2007 Chairperson: 12/31/2007	Dr. Duna Massillon Dept. of Nutrition Research Tower 609 Term Expires: 9/1/2008 Left Case Western Reserve University: 6/2007	Dr. Monica Montano Dept. of Pharmacology HG Wood 367 Term Expires: 9/1/2008
Dr. James Bruzik Dept. of RNA Molecular Biology/ Biochemistry HG Wood 103 Term Expires: 9/1/2008	Dr. Anthony Berdis Dept. of Pharmacology HG Wood 343 Term Expires: 1/1/2008	Dr. Thomas McCormick Dept. of Dermatology BRB 530 Term Expires: 9/1/2008
Dr. Zhenghong Lee Dept. of Radiation Oncology Bishop S109B Term Expires: 9/1/2007	Dr. Helen Evans Dept. of Radiology Oncology BRB 347A Term Expires: 9/22/2007 Retired: 10/2006	Dr. Eckhard Jankowsky Dept. of Biochemistry HG Wood 447 Term Expires: 1/1/2008
Dr. W. David Sedwick RSO Dept. of Medicine DOES Service Building, 1 st Floor		Dr. Virgil Muresan Dept. of Physiology and Biophysics Med East- Robbins 535 Term Expires: 9/1/2008 Left Case Western Reserve University: 4/2007

EX-OFFICIO MEMBERS

Kenneth Basch	Karen Janiga	Felice T. Porter
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RADIATION SAFETY ANNUAL REPORT 2006-2007

Operations at all Radiation Safety Committee (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.

RSOF AND AUTHORIZED USERS (AUs)

A shared responsibility for safety exists between the RSOF and the AU. 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

RADIATION SAFETY ANNUAL REPORT 2006-2007

ADMINISTRATIVE CONTROLS

Administrative controls are established and approved by the Radiation Safety Committee for laboratories where 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.

The General Safety Compliance Enforcement Policy prescribes sanctions for those who jeopardize safety or the continued favorable relationship between the University and the Ohio Department of Health. It is 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 include the following:

Improper Laboratory Records

**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

AU CATEGORIES:

RADIATION ACTIVE (RA)

RADIATION SAFETY ANNUAL REPORT 2006-2007

All non-laboratory personnel are required to attend Hazard Communication training, which incorporates radiation safety training. ARC, Security, Shipping/Receiving, and Custodial departments use a safety orientation DVD, allowing supervisors to train staff at shift changes, thereby greatly increasing training

RADIATION SAFETY ANNUAL REPORT 2006-2007

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. To this end, one additional Macintosh computer was dedicated to the Radiation Safety Program. 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 Legato backup service was set up on all personal computers (PCs). The Carbonite backup service was used for the DOES Server. A Website backup was started to ensure that key files could be replaced.

**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

RADIATION SAFETY ANNUAL REPORT 2006-2007

DISPOSAL OF RADIOACTIVE MATERIALS

Excluding decay of isotope in laboratories and minor inventory changes, isotopes were removed from laboratories either by 506 isotope waste pickups by RSOF staff (382.81 mCi) or by 98 AU-directed disposals into the sanitary sewers (13.58 mCi). The following table presents a tabulated breakdown by isotope of radioactive materials entering and leaving laboratories.

Isotope	Orders		Waste Pickups		Sewer Disposals		Transfers	
	#	mCi	#	mCi	#	mCi	#	mCi

RADIATION SAFETY ANNUAL REPORT 2006-2007

Meter Calibration	157	188	233	245	250
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RADIATION SAFETY ANNUAL REPORT 2006-2007

developing baby. 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 no 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 fluoroscopes. The five 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

RADIATION SAFETY

RADIATION SAFETY ANNUAL REPORT 2006-2007

IODINATION PROCEDURES	06/07	05/06	04/05	03/04	02/03
Total	6	6	7	11	

RADIATION SAFETY ANNUAL REPORT 2006-2007

2/7/2007	Major Incident	<p>use laboratory. The approximate activity was 0.001mCi.</p> <p>5.0 mCi of H3 was taken to a research facility in Kenya. No external transfer paperwork was submitted prior to this transfer, this constitutes a</p>	construction project.	acetate was used to preclude this from happening again.
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**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

RADIATION SAFETY ANNUAL REPORT 2006-2007

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.

RADIATION SAFETY ANNUAL REPORT 2006-2007

Short-lived solid waste is held for decay (equal to or less than 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. 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. Currently, only the outside of the bag is surveyed, followed by immediate disposal to simplify handling by staff and provide 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. Short-lived non-sewer (chemical waste.3(x)(chea132(t)8(o)-3(*)-121(W)6)-8(d)63238(co)6(m)-6(p)58easequseqhr(u)6

RADIATION SAFETY ANNUAL REPORT 2006-2007

In the past fiscal year, the RSOF obtained laboratory equipment from AU's who have either left the university or ceased to use RAM. The equipment includes radiation 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 program

RADIATION SAFETY ANNUAL REPORT 2006-2007

To continue to foster our excellent relationships with Cleveland Fire and our Community emergency response providers.

To continue our mutual development of campus Emergency response and Security with Protective Services to ensure that use of radioactive materials is carried out in a secure environment.

Continued enhancement of radiation training offerings to ensure that campus personnel understand the importance of safe and secure handling of radioactive materials.

Development of a new radiation program specific database to replace Helix, our current database. This is necessary because the Helix vendor no longer adequately supports our current database.

Continue to encourage radioactive waste minimization through procedural review and experimental practice.

Develop additional programs in the areas of non-ionizing radiation (microwave, electromagnetic, and ultraviolet radiation).

RADIATION SAFETY ANNUAL REPORT 2006-2007

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:

<u>AREA AUDITED</u>	<u># OF INDIVIDUAL FILES EXAMINED</u>
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
Irradiator	4

These audits were conducted between October and December 2006 and between April and June 2007. This effort resulted in the review of more than 100 files, in the program areas listed above.

RSC TRI-ANNUAL AUDITS FOR 2006-2007

RSC AUDIT COMMENT:

In November 2006 the Radiation Safety Committee Members, Drs. Virgil Muresan, Tom McCormick, Eckhard Jankowsky, James Bruzik and Zhenghong Lee, David Danielpour, Duna Massillon, and Monica Montano conducted a tri-annual audit of the following components of the Radiation Safety Office:

- Active/Decommissioning Surveys
- Bioassays
- DOES Webpage
- Survey Meters
- RGE Inventory/RGE Training
- Security Checks
- Semiannual Mailings
- Support Staff Training
- RAM Applications

RADIATION SAFETY ANNUAL REPORT 2006-2007

RSOF RESPONSE

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was subsequently placed in use and calibrated on 1/11/07.

RGE INVENTORY/ RGE TRAINING

Ten (10) AU files were randomly audited for trimesterly updates of RGE Inventory/ RGE worker Training status. None of these files were deficient.

RSOF RESPONSE

No response required.

SECURITY CHECKS

Five (5) of the ten (10) randomly audited RAM Security Checks noted radioactive material that was incorrectly secured. Of these five, two of the violations had been resolved and documented in the file, while the remaining three were noted to be deficient in follow-up information and resolution at the time of the audit.

RSOF RESPONSE

RAM security checks are carried out once a month. Follow-up information on one violation was completely documented. The remaining two (2) violations did not provide adequate follow-up information on file. The individual performing security checks was reminded to provide follow-up information on all security check forms. The laboratories missing follow-up information did not have any subsequent violations.

SEMI-ANNUAL MAILINGS

Of the ten (10) AU files randomly audited for semi-annual mailings, all were fully compliant.

RSOF RESPONSE

No response required.

SUPPORT STAFF TRAINING

RADIATION SAFETY ANNUAL REPORT 2006-2007

Two (2) of the five (5) files audited for Support Staff Training were noted to be deficient. One custodial worker was overdue for retraining, and nine (9) security workers were overdue for retraining.

RSOF RESPONSE

Each year approximately 400 ancillary support staff members are trained by the RSOF. All support staff training was completed by the end of December 2006 and will be completed in the same timeframe in 2007. Because of support staff turnover a mismatch between the date of initial training when hired and the first subsequent retraining date may occur.

RAM APPLICATIONS

Two (2) of the ten (10) files audited did not have updated room information. One (1) of the ten (10) files audited had a meter that was overdue for calibration.

RSOF RESPONSE

The two files with incorrect room information were generated prior to the relocation of the AUs. These files were updated after the AUs relocated. One meter that was listed as overdue for calibration has been calibrated.

RSC AUDIT COMMENT:

The second trimesterly audit by the RSC was conducted in March 2007. This audit included Shipping Papers, Irradiator User Training/Irradiators, Isotope Inventory, Sealed Sources, Valid Ram Applications, and AU files; and was conducted by the following Radiation Safety Committee members: Drs. Zhenghong Lee, James Bruzik, Tom McCormick, Monica Montano, Anthony Berdis, and Duna Massillon. Each audit consisted of randomly selecting five (5) to twenty (20) files from the past year to ensure items were up-to-date accurate and matched the database.

RSOF RESPONSE

No response required.

SHIPPING PAPERS

There were no deficiencies noted in any of the ten (10) shipping papers audited; however, problems were noted in two of the papers. One shipping paper was not

RADIATION SAFETY ANNUAL REPORT 2006-2007

clearly documented that a direct pickup was made. In another case, FedEx delivered Rad material directly to a laboratory in the Wolstein Building; however, the receiving laboratory took proper procedures and alerted RSOF. This material

RSOF RESPONSE

No packages are currently delivered from Receiving to University laboratories. The shipping paper with missing documentation failed to document that an AU picked up the package. This paper was updated with information denoting the

IRRADIATOR USER TRAINING/ IRRADIATORS

Irradiator User/Irradiators audit identified that three (3) of ten (10) randomly selected workers did not complete their training. Uджа044>-3004601(te)-5(n)6()-261((1e)4(

**RADIATION SAFETY
ANNUAL REPORT 2006-**

RADIATION SAFETY ANNUAL REPORT 2006-2007

ANCILLARY STAFF TRAINING

RSC AUDIT COMMENT:

An annual audit was conducted to verify the training status of ancillary personnel encompassing the following segments of this program: Animal Resource Center, Shipping/Receiving, Custodial, Security, and Plant Services. Ancillary staff worker training files were reviewed from July 1, 2006 through June 30, 2007. Forty-six custodial staff workers were found to be overdue for training, with 9 more that will be in need of retraining in 2 months. Thirty-nine Animal Resource Center workers were noted to be delinquent in retraining, although training for them was planned a couple of days from the time of this audit. Fifteen of the security staff workers were found to be overdue for training, with an additional 35 that will need retraining within two months from time of audit. None of the staff associated with Plant Services were overdue for training, and only one Shipping/Receiving staff member was overdue for training. All other ancillary staff was listed as being current in their training.

RSOF RESPONSE:

There are 402 Ancillary Staff workers. Annual ancillary training is in progress for all ancillary workers and will be completed by the end of 2007. All overdue ancillary workers were trained. For the first time, training of ancillary workers achieved 100% compliance in the middle of the 2006-2007 fiscal year and is on course to achieve the same goal in fiscal year 2007-2008.

AU AND WORKER TRAINING

RSC AUDIT COMMENT:

AU files were audited for AU and Worker training status, from July 1, 2006 through June 30, 2007. At the time of the audit, 48 AUs randomly selected, all but 8 files were current in their training status and one file was not found in database.

RSOF RESPONSE:

Eight workers were overdue and were notified according to the Radiation Safety Training Enforcement Policy Guidelines. Of these eight workers, seven

RADIATION SAFETY ANNUAL REPORT 2006-2007

RSOF RESPONSE

No response required.

DOSIMETRY PROGRAM

RSC AUDIT COMMENT:

Fifty randomly selected ()Tj-dnNo rENT:

**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

RADIATION SAFETY ANNUAL REPORT 2006-2007

RADIATION SURVEY METERS

RSC AUDIT COMMENT:

Files associated with 50 survey meters were randomly screened for calibration dates within the last twelve months. All but 9 of meters had a current calibration date, and were documented in both files and in Helix database. Of the nine deficiencies, two had overdue calibration dates, but only by 2 and 5 weeks, respectively. One had no hard copy file although it was in the database, another meter was broken and not in use; and 5 meters had neither hard copy nor been entered into the database.

RSOF RESPONSE:

One of the overdue meters was calibrated. The AU has been contacted regarding the second overdue meter. The file for the meter with the missing paper work was located. The five meters with no files or Helix entry were removed and placed in reserve for back-up use upon calibration if needed. These meters were old meters that belonged to the Radiation Safety Office but were broken and not in use.

SEALED SOURCE LEAK TEST

RSC AUDIT COMMENT:

Fifty files were randomly screened during the last 4 months (prior to the date of audit) for verification that the sealed source had been leak tested. All except 10 of these files were well documented and compliant. The deficiencies were all from being overdue in inspection.

RSOF RESPONSE:

Nine of the sealed sources were due August 2007 and were subsequently inspected by the RSOF as part of routine procedures. The remaining source was on a meter belonging to an AU who had retired and does not need to be inventoried.

SHIPPING PAPERS

RSC AUDIT COMMENTS:

RADIATION SAFETY

RADIATION SAFETY ANNUAL REPORT 2006-2007

WASTE DISPOSAL FACILITIES (DOA990/WOLSTEIN) & RSOF LABORATORY

RSC AUDIT COMMENT:

The Waste disposal facilities and laboratories of the RSOF were inspected to ensure safe operation and adequacy of amenities as required by programs of the RSOF, during the period of July 1, 2006- June 30, 2007. All records of The Facility Maintenance & General Housekeeping, Record Maintenance, and Waste Storage & Handling were evaluated as being compliant, adequate, orderly and secure.

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.

DOES 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 Specialist reviews all programs and Departmental records on a periodic basis and assists with resolving compliance issues in the RSOF.

Sealed Source
Shipping Papers
Valid RAM Applications
Isotope Orders/ AU Possession Limits
AU/ Worker Training
Waste Disposal Facility
Active/ Decommissioned Surveys

RAM Security Checks
Semi-Annual Mailings
RGE Inventory/ Training
Ancillary Training
Licensing
Incidents
Irradiator

Bioassays
Dosimetry
Survey Meters
Compliances
Website Accuracy
Liaison Program

RADIATION SAFETY ANNUAL REPORT 2006-2007

DOES audits have resulted in administrative modifications over the past year to improve record compliance and RSOF response to safety is laboratories. Full audit results of this program are available in the DOES office. Radiation Safety internal audits were conducted either monthly or quarterly.

INTERNAL AUDITS

This year, in response to audit finding, the RSOF has implemented changes to its procedures and programs. The

radioactive materials revealed that numerous applications should be updated to be consistent with existing application requirements. The Assistant RSO requested that protocols more than t is yeco8mld,71(t)-86 T JT*(b)-371 -91(u)-3(p)-3(d)6este b R

**RADIATION SAFETY
ANNUAL REPORT 2006-2007**

APPENDIX

RADIATION SAFETY ANNUAL REPORT 2006-2007

AUTHORIZED USERS

STORAGE MODE

Kumar Alagramam	11/15/2006	Piet DeBoer	8/17/2006
Helen Salz	9/13/2006	Nora Singer	5/23/2007
Yu Chung Yang	6/11/2007	Richard Zigmund	12/13/2006

RADIATION INACTIVE

Eben Alsberg	7/1/2006	Jeffrey Duerk	12/19/2006
Clifford Harding	10/30/2006	Timothy Kern	9/15/2006
Christopher King	3/12/2007	Michael Lamm	12/19/2006
Sam Mesiano	1/22/2007	Georgia Wiesner	11/1/2006

DEPARTED

Cheng Ming Chiang	6/30/2007	Richard Eckert	6/19/2007
Karl Herrup	7/7/2006	K. Ganesh Kumar	1/29/2007
Virgil Muresan	4/24/2007	Laura Nagy	8/3/2006
Stephanie Orellana	7/7/2006	Nanduri Prabhakar	12/31/2006
Bryan Roth	8/3/2006	David Schultz	11/6/2006
William Stanley	2/15/2007	Matthew Warman	6/28/2007

RADIATION SAFETY ANNUAL REPORT 2006-2007

X-RAY AUTHORIZED POSSESSOR LIST

<u>AP CODE</u>	<u>AP NAME</u>	<u>CONTACT PERSON</u>
AH-JS	Arthur Heuer	Wayne Jennings
BEN	Jay Bensusan	Jay Bensusan
CHO	Gary Chottiner	Gary Chottiner
DC	Sally Baden	Shelly King
FUJ	Hisashi Fujioka	Midori Hitomi
GRE	Edward Greenfield	Teresa Pizzuto
HAR	Ralph Harvey	Ralph Harvey
HIL	Anne Hiltner	Akshay Kamdar
LAG	Peter Lagerlof	Peter Lagerlof
LEE	Zhenghong Lee	Chris Flask
MAC	Alan McIlwain	Wayne Jennings
MAT	Gerald Matisoff	tisoT4Mid-98 111.98 ONXh

