

CASE RADIATION SAFETY ANNUAL REPORT

**W. David Sedwick, Director/ RSO
Karen Janiga, Assistant RSO
Felice Porter, Report Editor and
Departmental Auditor**

FISCAL YEAR 2005-2006

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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 (CASE's) Broadscope State of Ohio (Nuclear Regulatory Commission Agreement State) License. The report summarizes the activities of the Radiation branch of the Department of Occupational & Environmental Safety (DOES) at CASE. Its contents cover the period from July 1, 2005 through June 30, 2006.

OHIO DEPARTMENT OF HEALTH (ODH) LICENSE

At present, CASE 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 encompasses licensed use of 3 irradiators.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2010	Broadscope License
09-M-06944-01	May 31, 2008	Radiation-Generating Equipment Registration
0849-34-04	December 31, 2006	South Carolina Radioactive Waste Transport Permit

An unannounced, routine inspection of the Broadscope License was conducted on August 9 and 10, 2005. Five violations were found during these inspections and resolved with no financial penalty. The violations cited were:

1. FINDING: The Radiation Safety Office (RSOF) internal audits and Radiation Safety Committee (RSC) annual program audit did not provide adequate compliance oversight of the irradiator program (Ohio Administrative Code (OAC) 3701:1-38-11 (E) (1) & (E)(3). The Radiation Safety Office was instructed to separate the irradiator program as an individual entity for each irradiator instead of including it as part of the overall sealed sources program.

UNIVERSITY RESPONSE: The irradiator program is audited by the RSOF three times per year. The inspector reviewed the applicable records and noted that although the last audit was performed on May 17, 2006 for the four irradiators, it was difficult to isolate the specifics of the irradiator safety program since it was melded with the sealed source program. Suggested structural changes were implemented by clearly demarcating safety procedures within the overall program for each irradiator. This change was also necessary because of new security requirements mandated over the last year. No deficiencies were noted in the follow up inspection on July 18, 2006.

2. FINDING: The inspectors identified a defective locking mechanism on one of the doors of the Radiation Waste Facility located, in DOA 990, of the Dental school which opens to the parking garage (OAC 3701:1-38-17 (A)) and cited the program for failing to secure the radioactive materials in the waste facility.

UNIVERSITY RESPONSE: The lock is part of a door closure system that has redundancy in that it has no handles on the outside door. However, the automatic locking mechanism had accumulated dirt that interfered with its automatic function. In response to this observed defect, the Radiation Safety Office instituted a system of door inspections at each entrance and exit door of

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the waste room that requires sign-off by all personnel before leaving the Facility. Upon reinspection, this system was approved by the ODH and no deficiencies were noted in the follow up inspection on July 18, 2006.

3. FINDINGS: One of three radiation detectors used with the JL Shepherd irradiator located on the third floor of the Biomedical Research Building (BRB) used to make quantitative dose rate measurements was noted to be out of calibration. (OAC 3701:1-38-14(A)(2)

UNIVERSITY RESPONSE: During a physical review of the irradiators as part of the follow-up inspection on July 18, 2006, the inspector noted that the radiation detectors: Primalert 35 in BRB and Technical Associates model LAM-10 in Wolstein Research Building (WRB) were in current calibration. No deficiencies were noted.

4. FINDINGS: Shipping papers were noted to be incorrectly described in the full description box of the form as required in 49 CFR 172 subpart C. (OAC 3701:1-50-05 (A)(5)

UNIVERSITY RESPONSE: At the follow up inspection on July 18, 2006, the Radiation Safety Officer (RSO) and the Assistant Radiation Safety Officer (ARSO) demonstrated that material received since the last inspection was picked up and hand carried to recipients by authorized personnel instead of transported on public roadways. The ARSO showed that the material received by the University is comprised of 95% exempt quantity packages and 5% non-exempt packages and that the RSOF performs the receipt procedures specified in OAC 3701:1-38-18 (F). All future transport over public roadways will be in compliance with the requirements stated in OAC 3701:1-50-05 (A)(5). No deficiencies in procedure or shipping papers were noted.

5. FINDINGS: ODH postings distributed by the RSOF to all laboratories did not include a statement indicating where a copy of the License with applicable Ohio rules, and a description of safe operating procedures could be found. (OAC 3701:1-38-10 (A)

UNIVERSITY RESPONSE: At the follow up inspection, the inspector noted the new ODH forms with the required information were generated and posted. The inspector noted that the Ohio Notice to Employees posting in required use areas included a statement at the bottom that was in compliance with OAC 3701:1-38-10 (A)(2). No deficiencies were noted.

The Radiation-Generating Equipment (RGE) License was inspected from March 7 through March 23, 2006. Two violations were found during the routine inspection and are as follows:

1. FINDINGS: Level 2 – Inspection fee not paid OAC 3701:1-38-04 (G)(H) – As of the date of this written notice, our records indicate the inspection fee was not been paid. Penalty fees will be assessed for non-payments, which exceed one hundred eighty days.

This Level 2 violation required corrective action within thirty days.

UNIVERSITY RESPONSE: Follow-up by DOES found that the payment had been authorized by DOES but was held in accounts payable and had not been received by the ODH. This was corrected within the required 30-day period.

2. FINDINGS: Level 3 – Operator training not documented OAC 3701:1-66-04 (B)(5) – The quality assurance program did not include adequate documentation of operator training for each type of radiation-generating equipment to be handled in order to assure competency in the operating procedures.

Level 3 violations will be reviewed at the time of the next inspection.

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UNIVERSITY RESPONSE: The DOES has instituted inspection procedures to ensure that documentation of operator training for each type of RGE is in place at each equipment location.

DECOMMISSIONING FUNDING PLAN

The Broadscope License and its attendant Decommissioning Funding Plan were updated and became effective March 15, 2005. The Standby Letter of Credit carried by the University for this plan was decreased by more than 40% to \$288,000 consistent with radioactive materials currently located at the University.

RADIOACTIVE MATERIAL USE AND STORAGE LOCATIONS

Radioactive material is located at the following facilities:

- Main campus of 10900 Euclid Avenue, Cleveland, OH
- University Hospitals (UH), 2065 Adelbert Road, Cleveland, OH
- University Circle Research Center II (UCRC II), 11001 Cedar Avenue, Cleveland, OH
- Wolstein Research Building, 2103 Cornell Road, Cleveland, OH

Radioactive material is received and stored at the following sites:

- Shipping and Receiving, 2232 Circle Drive, Cleveland, OH
- Cedar Service Center, 10620 Cedar Avenue, Cleveland, OH
- Wolstein Research Building, 2103 Cornell Road, Cleveland, OH

PURPOSE FOR RADIOACTIVE MATERIAL USE

The majority of isotope usage on the campus is for biomedical research. The most typical isotopes used are ^{14}C , ^3H , ^{125}I , ^{32}P , ^{33}P , and ^{35}S . Additional isotopes used in sealed sources contained within irradiators, scintillation counters, gamma counters, check sources, and calibration standards are most commonly ^{137}Cs , ^{133}Ba , and ^{241}Am . Four licensed high activity radiation sources are currently used for biomedical and other research. These include a ^{241}Am -Be Neutron source and four irradiators that contain ^{60}Co or ^{137}Cs sources.

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RADIATION SAFETY PROGRAM RESPONSIBLE PARTIES

SENIOR MANAGEMENT

The Radiation Safety Program is designed to monitor, inspect, and/or audit activities of the AUs and their personnel. Senior management oversight is assured by attendance of the Vice President for Campus Planning and Operations at all RSC meetings. The Radiation Safety Committee conducts independent audits of the Radiation Safety Program. RSOF Staff immediately responds to audit findings. Both the audit findings and responses are reported to senior management and the Committee.

RSOF AND 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 programmatic safety procedures are implemented and that the AUs are fulfilling their responsibilities for the monitoring of safety during experiments carried out in their laboratories. Audits of the laboratories are conducted by the RSC at least twice per year by the RSOF to ensure compliance with the CASE license. This audit program includes routine unannounced inspections of each AU's laboratory.

RADIATION SAFETY COMMITTEE (RSC)

The Radiation Safety Committee assists the President and the University by ensuring compliance with the University's Radiation Safety Program as outlined in the University's Ohio Department of Health (ODH) Broadscope License. The Radiation Safety Committee members are chosen from a variety of disciplines to provide comprehensive expertise. The Committee reviews all applications for use of radioactive materials.

The 2005-2006 Radiation Safety Committee members 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: 12/31/2006	Dr. Duna Massillon Dept. of Nutrition Research Tower 609 Term Expires: 9/1/2008	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	Dr. Eckhard Jankowsky Dept. of Biochemistry HG Wood 447 Term Expires: 1/1/2008
Dr. W. David Sedwick RSO		Dr. Virgil Muresan Dept. of Physiology and

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Dept. of Medicine DOES Service Building, 1 st Floor		Biophysics Med East- Robbins 535 Term Expires: 9/1/2008
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EX-OFFICIO MEMBERS

Kenneth Basch Vice President of Campus Planning and Operations Adelbert 329	Karen Janiga ARSO DOES Service Building, 1 st Floor	Felice T. Porter Quality Assurance Specialist DOES Service Building, 1 st Floor
Kevin Wunderle University Hospital Asst. RSO Dept. of Radiology Bishop S611		

SUPPORT STAFF

Shirley Mele Office Supervisor Service Building, 1 st Floor	Gwendolyn Cox-Johnson Department Assistant Service Building, 1 st Floor
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The Radiation Safety Committee acts as an advisory and enforcement body to ensure that radioactive materials are safely used in accordance with approved ALARA (As Low As Reasonably Achievable) principals. The Committee conducts audits on a quarterly basis. These audits 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 Radiation Safety Manual and license.
- Accurate documentation for program conformance and license compliance
- Adequate training for all classes of workers.
- RSC member familiarity with the daily function of the RSOF to improve their oversight abilities.

The committee met on eight occasions during the last fiscal year to review applications for radioisotope usage and act on other business. The minutes of the RSC meetings and Executive Committee actions are available in the RSOF, through the RSC, or through the University Administration.

APPLICATIONS	05/06	04/05	03/04
New AU	11	8	3
Additional Isotopes	6	10	2
Radioisotope use in Animals	5	7	4
Sealed Sources	6	1	1
AU Reactivation	1	0	1
Possession Limit Increase	0	1	0
AU Protocol Update	0	3	0
TOTAL APPROVALS	29	30	11

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AUDITS

RSC PERFORMANCE & RECORD AUDITS OF RSOF ACTIVITIES IN 2005-2006

The audit process by the Radiation Safety Committee (RSC) is carried out in two different ways:

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

Performance audits of RSOF activities included the following areas:

<u>AREA AUDITED</u>	<u># OF INDIVIDUAL FILES EXAMINED</u>
Valid 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

These audits were conducted between October and December 2005 and between April and June 2006. This process resulted in review of more than 100 files and examination of the program areas listed above.

RSC TRIMESTERLY AUDITS FOR 2005-2006

RSC AUDIT COMMENT:

In October 2005 the Radiation Safety Committee Members, Drs. Virgil Muresan, Tom McCormick, Eckhard Jankowsky, James Bruzik and Zhenghong Lee conducted a trimesterly audit of the following components of the RSOF: AU Worker Training, Isotope Ordering/Possession Limits, Sealed Sources, Shipping Papers, and Radiation Waste Disposal Facility. Each audit consisted of randomly selecting five to 20 files in the past year to ensure items were present, up-to-date, accurate and matching with the database. AUs/Workers 30 and 60 days overdue for training were audited for recent exposure records and the most recent retraining dates. Three AU/Workers were found to be 30 days overdue for retraining and one worker was overdue by 60 days. All of these AUs were notified by email on the day of this audit. Deficiencies in compliance were also noted in two to the 10 sealed source files audited. Those deficiencies included overdue radiation monitoring surveys [3 days (one file) and one month (one file)]. Isotope order shipping papers were audited for orders received in the last three months. No deficiency in shipping papers was noted in this audit. The Radiation Waste Disposal Facility audit consisted of monitoring all components of the facility, which includes Facility Surveys, Air

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Monitoring, Barrel Inventories and Disposal Records. There were no deficiencies noted in any of the components of this survey of Waste Disposal Facility.

RSOF RESPONSE:

Retraining was completed by all of the individuals found to be overdue for training.

The one beta sealed source that was overdue required a 6-month inventory based on its low activity. The source was inspected. The second source required a leak test and was 1 day overdue. This source was leak tested.

RSC AUDIT COMMENT:

The second trimesterly audit by the RSC was conducted in February 2006. This audit included Bioassays, Valid RAM application, Survey Meters, Security Checks, Support Staff Training, Web Page, Semiannual Mailing, Radiation Generating Equipment (RGE) Programs, and Active/Decommissioning, and was conducted by the following Radiation Safety Committee Members: Drs. Virgil Muresan, James Bruzik, Anthony Berdis, Zhenghong Lee, Duna Massillon, Monica Montano, Helen Evans, Tom McCormick, and Eckhard Jankowsky. Each audit component consisted of randomly selecting five to 20 files in the past year to ensure items were present, up-to-date, and accurate and matched the database. There were no deficiencies noted in any of the components of the waste disposal survey. There were also no deficiencies noted in Valid RAM Applications (10 files), Survey Meters (10 files), security checks (10 dates), Web Page (15 links) and support staff training. There was one deficiency noted in Bioassays (required for AUs ordering greater than or equal to 1 mCi ¹²⁵I or greater than or equal to 10 mCi ³H) surveyed over the last six months. Three deficiencies were found in the RGE Program audit (10 files audited). These deficiencies were from lack of site training records in the RSOF files. There were five deficiencies in the Active/Decommissioning Surveys (19 files). In one case the file was missing, and the other deficiencies were due to the absence of dates in files found in the Helix database. The Semiannual Mailing Audit (10 files audited) caught three deficiencies, in which there was no current hard copy of radiation inventories on file.

RSOF RESPONSE:

This Bioassay issue was appropriately followed-up by the RSOF with an e-mail to the AU. However, the worker in question never came in for the bioassay after the e-mail was sent. A repeat occurrence involving the same worker happened in July 2006, and was finally resolved. The AU counseled the worker on the importance of timely response to these RSOF requests.

All users of RGE are required to attend the general training conducted by our office. The PI conducts site-specific training. The workers listed in 2 of the 3 files have left CASE. Site-specific training of the workers listed in the 3rd file is pending.

All of the above issues concerning the surveys were corrected. Three of the AU files that were audited did not require a copy of the Environmental Release Summary, because the individuals were in storage mode and were not required to fill out this report. A notice to this effect has been placed in their files to avoid confusion in future audits.

RSC AUDIT COMMENT:

A third trimesterly audit by the RSC was carried out in early June 2006. The audit included Irradiator User Training/Irradiators, Shipping Papers, AU/Worker Training, Sealed Sources,

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Isotope Possession Limits, and Waste Disposal Facility and was done by Drs. Jim Bruzik, Zhenghong Lee, Duna Massillon, Monica Montano, Anthony Berdis and Thomas McCormick. Each component consisted of randomly selecting five to 20 files in the past year to ensure items were present, up-to-date, and accurate and matched the database. Two of 10 Irradiator Program files were deficient in training documentation. Two deficiencies were found in Shipping Papers documentation, as no remarks were recorded in the file. One deficiency occurred in the AU/Worker Training file, with an overdue date of 30 days. One out of 10 Sealed Source files was deficient by being misfiled. No deficiency was noted in the isotope possession limit audit. There were no deficiencies noted in any of the components of this survey of Waste Disposal Facility.

RSOF RESPONSE:

All Irradiator training dates have been updated

Both Shipping Paper deficiencies involved packages that were picked up directly by laboratory personnel. A comment indicating direct pickup is written on the package receipt form that is attached to the package. This comment was missing on 2 of the forms. The importance of documenting this procedure was addressed with RSOF personnel during a monthly staff meeting. The overdue worker retrained on June 11, 2006, which corrects the Worker file. This sealed source issue regarding the missing file was corrected

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 quarterly audit.

ANNUAL RADIATION SAFETY PROGRAM AUDIT REPORT

The Radiation Safety Committee conducted its annual audit of the RSOF the week of July 10, 2006. The Audit was conducted by: Drs. David Danielpour (General Medical Sciences-Oncology), Duna Massillon (Nutrition), Monica Montano (Pharmacology), Anthony Berdis (Pharmacology), Eckhard Jankowsky (Biochemistry), James Bruzik (RNA Center), Tom McCormick (Dermatology), Zhenghong Lee (Radiology UH), and Virgil Muresan (Physiology & Biophysics). The committee reviewed the performance of 17 components of the RSOF. The areas were:

- Ancillary Staff Training
- AU and Worker Training
- Bioassays
- Compliance Review
- Correspondence Between Isotope Orders, AU Possession Limits, and the Helix Database
- Dosimetry Program
- Incident Reports
- Irradiator Program
- Isotope Security Checks
- Licensing Status
- Radiation Generating Equipment Inventory and Training
- Radiation Survey Meters
- Seal Source Leak Test
- Shipping Papers

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- 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 ancillary personnel encompassing the following segments of this program: Animal Resource Center, Shipping/Receiving, Custodial, Security, and Plant Services. A total of 107 ancillary staff workers were surveyed from July 1, 2005 - June 30, 2006. All custodial staff workers were found to have current training, being retrained less than a year ago. The remaining ancillary staff were listed as being overdue in their training.

RSOF RESPONSE:

Ancillary training was conducted for Plant, Security, Shipping, Animal resource center personnel, and CASE and contract custodial. Follow-up training will be done to ensure that all of those individuals who did not attend the scheduled training classes are trained.

AU AND WORKER TRAINING

RSC AUDIT COMMENT:

AU files were audited for AU and Worker training status, from July 1, 2005 - June 30, 2006. Of the 48 AUs randomly selected, all but 9 of their files were current in training status and one file was misplaced (with first name switched with the last name). One of those files was found to be delinquent by three years, another by two years and the remaining by less than two months.

RSOF RESPONSE:

The 2 files noted above are for workers listed as Ancillary Optional, and do not require annual retraining based on their worker classification which is stated in the Training Enforcement Policy. The remaining workers were not overdue based on our Training Enforcement Policy.

BIOASSAYS

RSC AUDIT COMMENT:

Audits were conducted to ensure completion of bioassays for laboratories using greater than 10 mCi of ^3H and/or 1 mCi ^{125}I during the period of July 1, 2005 - June 30, 2006. All qualifying user

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files were audited. There were five non-compliant files. Four of the violations were from the same worker. The remaining violation occurred in the laboratory of an AU who left CASE.

RSOF RESPONSE:

Follow-up e-mails were sent to the worker, who did not respond. A follow-up e-mail was then sent to the AU regarding the worker. The AU counseled the worker and the worker came in for a bioassay on July 11, 2006. No follow-up could be done on the worker who left CASE since the worker left prior to completion of this audit.

COMPLIANCE REVIEW

RSC AUDIT COMMENT:

This audit was conducted to verify that AU laboratories were audited within the last six months, and that any non-compliant issues were appropriately followed-up. From fifty, randomly selected Compliance Review files, all but three reports were thorough and up-to-date. One of these files had the AU listed in storage mode, and AUs for the remaining two files were confirmed by the RSOF to be minor violations that will be followed up if further violations are noted.

RSOF RESPONSE:

No letter or follow-up is routinely sent to the AUs unless there are 3 minor violations within a calendar year. In the case of both files noted by the Radiation Safety Committee auditors, one violation occurred in 2005 and was also found in the first audit carried out in 2006. This case was followed up by a letter, consistent with the ARSO's practice of routinely ensuring that any deficiencies found in previous audits are followed up in the next audit period.

CORRESPONDENCE BETWEEN ISOTOPE ORDERS, AU POSSESSION LIMITS, AND THE HELIX DATABASE

RSC AUDIT COMMENT:

Fifty files were selected within the period of July 1, 2004 - June 30, 2006, to verify that the amount of RAM ordered is within AU possession limits and that the orders are in the Helix database. The correspondence between isotope orders, AU possession limits and Helix database was complete and up-to-date for all but one file. This file was deficient by data entry in the Helix database. This error was corrected immediately.

DOSIMETRY PROGRAM

RSC AUDIT COMMENT:

Fifty randomly selected workers associated with 28 AUs were reviewed for having current dose records within the past year. No dose record was found for 14 of these 50 workers. In addition, five workers with dose records were not current, bringing the total number of violations to 19.

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However, the survey did not assess which of these workers are in storage mode or no longer active.

RSOF RESPONSE:

The fifteen files that did not contain dosimetry records are individuals working with H-3, C-14, and S-35 that do not require a badge. The five workers with dose records that were not current either left the university or are BSTP or MSTP students rotating in labs that do not currently use radioactive materials.

INCIDENT REPORTS

RSC AUDIT COMMENT:

During the period of July 1, 2005 - June 30, 2006, monthly incident reports were reviewed for verification and documentation of follow-up by the RSOF. There were no incidents reported during this time.

IRRADIATOR INFORMATION REVIEW

RSC AUDIT COMMENT:

Irradiator Information files were audited to verify that the irradiator was audited by the RSOF within the last six months, and that non-compliance issues were appropriately followed up and pending issues resolved. There are currently three active (BRB Cs137, BRB Co60, WRB Cs137) and one inactive (ME Cs137) irradiators at CASE, serving a total of 91 end users). Inspection and leak test review dates of all irradiators are current. All but four users showed current training status. The AUs of four users with delinquent training record have been notified. In addition, although all file records are current, computerized database needs to be updated and corrected for the training dates of all users.

RSOF RESPONSE:

Since the irradiator database must now be kept on a secure computer, all data must be entered separately from the main database. All training dates of users were updated and are now current.

ISOTOPE SECURITY CHECKS

RSC AUDIT COMMENT:

The audit was to ensure that security checks by the RSOF were conducted monthly and follow-ups of these audits were complete (July 1, 2005 - June 30, 2006). Our audit confirmed that security checks were conducted monthly. The summary sheets show that there is approximately one minor violation per month for each building. This exhibits good compliance for this program. All but one security check was completed with satisfactory documentation of follow-up and complete resolution of pending issues.

RSOF RESPONSE:

The one security check noted was corrected at the time the security check was done. The documentation has been attached to the security check form.

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LICENSING STATUS

RSC AUDIT COMMENT:

An annual audit of the radiation licensing status of our RSOF was conducted. Components of this audit included Broadscope Licensing, REG Registration Waste License, Radiation Manual, X-ray Manual, Radiation Training, X-ray Training, Radiation Online Retraining Licensing, and RSC Guidelines. All above licenses except the RGE Registration were found to be current. The RGE Registration, which expired May 31, 2006, will be sent when the inspection fee is received by the ODH.

RSOF RESPONSE:

The inspection fee was received by the ODH and the updated Registration was received by the RSOF on July 26, 2006.

RADIATION GENERATING EQUIPMENT INVENTORY AND TRAINING

RSC AUDIT COMMENT:

Thirty files were randomly audited for inventory status and last survey date of equipment, during the period of July 1, 2005 - June 30, 2006. Among these files, three of the AU files were missing. Ten files had memos sent but not returned. Two AU files became inactive. All other quarterly inventories were returned and are complete.

RSOF RESPONSE:

Since the next quarterly inventory was due soon after completion of this audit, no follow-up was done on the inventories that were not returned. However, it was stated in the next inventory memo that RGE will be locked out if the inventory is not returned.

RADIATION SURVEY METERS

RSC AUDIT COMMENT:

Files associated with 40 survey meters were randomly screened for calibration dates within the last twelve months. All but 4 of meters had current calibration dates, and the file for one of the survey meters was missing.

RSOF RESPONSE:

Two noted meters had incorrect calibration dates. This was corrected. One meter was placed in non-use status since the AU has left CASE. The remaining meter was overdue for calibration and an email was sent to the Authorized User requesting that the meter be brought in for calibration. The meter is now calibrated. The missing file was found and refiled.

SEALED SOURCE LEAK TEST

RSC AUDIT COMMENT:

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Seventeen files were randomly screened during April 1 - July 30, 2006 for verification that the sealed source had been leak tested. All except five of these records were well documented and compliant. Four of the non-compliant files appeared to have resulted from a misfiling error due to some mismatches of the inspection dates in folders with that in Helix database.

RSOF RESPONSE:

Helix records indicated that the RSOF staff had inspected the 4 sealed sources. One paper record was found and placed in the correct folder. The other 3 were not located after an intense search of the sealed source records for the AU. The sources have been inventoried and new files have been created.

SHIPPING PAPERS

RSC AUDIT COMMENTS:

Fifteen shipping paper files were randomly audited to ensure that shipping papers were adequately completed for the transfer of RAM material from site to site, for the period of July 1, 2005 - June 30, 2006. All but one of these forms was incomplete or noncompliant. In one case a shipping paper was missing and in three other instances the shipping papers were not entered into the Helix system. The isotope amount was missing on six of these shipping papers and there were problems noted with the dates on three other shipping papers.

RSOF RESPONSE:

All packages going to off-campus buildings were picked up by the laboratory and did not require shipping papers. However, for clarification, a note stating direct pickup by the laboratory should be noted on the package receipt form. This note was missing from 15 package receipt forms that were audited. This issue was addressed with the RSOF staff at the July 27, 2006 meeting. All data entry, Isotope amounts, and dates were corrected. RSOF follow-up to ensure clarification of this issue has been implemented.

SEMI-ANNUAL MAILINGS (AIR/ SEWER INVENTORY)

RSC AUDIT COMMENT:

Fifty files were audited for receipt of semi-annual mailings for the last 6 months. Four of these files were incomplete or not current. There was a follow-up with all of these files by mid July. One of the files was found to be inactive.

RSOF RESPONSE:

One AU was inactive. The file was placed in the inactive AU file. A follow-up e-mail was sent to the 3 remaining AUs. All forms were received and placed in the AU files.

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VALID RAM APPLICATION

RSC AUDIT COMMENT:

Fifty RAM applications were audited (from Nagy - Boothman) to confirm they were valid, complete and current, within the last year (July 1, 2005 - June 30, 2006). All these RAM applications except 5 were current and complete. The deficiencies included the following: File not in computer database (two files), AU left CASE (one file) and Form 7-1 missing (two files).

RSOF RESPONSE:

The two files not in the computer database involved incorrect personnel listings. The involved personnel left CASE after the personnel report was printed for the application file. The file of the AU that left CASE was removed and placed in the inactive AU file. The 2 AUs whose files were missing Form 7 of the RAM application were contacted and the forms were received and refiled.

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 equipment as required by programs of the RSOF, during the period of July 1 - June 30, 2006. All records of The Facility Maintenance & General Housekeeping, Record Maintenance, and Waste Storage & Handling were found to as being orderly and secure.

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 the careful audit of its safety activities over the past year. Record problems uncovered by the committee were referred to the RSOF auditor for increased scrutiny during the coming year.

DOES INTERNAL AUDITS

Two layers of audit are utilized on an ongoing basis to ensure that the Radiation Safety programs and procedures are working smoothly. In addition to audits conducted by the Radiation Safety Committee, the Department's Quality Control specialist reviews all programs and Departmental records on a periodic basis and assists with resolving compliance issues in the RSOF.

The DOES Internal audits address program effectiveness and efficient operation. These audits have resulted in administrative modifications over the past year. Full audit results of this program are available in the DOES office. Most Radiation Safety Internal Audits were conducted on a monthly basis. Some were conducted quarterly.

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INTERNAL AUDITS

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

This year, in response to audit queries, the RSOF has moved forward with implementation of the following changes to its procedures and programs.

The RSOF's audit of applications for use of radioactive materials revealed that numerous older applications have not been reviewed or updated since the application procedures for AUs were modified by the RSOF. The ARSO requested that protocols more than ten years old, be updated by the AUs. Application possession limits and protocols must be updated to be consistent with procedures and standards that are consistent with the current program. This process is ongoing. There were no protocols updated this year due to decreased staff and commensurate increase in commitments by members and ex-officio members of the Radiation Safety Committee.

Internal Audits of the Radiation Safety Program were conducted during this fiscal year in the following areas:

- Purchasing Requisitions
- Radiation Waste Pickup
- Compliance Reviews
- Meter Calibration
- Package Receipt
- Environmental Release Inventory
- Surveys
- X-Ray Personnel
- RAM Personnel Files

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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, dosimetry, and required services. Written procedures document the control of procurement, control of use, and the control of disposal of all RAM at the University.

The Small Animal Imaging Center (SAIRC) and a Dental CT unit became operational in the fall of 2005. The Assistant RSO, with the RSOF staff and RSO, have also updated and revised most of the Departments manuals, training, licenses, certificates, and standard operating procedures in 2005-2006.

AU CATEGORIES:

RADIATION ACTIVE (RA)

These AUs actively use RAM and have RAM inventory at the University in 281 laboratories. 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 copy of AUs of Radioactive Materials can be found in the Appendix.

RADIATION GENERATING EQUIPMENT/ X-RAY (RX)

These AUs actively uses RAM and X-Ray equipment.

RADIATION GENERATING EQUIPMENT/ X-RAY (X)

These AUs actively uses X-Ray Equipment.

RADIATION INACTIVE (RI)

These AUs do not currently use RAM and do not possess radioactive materials and are consequently placed in the Radiation Inactive status this fiscal year.

RADIATION ACTIVE (STORAGE MODE) – RA (SM)

These AUs have been placed in storage mode, at their request, and are not currently using RAM, but still have RAM inventory.

DEPARTED (D)

These AUs no longer do research at CASE and their laboratories have been decommissioned.

AUs	05/06	04/05	03/04
RA	124	116	123
RX	2	3	1
X	23	27	27
RI	12	2	7

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SM	4	9	8
D	11	12	12

MASTER ISOTOPE LIST

The master isotope (APPENDIX) list shows the University's Isotope Inventory, the sum of the AUs' inventory (excluding sealed sources), the sum of the AU Possession Limits, and the NRC/ODH Registration Limit.

AU RADIOISOTOPE INVENTORY

The Radioisotope Inventory Report (APPENDIX) lists researchers authorized to use radioactive material, the authorized radioactive materials used, the AU's possession limits, and the activity of the isotopes on hand in each AU's laboratories.

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RSOF

STAFFING

The RSOF operates under University approval with the following positions:

RSO (1)	ARSO (1)
Specialist Positions (5)	Department Administrator (1)
Department Assistant (1)	2 nd Shift Specialist (1)
Quality Assurance Specialist (1)	Student (1)

One staff member in the Specialist Position of the RSOF left CASE during this fiscal year. Experienced specialists are encouraged to attend training for their specialized functions. Seminars, Training, and Conferences attended in 2005-2006 included RCRA Hazardous Materials Manager 8-hour Refresher training, 8 hour HAZWOPER, 8-hour National Incident Management System (NIMS) & IMS Practical Drills, and DOT Refresher Training.

One member of the Radiation Safety Staff is also responsible for the DOES Home Page that houses all on-line departmental training programs and schedules, Safety manuals, Safety Newsletters, MSDSs, and Safety Information resources. This living document is an essential resource for the Campus Community that requires continuous updating. This individual also monitors and backs up all DOES databases.

Training and education are central to our departmental philosophy of developing diverse skills to respond to safety incidents and regulatory mandates. To this end, one RSOF Staff member has received the Cisco Certified Network Associate Certification and is now certified to be a program analyst.

LIAISON PROGRAM

The Liaison Program requires RSOF personnel to visit University laboratories on a routine basis to offer safety advise 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. Each designated-laboratory building is contacted, through the Liaison Program, by an assigned staff member.

DOES EMAIL

Since implementing the email "hotline" for our researchers the number of inquiries and safety concerns from CASE personnel have averaged ten emails per day. This email communication has led to swift response and follow-up of safety concerns voiced by our user community.

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.

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Ancillary workers (non-radiation workers) who occasionally have contact with RAM are retrained annually. Targeted personnel that are trained include:

AUs

A Faculty member who uses RAM is called an Authorized User.

RADIATION WORKERS

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 Facility Maintenance, Protective Services, CASE Custodial/ Contractor 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

The X-Ray Worker is any person that uses RGE under the supervision of an AU.

IRRADIATOR USERS

Personnel that use the irradiator are required to attend initial training conducted by the RSOF and site-specific training with the Irradiator Manager.

TRAINING

The RSOF records the dates of training, attendees, and content of training on file. A record of the Refresher Training that is offered online also is maintained. Classes and online sessions attended indicate overall impact of Safety training at CASE. Training is audited on a monthly basis by the Assistant RSO to ensure compliance.

Type	New Classes	New Users	Online	Retraining
Radiation Safety	30	284	724	0
Ancillary	4	84	0	0
X-Ray	15	51	N/A	N/A
Laser	8	31	11	N/A
RTK (Right to Know)	5	80	0	0
RTK Fluoroscopy	3	22	0	0
ARC (Animal Research Center)	3	9	0	0
Shipping	3	10	0	0

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Protective Services	1	31	0	0
Custodial	4	187	0	0
Irradiator	0	50	0	0

Both new isotope user and retraining classes are offered at least three times per month. The X-Ray training classes are conducted on an as-needed basis. The AUs are responsible for annual machine and performance-specific refresher training for the workers who use X-Ray equipment in their laboratory programs. Right-To-Know Fluoroscopy training is also given on an as needed basis to outside observers of the Fluoroscope located in the BRB basement. Additionally, there are monthly training classes for users of Class 3B and Class 4 lasers. The RSOF requires annual retraining offered via the Internet.

Non-laboratory personnel attend the Hazard Communication training that incorporates Radiation Safety training. Currently, the ARC, Security, Shipping/ Receiving, and Custodial departments use a Safety Orientation DVD, allowing supervisors to train staff at shift changes, thereby greatly increasing training compliance. Employees who do not complete training are restricted from working in areas where radioactive materials are used.

Training	05/06	04/05	03/04	02/03
Radiation	284	284	283	322
Retraining	0	0	0	11
Online	724	775	793	754
X-Ray	51	74	45	84
Ancillary	413	356	448	540
Laser	31	116	0	0
Laser Online	11	0	0	0
Irradiator	50	0	0	0

FACILITIES AND EQUIPMENT

The CASE administration and the RSC ensure that all facilities, equipment, and personnel are available and adequate for safe operation, storage, and disposal of licensed material. The RSO is responsible for the review of applications and inspection of the all facilities, equipment, and personnel that use licensed material. The facilities that are available at CASE for the use of licensed material include:

AW Smith	Bingham	Biomedical Research
Bishop	Bolwell	DeGrace
Glennan	Hanna Pavilion	HG Wood
Kent Hale Smith	Med East	Millis
Olin	Pathology	RBC
Rockefeller	Service	Wearn
White	Wickenden	UCRC II
Wood Research Tower	Lerner Tower	Wolstein Research

LABORATORIES

There are approximately 281 radiation laboratories on the campus. All of these laboratories are 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.

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RSOF

Facilities and equipment for laboratory inspection or isotope storage are located in the Service Building (1st Floor), Medical School (DOA990), and the Wolstein Building (1118, 1119, & 1120).

PROGRAM OFFICE:

Service Building (1st Floor)-Program offices (Clerical, RSO, & staff) & Conference Room:

Up-to-date hardware is crucial for the amount of data that is accumulated and 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.

Radiation Laboratory:

Service Building (1st Floor):

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 (a duplicate machine is 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 multi-channel 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 includes 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. The dry solid waste and the liquid scintillation vials are packed in standard 55-gallon drums. Liquid waste is stored in 5-gallon carboys placed in spill trays so as to contain leakage. Radioactive animal carcasses are kept in a designated freezer in the ARC until they are disposed.

Wolstein Building Waste Facility:

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This facility has a counting room (1120) that contains a chemical hood, a liquid process/ storage area (1119) that contains a walk-in chemical hood and solid process/ storage area (1118) for radioactive material and 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 of this facility also has been developed as a combined Chemical and Radioactive Materials Emergency Response center for the Wolstein Building. 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 spills.

IODINATION EQUIPMENT

Special iodination hoods, air pumps and activated charcoal-filter exhaust are placed in laboratories that conduct iodinations. Currently three laboratories are able to perform iodinations while four iodination hoods are in storage. Iodination hood locations are as follows:

Bishop S630/ S629 Robbins (Med East) 564 WRB 1119 (Rad Waste Facility)
DOA 990 (Storage)

ANIMAL RESOURCE CENTER (ARC)

Animal care facilities are located in the Robbins (Med East) and the Wolstein Research buildings (WRB). Conventional animal care facilities are available in the Animal Resource Center and are used by AUs to conduct animal studies with radioactive materials. A variety of animals (mice, rats, hamsters, rabbits, ferrets & large animals such as sheep, dogs, pigs) are housed within the facilities. The WRB Facility predominantly houses mice and rats. Contaminated items are stored in the ARC freezer until disposal.

EQUIPMENT CALIBRATION

Annual calibration procedures consist of an electronic check 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.

Liquid Scintillation Counter (LSC) and Packard Auto Gamma Minaxi 500 Counter calibrations are conducted weekly for the DOES Radiation Laboratory and occasionally for the LSC in both DOA 990 and WRB 1119. The CAM in DOA 990 was repaired and recalibrated.

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RADIATION SAFETY PROGRAM

PURCHASE OF RADIOACTIVE MATERIALS

The AU or their designees purchase radioactive material. The AU lists their designee in the isotope application. 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 ordered. The activity, when added to the current 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 all transfer of radioactive material internally (on campus) and externally (off campus) to or from an AU. Before initiating the transfer, either the internal or external transfer form must be completed and forwarded to the RSOF for approval. There were 124 isotope transfers approved this year, for a total of 272.77 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 the 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 on the package confirm that inspection has been completed by the RSOF. Direct pickup by the 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 surveys all radioactive material packages upon receipt for contamination and evidence of damage or breakage.

Radioisotope use, for biomedical research, results in frequent flow of radioactive materials to and from the campus. The Ohio Department of Health (ODH) Broadscope license requires that shipments be surveyed within three hours of arrival. In the past year, 933 isotope shipments (totaling 1.33 Curies) were inspected and approved by the RSOF after receipt on the campus.

DISPOSAL OF RADIOACTIVE MATERIALS

Excluding decay of isotope in the laboratories and minor inventory changes, isotopes were removed from the laboratories either by 634 isotope waste pickups by RSOF staff (303.831 mCi) or by 119 AU-directed disposals into the sanitary sewers (11.66 mCi). The following table presents a tabulated breakdown by isotope of the radioactive materials entering and leaving laboratories.

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

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¹¹ C							4	3.65
¹⁴ C	28	20.21	46	29.62	9	1.08	14	13.16
⁴⁵ Ca	3	4.00			2	0.11		
³⁶ Cl							1	0.50
⁵⁷ Co			1	0.03				
⁵¹ Cr	12	13.00	17	2.53	2	1.03		
¹⁸ F							33	181.81
⁵⁹ Fe	10	9.49	19	9.16	2	0.01		
³ H	85	53.55	234	67.29	25	2.49	27	26.20
¹²⁵ I	34	26.87	38	5.42	8	0.80	19	6.74
¹¹¹ In							3	16.03
⁵⁴ Mn			4	0.11				
²² Na	1	0.2	1	0.001				
⁶³ Ni			2	0.12				
³² P	668	960.35	196	109.01	55	5.45	19	23.99
³³ P	25	6.09	4	1.13	7	0.34		
⁸⁶ Rb	3	3.00			2	0.07		
³⁵ S	64	235.26	72	79.41	7	0.28		
^{99M} Tc							4	0.69
Total	933	1332.02	634	303.831	119	11.66	124	272.77

RADIATION MATERIALS	05/06	04/05	03/04	02/03
Orders	933	1036	1310	1594
mCi	1332	1428	1470	1570
Pickups	634	725	796	1064
mCi	304	503	327	61
Sewer Disposals	119	98	148	160
mCi	12	12	17	18
Transfers	124	66	31	0
mCi	273	149	21	0

SEALED SOURCES

CASE houses 168 sealed sources. There are 154 sealed sources that are inventoried every six months. Of those 168 sources, 17 require a six-month leak test, as stated in our license with the ODH. There are 4 of the 17 sources that are high-level dose irradiators, and one is used to irradiate material with neutrons. These are the only radioactive material sources that could produce significant external dose hazards if their shielding were compromised during an emergency. 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, 9 sealed sources were disposed.

INVENTORY	05/06	04/05	03/04	02/03
Sealed Sources	168	204	204	171
Exempt	154	183	186	158
Irradiator	4	3	3	3
Neutron	1	1	1	1

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RADIATION SURVEY METER CALIBRATIONS

The CASE ODH Broadscope license requires annual calibration of portable survey meters. Properly calibrated meters allow 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 in-house services provided by DOES generated \$12990 in cost saving over the fiscal year in lieu of using outside vendors.

CALIBRATION/ SERVICE	COST PER SERVICE	COST SAVINGS
188 meters	\$55/meter	\$10340
4 pumps	\$50/pump	\$200
52 thyroid assays	\$25/assay	\$1300
23 filter changes	\$50/ filter change	\$1150
	TOTAL COST SAVINGS	\$12990

There are 294 survey meters on campus. The RSOF calibrated 188 of these meters in the last fiscal year. There were 79 meters that were not in service. In-service meter calibrations including new meters totaled 215. Six meters required outside service for dose calibration. Certificates of calibration are kept in the RSOF for all meters that are in service at the University. Records for all meters include instrument efficiencies for isotopes used in laboratories.

Four operational pumps for radioactive materials were also calibrated for use in the iodination hoods. Our program also calibrated one iodination probe for thyroid assays weekly. The continuous air monitor that is housed in the Med School Waste Facility (DOA990) required 23 filter changes with ¹²⁵I accompanying analysis. Thyroid dose assays were provided for individual radiation workers and air monitoring in the University radioactive waste facilities.

CALIBRATION/ SERVICE	05/06	04/05	03/04	02/03
Meter Calibration	188	233	245	250

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 have a security lock to limit access to materials or must contain a security lock attached the storage units within a labeled lock-box. Access to isotope inventory also is 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 areas where radioactive materials are present are properly secured. All buildings undergo radiation security inspections each month. Only minor violations of required security procedures were found.

RAM Security Checks	05/06	04/05	03/04
Violations	74	89	104

PERSONNEL MONITORING

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

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laboratory workers, visitors to the laboratory, maintenance workers and contractors working in the laboratory are potentially included in the University dosimeter program. Other personnel may request dosimeters that are provided at the discretion of the RSOF. Radiation workers 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 to ensure 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.

PREGNANT WORKER PROGRAM

Any radiation worker who is or feels she may be pregnant is advised to complete a Declaration of Pregnancy Form and send it to RSOF. Counseling is provided and an additional dosimeter is issued to the worker that is read every month. This additional fetal dosimeter is worn to conservatively measure any dose to the developing baby. No 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 also provides special dosimeters for individuals carrying out experiments and procedures involving the use of radiation generating (x-ray) equipment, such as fluoroscopes. The six Fluoroscopy users had collar badges.

Although only 20% of the workers would be required to wear dosimeters to meet terms of the CASE Broadscope radioactive materials license or Radiation generating equipment programs, the use of dosimeters is encouraged because it provides an excellent method to detect any activities that might be dangerous to individual workers. Notably, no significant exposures were noted in 2005-2006.

PERSONNEL MONITORING	05/06	04/05	03/04	02/03
Pregnant Workers	6	6	13	15
Neutron	0	0	0	0
RGE/ X-Ray	60	201	160	180
General	905	1005	970	1030

CASE radioactive material users use Luxel badges that employ the latest radiation detection technology for personnel dosimetry. The 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 the spring of 2006.

RADIATION GENERATING EQUIPMENT

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Machines that produce ionizing radiation (RGE) require safety labeling of appropriate warning indicator systems and 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. Radiation-generating equipment is inventoried quarterly and surveyed annually for leakage. The investigators in charge of the RGE, not the RSOF, offer site-specific training programs for workers using this equipment. DOES provide general safety classes for individuals using RGE.

RADIATION-GENERATING UNITS	05/06	04/05	03/04	02/03
Health Care & Diagnostic Research	42	32	32	32
Analytical Research	40	48	51	51
Tubes Only	17	19	18	19
TOTAL	99	99	101	102

RADIATION-GENERATING UNITS	05/06	04/05	03/04	02/03
Analytical units In storage	23	21	23	23
Analytical units Disabled	3	7	5	7
Analytical units Out of Service	11	9	7	7
Diagnostic units Disposed	7	3	2	1
Diagnostic units Purchased	11	2	1	1

RADIOACTIVE MATERIAL RELEASES

SEWER EXPOSURE CONTROL & MONITORING

State and Federal regulations permit CASE to dispose of low levels of radioactive materials in the sanitary sewers. The Northeast Ohio Regional Sewer District (NEORS) requires semiannual reports on radioactive material discharged to the sanitary sewer system. CASE's sewer releases were in compliance with both Federal and State regulations. In the past fiscal year, the report for July through December 2005 was filed on January 24, 2006 and the report for January through June 2006 was filed on July 25, 2006. AUs in Storage Mode or using only Sealed Source are 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 2005 calendar year, radioactive material releases to the air were less than 10% of the maximum levels set by the EPA. Therefore, CASE had no reports to file, and the University is in compliance with the air effluent releases stipulated by the EPA Clean Air Act, the NRC, and the ODH.

With regard to airborne exposures, the primary concern is to preclude airborne exposure to radioactive iodine that is used for protein iodination experiments. To control exposures the RSOF requires that reactions involving use of free 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

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prevent airborne release of radioiodine. The number of airborne iodine exposures has decreased due to the infrequent use of radioactive iodine in experiments.

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

There were, during 2005-2006, three active iodination laboratories. Four iodination hoods are in storage in the DOA990 Waste facility for implementation when required. A bioassay is required when more than 1 mCi of radioactive iodine is used in volatile form. The RSOF also must be notified when such experiments require:

- Handling of more than 1.0 mCi of volatile radioactive iodine.
- 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 of radioactive iodine to the environment.

After iodination, 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 materials waste handling. Bioassays for radioiodine were performed for a total of six iodination procedures. No workers were found to have radioactive materials accumulated in their thyroids that exceeded 10% of the ODH limits. This chart highlights the decrease in iodination procedures in University laboratories.

IODINATION PROCEDURES	05/06	04/05	03/04	02/03
Total	6	7	11	20

¹²⁵ I BIOASSAYS	05/06	04/05	03/04	02/03
RSOF Staff	64	67	64	40
Additional	7	10	13	20
Total	71	77	77	60

TRITIUM

Urine bioassays must be carried out for tritium users in accordance with the schedule below, with a baseline bioassay required prior to experiment. No urine bioassays were required during this fiscal year.

RADIOACTIVE MATERIALS INCIDENTS

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EMERGENCY RESPONSE

General emergency 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 emergency situations involving RAM. Such actions are taken upon determination by the RSO of conditions that present imminent danger or threat to personnel, property, or the community at large. There were no radiation incidents documented over the past fiscal year.

INCIDENT/ SPILL RESPONSE

MAJOR INCIDENT/ SPILL

This is a spill that involves personnel contamination or results in contamination outside of the intended work area; one 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.

INCIDENTS	05/06	04/05	03/04	02/03
Major	0	1	1	5
Minor	0	4	8	5
TOTAL	0	5	9	10

DOES WEB SITE & NEWSLETTER

The DOES home web site (<http://does.case.edu>) provides integrated web-based access to DOES 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 DOES 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 and addenda, addresses concerns that are found during laboratory inspections, and answers to questions frequently asked by laboratory personnel. Articles that were submitted during this year included:

- Laser Safety Committee Volunteer
- Irradiator Program;
- Security of Radioactive Materials
- Radioactive Waste Segregation
- CASE Laser Safety Updates
- A New UV Safety Program Is in the Works at DOES
- Irradiator Audit Program Coming to CASE
- Security of Radioactive Materials
- Separation of Background Scintillation Vials from Radioactive Scintillation Vials
- Radiation-Generating Equipment: Label It!
- Radiation Shielding Available Free of Charge;

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LASER SAFETY PROGRAM

Successful completion of an audit of all lasers on campus was done in 2005 and all laser users were trained. Laser Safety Training has progressed well since its inception during September of 2004. A standard operating procedure is incorporated into the Physical Safety Manual that is provided to all laser users. The Specialist in charge of this program successfully completed Laser Safety Officer Training in February 2005.

The lasers of greatest concern are those labeled Class 3B and Class 4. The laser inventory was updated and new signs were posted. There are a total of 150 lasers on the campus in 10 buildings that are used in the laboratories of 39 researchers. There are 65 Class 4 lasers, 55 Class 3B lasers, and 30 lasers fall in the other classes of 1, 2, and 3A.

Development of the internal operating procedure for the Laser Safety Program was completed. A spreadsheet was developed this year for the Laser Safety Program. Each PI received a copy of this spreadsheet that displays the status of the entire Laser Safety Program. More importantly, it allows each PI to select the lines applicable to only their program for maintaining an updated program file and inventory. A consolidated Laser Safety Guidance Packet was developed and sent to each PI. This packet was developed to assist PIs in implementation of their Laser Safety Programs. The guidance packet includes additional instructions on the following Laser Topics: OSHA Tech Manual, Guidance for Controlled Entries, Site SOP Guidance, Laser MAP Guidance, UV and Laser Safety, Laser Pamphlet of Calculations, Laser Sign Guidance, Guidance pertaining to Dye Lasers, Duties of the Laser Safety Supervisor, Overview of the ANSI Standard Laser Safety Controls and instructions for a Laser Safety Committee.

CLEARANCES/ RELOCATION PROGRAM

Researchers on the campus are often relocated. This process requires decommissioning of old equipment, and relocation or termination of use of laboratory space. The RSOF requires at least three weeks notice for the clearance and relocation of laboratories. An orchestrated effort between the RSOF, Facilities Management, and the AU facilitates these operations. There were 505 clearances for 570 pieces of equipment. A total of 17 relocations and 4 terminations were completed over the past year.

WASTE MANAGEMENT

RADIOACTIVE WASTE FACILITY

The Barnwell Waste Facility remains open and we are required to use Barnwell services as long as they are available. 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 Radioactive Waste Facility (RWF) is used to segregate waste streams and prepare the waste for disposal. The different waste streams include aqueous waste, sharps, acrylamide or agarose gels, animals, scintillation vials, and dry solid waste.

Short-lived solid waste is held for decay (= or > 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 promoted by the RSOF. As part of the waste minimization program, isotope users are encouraged to reduce the volume of waste generated in the

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laboratory by minimizing the use of extraneous paper products through routine survey to ensure that material is free of high-energy beta emitters before disposal. 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. Short-lived non-sewer (chemical waste) is held for decay, resurveyed after ten half lives, and disposed by Chemical Analytics, a commercial hazardous waste disposal company.

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 10 CFR 20 Appendix B. A sewer disposal log is kept in the DOES offices. The total sewer disposals are reported semi-annually to the Sewer District.

COLLECTION & DISPOSAL OF ANIMAL REMAINS AND BIOHAZARDOUS WASTE

The Animal Resource Center (ARC) maintains a -20°C freezer for storage of radioactive animal remains and waste. These wastes are bagged and labeled in the same manner as dry solid waste. All waste placed in the freezer must be logged in the animal disposal sheet on the cold room door. A log sheet for animals disposed in this manner is also kept in the waste generating laboratories for inventory purposes.

Any item that has come in contact with an etiologic agent is considered biohazardous and is placed in a red biohazardous container. Etiologic agents include bacteria, viruses, and parasites. Due to reconstruction of the ARC, infected animal waste is autoclaved (unless the radioactive isotope is volatile) and placed in the ARC (EB04B instead of EB09A) for disposal by the RSOF. Radioactive animal waste includes cage bedding, carcasses, viscera, excrement, serum, blood or other animal tissue containing radioactive materials.

RECYCLING PROGRAM

In the past fiscal year, the RSOF obtained radiation safety 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 resulted in relocation of equipment that saved AUs more than \$8,000 during 2005-2006.

DISTRIBUTION OF WASTE GENERATED IN JULY 1, 2005 - JUNE 30, 2006

	Generated 7/1/2005- 6/30/2006	Disposed: Stericycle (Burned)	Disposed: Sewer	Disposed: Safety	Disposed: ADCO	In Storage As of 6/30/2006
Short-Lived Dry	72	83 *	0	0	0	57 **
Long-Lived Dry	25	0	0	0	25	0
Scintillation Vials	47	0	0	0	47	0
Animals	3	2	0	0	1	0
Long-Lived Sewer	46	0	46	0	0	0

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Long-Lived Non-Sewer	15	0	0	0	0	15
Short-Lived Sewer	125	0	125	0	0	0
Short-Lived Non-Sewer	20	0	0	15	0	5

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, 2005, kept for decay in storage, and disposed during the period of July 1, 2005–June 30, 2006. The double asterisk (**) denotes the drums that were generated prior to July 1, 2005 and still held for decay in storage. During this fiscal year, all long-lived hazardous aqueous waste was disposed.

Barnwell animal waste cost = \$2,634 per 32-gallon drum
ADCO DIS dry waste cost = \$555 per 55-gallon drum

The cost of disposal for one drum of biomedical waste at Stericycle is \$40 per drum. There were 83 drums of dry waste and two 32-gallon drum of animal waste surveyed and disposed during 2005-2006 fiscal year at a cost of \$3400. Without the decay in storage program, it would cost \$555 to send one 55-gallon drum of decay in storage (DIS) dry waste and it would cost \$2,634 per 32-gallon drum of animal waste through ADCO services. Therefore, in the absence of decay in storage, the cost to send the waste drums through ADCO would have been \$51,333. Therefore, the indirect savings to researchers due to the decay in storage program was \$47,933.

WASTE GENERATION	05/06	04/05	03/04	02/03
Short-Lived Dry	72	66	63	66
Long-Lived Dry	25	28	31	26
Scintillation Vials	47	44	45	39
Animals	3	2	1	3
Long-Lived Sewer	46	55	60	50
Long-Lived Non-Sewer	15	5	0	0
Short-Lived Sewer	125	115	80	76
Short-Lived Non-Sewer	20	35	75	85

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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. The RSOF has developed programs that meet or exceed regulatory requirements in most Safety areas and proactively anticipate new safety requirements as new programs are promulgated thanks to 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 2005-2006

Over the past year, the DOES continued to improve the effectiveness of the Radiation Safety Program. Notable new accomplishments included:

- After departure of a technical staff member, DOES successfully reorganized the Department to meet the challenge of operating with a smaller technical staff.
- DOES developed and carried out more comprehensive internal audit of all programs.
- DOES maintained its Liaison program to provide a service connection to the safety programs for all Faculty, Staff and students.
- Initiated development of new Laser irradiation and UV radiation safety programs.
- Accomplished its highest historical level of compliance with its training programs.
- Developed closer liaison with the University Hospitals Programs.
- With Radiation Safety Committee and involved Faculty AUs, developed a master isotope approval protocol, and safety program for the new Imaging Facilities.
- Reorganized irradiator programs into a discrete license unit and developed new security programs for these facilities in compliance with new State and Federal Guidelines.
- Generation of \$68,923 in cost savings for the University as a result of services provided by DOES versus in-house use of outside contractors, and recycling materials.

RADIATION SAFETY GOALS FOR 2006-2007

The overall goal of the Radiation Safety Program in the future will be to position DOES for more effective interaction with the educational and research goals of the University through training and training development. A secondary goal will be to increase the impact of CASE Safety Programs on the surrounding community through educational and programmatic interaction with local partners and emergency responders. Specific efforts will also address:

- Promotion of community benevolence through complementary services and materials.
- Provision of comprehensive safety monitoring and new program initiation for the Case Western Reserve Campus in the face of significantly reduced staffing. Accomplishment of this goal requires attention to the balance of the Departments safety programs to ensure that no critical safety areas are left unaddressed. To

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

- To continue our mutual development of campus emergency response with Protective Services.
- Incorporation of brief movies illustrating procedures in the radiation retraining for next year, which could eventually be used in other radiation training presentations.
- Redesign of a compliance review paper trail in order to decrease the amount of paperwork and data entry that is required by staff. This review aid will be placed on Palm Pilots for rapid entry when it is completed.
- Development of more effective enforcement policies for both the Irradiator and Radiation Generating Equipment programs.
- Develop of procedural follow-up for overdue survey meters. A teaching video for staff on meter calibration, surveys and other internal procedures will also be developed.

Prepared by Felice Thornton-Porter on 9/21/2006.

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APPENDIX