INTRODUCTION

This report is submitted to the president and appropriate members of the administrative staff of the university, as required by the Radiation Safety Committee (RSC) operating guidelines and Case Western Reserve University's (CWRU) Broadscope State of Ohio (Nuclear Regulatory Commission Agreement State) License. Its contents cover the period from July 1, 2001 through June 30, 2002.

OHIO DEPARTMENT OF HEALTH (ODH) LICENSE

At present, CWRU has one Ohio Department of Health (ODH) Broadscope license. The license incorporates possession and use of both naturally accelerator-produced radioactive material (NARM) and naturally occurring radioactive material (NORM) for experimental purposes, as well as three irradiators.

ODH LICENSE	EXPIRATION DATE	PURPOSE
011-011800-11	January 1, 2005	Broadscope License

RADIATION SAFETY COMMITTEE (RSC)

Listed below is the 2001-2002 Radiation Safety Committee membership. Changes to the voting membership must be approved by the president of the University, and sent to the ODH before the new member can be a "voting member".

VOTING MEMBERS

Dr. David Boothman Dept. of Radiation Oncology	Dr. Hue-Lee Cheng Kaung Dept. of Pediatrics / Anatomy

BRB 347 Term Expires: 3/11/2002	BRB B32 Term Expires: 8/30/2002
David Danielpour Dept. of Medicine UCRC II Suite 200 Term Expires: 3/11/2005	Dr. Irene Lee Dept. of Chemistry Millis 4N Term Expires: 10/1/2003
Dr. Cathleen R. Carlin Dept. of Physiology/Biophysics Med East 564B Term Expires: 2/1/2004 Chairperson: 1/1/2002	Dr. David McPheeters Dept. of Biochemistry Wood 432 Term Expired: 5/1/2001
Dr. Helen Evans Dept. of Radiology BRB 325 Term Expires: 8/8/2004	Dr. Ellen Rorke Dept. of Environmental Sciences BRB B04 Term Expires: 2/1/2004 Chairperson: 3/11/2003
	Dr. David Sedwick Radiation Safety Officer DOES Service Building, 1st Floor

EX-OFFICIO MEMBERS

Kenneth Basch Asst VP of Facilities Mgmt. Oper. Crawford Building, 215	Dr. William Stephany Asst. Radiation Safety Officer Service Building, 1st Floor
Shirley Xu University Hospital Asst. RSO Dept. of Radiology Bishop S-629	

SUPPORT STAFF

Karen Janiga Technical Support Manager Service Building, 1st Floor	Felice T. Porter Quality Assurance Specialist Service Building, 1st Floor
Gwendolyn Cox-Johnson Department Assistant Service Building, 1st Floor	Shirley Mele Office Supervisor Service Building, 1st Floor

The committee met on nine occasions during the last fiscal year to review applications for radioisotope usage and act on other business. A total of seven new authorized users were approved during the period covered by this report.

Fourteen requests for additional radioisotope usage were approved. One new request for radioisotope use in animals was considered. The minutes of the RSC meetings and Executive Committee actions are available in the RSOF, through the RSC, or through the university administration.

RSC PERFORMANCE & RECORD AUDITS OF RSOF ACTIVITIES IN 2001-2002

RSC members conducted a systemic audit of the following areas of the radiation safety program during this fiscal year.

AREA AUDITED	# OF INDIVIDUAL FILES EXAMINED	OTHER AREAS AUDITED
Authorized user files	10	
Radioactive isotope inventory	10	
RPE inventory & training	10	
Ancillary staff training	7	
AU & worker training	6	
Radiation survey meters	5	
Waste disposal facility	5	
Shipping papers		X
Radioisotope security checks		X
Bioassays	5	
Monthly mailings	10	
Sealed source leak tests	5	
Radiation generating equipment		X

These audits were conducted in October - December 2001 and April - June 2002. This process resulted in audit of more than 60 files and examination of the program areas listed above during the year.

During this year's audit of the radiation safety program it became apparent that there is a need to update several of the bi-annual audit formats, as they did not always reflect current procedures. Program areas for which audits required

modification included support staff training, sealed source leak tests, and shipping papers. These changes to audit procedures will be implemented by the Radiation Safety Committee.

The bi-annual audits were 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.

ANNUAL RADIATION SAFETY PROGRAM AUDIT REPORT

The RSC met on July 17, 2002 to conduct the annual audit of the CWRU radiation safety program. The committee members participating in the audit were Drs. David Danielpour, Helen Evans, Hue-Lee Kaung, Irene Lee, and Ellen Rorke.

This memo summarizes results of the RSC audit of seven areas that were reviewed.

1. **Compliance reviews**: Approximately 50 files were reviewed to verify that laboratories were audited within the last six months and, when needed, follow-ups were done on non-compliance issues. Seven files were identified that required follow-up. Areas highlighted for specific review included surveys, meter calibration, and documentation maintenance.

2. **Inventory and mailings**: Approximately 50 files (Greenspan-Marengo) were reviewed to verify receipt of semi-annual mailings for the last 6 months. One investigator had no report filed for either December 2001 or June 2002, two files were identified which lacked the December 2001 inventory report and 16 files were identified which lacked the June 2002 inventory report. Upon

speaking to the support staff it was apparent that the staff was dealing in a timely fashion with the July non-responders.

3. **Applications for use of radioactive materials and training of AU and radiation workers**

within the last 12 months. This audit was particularly difficult, since the survey meter list was organized alphabetically by AU name, but the meters are filed by manufacturer. Prior to next years audit, the survey meter list should be resorted by manufacturer and instrument serial number for the purpose of the audit. This change was suggested after last years audit but was not implemented. It was suggested that the file be placed in Excel or a similar program to facilitate this process.

6. **Security checks by the RSOF (July 1, 2001 to June 30, 2002):** It was verified that security checks by the RSOF were conducted on a monthly basis and that

reviews all programs, audits all departmental records on a periodic basis and assists in the Radiation Safety Office. This year, in response to audit queries, the Radiation Safety Office presents the following explanations and will implement the following changes to procedures that can be considered by the Radiation Safety Committee in subsequent follow-up audits.

During the audit of the compliance reviews and the inventory reports, minor inconsistencies were found. These areas are audited on a monthly basis and corrected as they occur. Those individuals requiring retraining were within the normal time frame. Inconsistencies noted by the RSC were corrected in a timely manner after the audit.

An audit of the applications for use of radioactive materials revealed an area that will need to be reviewed by the RSC in the future. There are numerous applications that have not been reviewed or updated since the 1980's. Several of these applications were identified that lacked RSC signatures. Over the coming year, the RSC will review old applications to ensure that they are in compliance with current programs.

The possession limit of one AU was found to have exceeded the level of present usage in the laboratory. At this time the university is well within the boundaries of its license allocations so there is no need for action that alters general procedures. However, the Radiation Safety Office's current policy is to review isotope allocation levels at the time that alterations are made to AU files. The office also makes reductions in isotope authorization levels at other times following usage review after consultation with AUs. In this case, the communication concerning reduction of isotope authorization levels was either not adequately communicated to the AU or the AU failed to make note of the

authorization level change. Reduction in isotope authorization levels does not require RSC action.

Further, the Radiation Safety Office is in the process of implementing on-line access for AUs to their radiation safety records. On-line AUs that do not have inventory information would not have received data by date if they have not ordered isotope or use sealed sources only.

Although there were few problems with security checks over the past year, two incomplete security checks by one individual impeded the security audit system in May and June. In the coming year, however, a new staff person will join the Department of Occupational and Environmental Safety and work evening hours to assume responsibility for all security audits. Stronger oversight will be implemented in the future.

The Radiation Safety Office thanks the Radiation Safety Committee for the audit of its safety activities over the past year.

RADIATION SAFETY OFFICE (RSOF)

STAFFING

The RSOF operates under university approval with the following positions:

Radiation Safety Officer (1)
Assistant Radiation Safety Officer (1)
Specialist Positions (6)
Department Administrator (1)
Department Assistant (1)

Reorganization of the RSOF infrastructure continues to incorporate more individuals into the specialist position to improve the department's knowledge base and provide for more flexible response to emergencies and other issues.

FLOWSHEET FOR RADIOACTIVE MATERIALS

Radioisotope use for biomedical research requires continuous receipt and shipment of radioactive materials to and from the campus. In the past fiscal year, 3144 isotope shipments (totaling 2.62 Curies) were approved by the RSOF for receipt on campus. The Ohio Department of Health (ODH) and our Broadscope license require that shipments be surveyed within three hours of arrival. The surveys are performed by the RSOF. Special printouts are attached to each package to facilitate recording of labora

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more than 10% of his or her applicable dose limits. No significant exposures were noted in 2001/2002. During the past year, 13 pregnant radiation workers received additional monitoring for fetal doses. All fetal doses were at background levels of radiation.

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 2002.

CWRU radioactive materials users use Luxel badges, which employ the latest radiation detection technology for personnel dosimetry. The Luxel badges can measure minimum detectable limits of 1.0 mRem.

AUTHORIZED USERS OF RADIOACTIVE MATERIALS

CWRU has 171 principal investigators (PIs) authorized by the RSC to use radioactive materials in 256 laboratories. Laboratories are inspected by the RSOF at least three times per year. Audits are more frequent if there are particular concerns in a laboratory. During this fiscal year, one researcher that has stopped using isotopes became inactive, and nine researchers left CWRU.

TRAINING SESSIONS

Both new isotope user and retraining classes are offered at least three times per month. During the past year the office held 23 new user classes for 460 new isotope users. Five retraining classes we

training classes have been converted to Powerpoint presentations. This is audited on a quarterly basis.

The X-Ray training classes are conducted on an as-needed basis. Last year there were 19 classes held for 95 new workers. Retraining classes are not presented by the RSOF for X-Ray users. The authorized users of the X-Ray equipment are responsible for annual machine and performance-specific refresher training for their workers who use X-ray equipment.

RADIOACTIVE MATERIAL RELEASES

a. SEWER

State and federal regulations permit CWRU to dispose of low levels of radioactive materials in the sanitary sewers. The Northeast Ohio Regional Sewer District (NEORSD) requires semiannual reports on radioactive material discharged to the sanitary sewer system. CWRU's sewer releases were in compliance with both federal and state regulations. In the past fiscal year, the report for July through December 2001 was filed on January 30, 2002 and the report for January through June 2002 was filed on July 26, 2002.

b. AIR

During the 2001 calendar year, radioactive

BIOASSAYS

Bioassays are conducted to monitor the internal disposition of radioactive materials due to inhalation or ingestion during experimental procedures. For example, some experiments require the use of volatile forms of radioactive iodine. Due to the potential for internal contamination, these identified users are required to have bioassays performed to determine if any radioactive materials were inhaled or ingested. In the past year, 88 thyroid bioassays for radioiodine were performed for a total of 35 iodination procedures, which included effluent air monitoring. No workers were found to have radioactive materials accumulated in their thyroids that exceeded 10% of the ODH limits.

RADIATION PRODUCING EQUIPMENT

Machines that produce ionizing radiation (RPE) are regulated by ODH for labeling, appropriate warning indicator systems and radiation leakage. CWRU has a total of 102 units on campus (19 are tubes only), of which 10 are in storage, 7 are disabled, and 7 are out of service. There are 51 X-Ray units used for analytical research that include electron microscopes, X-Ray diffraction and particle accelerators. There are also 32 X-Ray units for health care & diagnostic research, which consist of dental X-Ray units and veterinary X-Ray units. Four units were disposed and five units were purchased. These units are inventoried quarterly and surveyed annually for leakage. As listed above, the owners of the RPE, not the RSOF, offer specific training programs for workers using X-Ray producing equipment. The general X-Ray training program has been modified for Powerpoint slide presentation.

RADIATION SURVEY METER CALIBRATIONS

The University ODH Broadscope License requires annual calibration of portable survey meters. Properly calibrated meters are necessary for laboratories to perform accurate radiation surveys and provide results with proper radiation measurements.

There are 286 survey meters on campus, of which the RSOF calibrated 215 meters in the last fiscal year. Nine meters were returned for repair to the manufacturer while 25 meters were repaired in-house. The RSOF is licensed to perform electronic and isotope efficiency meter calibrations for the faculty and staff on campus, a procedure that saves AUs approximately $35 - $50 per instrument calibrated.

The creation of a calibration database has substantially lessened the meter calibration time by reducing data entry. Notification of meter calibration status via email gives the RSOF documentation that the authorized user was notified to pick up the meter and that repairs were performed as needed.

MASTER ISOTOPE LIST

The master isotope list shows the university's isotope inventory, the sum of the authorized users' inventory (excluding sealed sources), the sum of the

possession limits, and activity on hand in AUs' laboratories. A copy of this list is in the Appendix.

DOES WEB SITE & NEWSLETTER

The RSOF has developed a revised DOES home web site (http://does.cwru.edu) and integrated web-based access to DOES services. Information on training classes, on-line retraining, and safety manuals are available. We have also converted the "Radiation Safety Manual" to an Adobe Acrobat format, allowing users to download the document, and either read, or print appropriate sections for use in their laboratories.

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 addendums, addresses concerns that are found during laboratory inspections and answers questions frequently asked by laboratory personnel.

RADIOACTIVE WASTE FACILITY

The Barnwell Waste Facility remains open at a high price. However, we are required to use their services as long as they are available. Our Radiation Waste Facility decay-in-storage licensing with the NRC specifies that we must dispose of any interim generated waste as soon as practical when a waste site is open. Plans for locating Ohio's Midwest Compact Low-Level Radioactive Waste site have been recently reviewed, and the plans for locating radioactive waste in Ohio have been suspended.

The CWRU Radioactive Waste Facility is used to segregate waste streams and prepare the waste for disposal. The different waste streams include aqueous waste, scintillation vials, and dry solid waste. Some radioactive isotopes have relatively short half-lives and are decayed to background in our facility. Other radioactive isotopes have longer half-lives and must be stored on an interim basis before disposal. Short-lived waste types are picked up from laboratories by the RSOF staff for interim storage in the Radioactive Waste Facility.

Short-lived solid waste is held for decay in the Radioactive Waste Facility. A find survey is performed of the waste and subsequently sent to 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 laboratory by minimizing the use of extraneous paper products, routine surveys of high energy beta emitter, using GN meters, and by insuring that non-radioactive waste is not included with radioactive waste.

In the past, significant amounts of radioactive waste were disposed through commercial vendors since time constraints on in-house disposal were caused by the length of time it took to unpack compacted waste, opaste, o1 (wate,)8.4o19.core dusjstraia t

DISTRIBUTION OF WASTE GENERATED IN JULY 1, 2001 - JUNE 30, 2002

InStorage	Generated	Disposed	Disposed	Disposed
7/1/2001		BFI	Sewer	

The total indirect cost savings to researchers by disposing of all DIS dry / solid waste through Browning Ferris Industries (BFI) was $10,296.

INCIDENTS INVOLVING RADIOISOTOPES

February 18, 2002 - A bag containing 0.01 Ci of H-3 dry waste was picked up by housekeeping and disposed as regular trash. Although the amount of radioactive material involved was not reportable, the procedural oversight was significant. The individual from housekeeping admitted that he had emptied the trash into a regular waste container. The container was clearly marked with radioactive labels. The Radiation Safety Office, his supervisor, and the asst. director of Housekeeping Services counseled the individual as to proper procedures.

March 7, 2002 - A technician found nCi P-32 contamination on the bottom of her shoe while performing a post-experiment survey. She decontaminated the shoe

2002-03 RADIATION SAFETY OFFICE GOALS

General Administrative Goals - Procedures for most operational areas of the department have been completed as of last fiscal year. We will begin the first of our annual review and updating of all standard operating procedures in the coming year.

At the close of fiscal year 2002, the Radiation Safety Office began a search for a new assistant radiation safety officer. Until a permanent replacement for our Assistant RSO is identified, Karen Janiga will fill the position of acting assistant RSO. A search will also be initiated for a new specialist who will be cross-trained in both radiation and safety service response areas to monitor after hours security and safety on the CWRU campus in the evening and on Saturday. (Note: as of the date of submission of this report (10/23/2002), this goal has been accomplished. Karen Janiga was appointed to the assistant RSO position and Edward Traverso (RRPT) has taken over her former position as operational manager in the Radiation Safety Office.)

Emergency Response - Over the past year, our department developed emergency response plans for incidents involving radioactive, chemical and biological materials.

These plans have been reviewed with input from University Protective Services and local fire and emergency response officials. Over the last year, all responding and administrative personnel in

New operational procedures for H-3 bioassays and gamma counter usage will be developed and introduced.

APPENDIX

Sealed Sources