

Radiation Safety Program at the National Institutes of Health

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BACKGROUND

At the National Institutes of Health (NIH), one of the world's foremost biomedical and clinical research institutions, much of the research is performed using radiation or radioactive materials. To maintain a safe environment, minimize risks, and protect the health and safety of employees, patients, visitors, and the surrounding community, a radiation safety program is required. Under US Nuclear Regulatory Commission (NRC) licenses and NIH policies, the radiation safety branch (RSB), administers a comprehensive radiation safety program covering over 3,000 NIH laboratories and over 6,000 laboratory and 2,700 ancillary staff workers. The radiation safety program provides for the effective supervision, control, and monitoring of all radioactive materials and radiation sources at NIH. This includes activities such as personnel monitoring, laboratory inspections, waste management, consultation, environmental monitoring, and training. As a result of this comprehensive program, exposure of NIH employees to external and internal radiation has been kept well below the NRC's radiation dose limits and consistent with the NRC's As Low As Reasonably Achievable (ALARA) concept.

INTRODUCTION

The National Institutes of Health (NIH) is the federal government's principal facility for the conduct of biomedical and clinical research on the causes, effects and treatment of disease in humans. Table 1 lists the institutes and centers comprising the NIH. The NIH's mission is to uncover new knowledge leading to improved health by:

- a) conducting research in its own laboratories;
- b) supporting the research of non-federal scientists in universities, medical schools, hospitals and research institutions throughout the country and abroad;
- c) helping in the training of research investigators; and
- d) fostering and supporting biomedical communications.^[1,2]

The NIH is one of eight health agencies of the US Public Health Service, a component of the US Department of Health and Human Services. The principal laboratories, clinics, offices, animal quarters, and other specialized facilities of NIH are located on a 306-acre campus in Bethesda, Maryland, and at several off-campus sites located in Rockville, Poolesville, Kensington, Gaithersburg, and Baltimore, Maryland. Although NIH has several other sites (e.g., North Carolina, Arizona and Montana), only Bethesda and its associated sites are included under the Bethesda NRC license. The other locations have their own licenses. Along with its many research institutes, the NIH has a 350-bed clinical research hospital

Table 1. *The National Institutes of Health Components*

Office of the Director
National Cancer Institute
National Eye Institute
National Heart, Lung & Blood Institute
National Human Genome Research Institute
National Institute on Aging
National Institute on Alcohol Abuse & Alcoholism
National Institute of Allergy & Infectious Disease
National Institute of Arthritis & Musculoskeletal & Skin Diseases
National Institute of Child Health & Human Development
National Institute on Deafness & Other Communication Disorders
National Institute of Dental & Craniofacial Research
National Institute of Diabetes & Digestive & Kidney Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders & Stroke
National Institute of Nursing Research
Warren G. Magnuson Clinical Center
Center for Informational Technology
National Center for Research Resources
National Library of Medicine
John E. Fogarty International Center
Center for Scientific Review

and an ambulatory care research facility. The NIH employs over 19,000 scientists, physicians, dentists, veterinarians, technicians, administrative staff and support personnel. More than 4,500 of the NIH staff have advanced education with either medical or research doctoral degrees. In addition, numerous guest scientists from the US and abroad collaborate in NIH research activities.^[1,2]

The NIH intramural programs involve the use of a wide variety of radionuclides and radiation-producing equipment in research as well as in medical diagnostic and therapeutic applications, including research involving animal and human subjects.^[3,4] Much of the biomedical research involves the use of radiation and radioactive materials. Radioactive materials and radiation sources are the most strictly regulated tools used in biomedical research, medical diagnosis and treatment.

The NIH radioactive materials program is among the largest of biomedical research institutions in the world in terms of the numbers of radionuclide and radiation users (approximately 6,000), numbers of laboratories (over 3,000) and shipments of radioactive materials (approximately 20,000 per year).

LICENSING AND ADMINISTRATION

The NIH radiation safety program employs both in-house and contract personnel to ensure radiation activities are in compliance with applicable NRC and governmental regulations and NIH employees, patients, visitors and the surrounding environment, including members of the general public, are protected from the potential harmful effects of radiation.

Most radioactive-tracer work done at NIH is conducted with NRC-licensed byproduct material under a broad-scope, Type A, specific license, while certain radioactive sources, such as irradiators, are licensed separately by the NRC.^[5] Other radiation-producing devices such as x-ray machines, accelerators and cyclotrons are not regulated by the NRC and do not require licensing, but radiation exposure from such devices fall under the regulation of the US Department of Labor. There are also certain radionuclides which are not byproduct materials (²⁰¹Tl,

⁶⁷Ga and ⁵⁷Co are some of the more commonly used isotopes) and therefore are regulated by agreement and licensing states rather than the NRC. However, the NIH Radiation Safety Program oversees the use of all radioactive materials, whether NRC- licensed or not, and all instruments or machines capable of producing ionizing radiation.

The NRC routinely inspects the NIH to determine if activities with licensed materials or sources are being conducted in accordance with applicable NRC regulations and the conditions of the licenses issued. These inspections focus not only on the program but also on individual laboratories, authorized users (AUs) and individual users (IUs) working under the supervision of AUs. The NRC has an enforcement program, wherein they report violations of regulations in the *Federal Register* and the press, and can impose civil penalties (i.e. monetary fines) on the licensee. Severe or repeated violations can result in suspension or revocation of the license.

In addition to the NRC regulations and licenses, the NIH radiation safety program must conduct operations in accordance with other federal, state, and local regulations and requirements. These include the US Department of Transportation (DOT), US Department of Labor (DOL), US Environmental Protection Agency (EPA), State of Maryland and the Washington Suburban Sanitary Commission.

The radiation safety program^[6-8] is a joint effort of the NIH radiation safety committee (RSC) and the radiation safety branch (RSB). The RSC, mandated by the NRC, establishes the policies, requirements, and guidelines for the use of radiation sources at the NIH in accordance with the NRC license and regulations. The RSC, acting on behalf of the director of the NIH, provides advice and approval to the radiation safety officer (RSO) for the conduct of the radiation safety program. Members of the RSC are appointed by the director of the NIH.

The program is administered under the authority and supervision of the RSO. The RSO is appointed by, and reports to the director of the NIH for the program's content and execution. The RSO is also the chief of the radiation safety

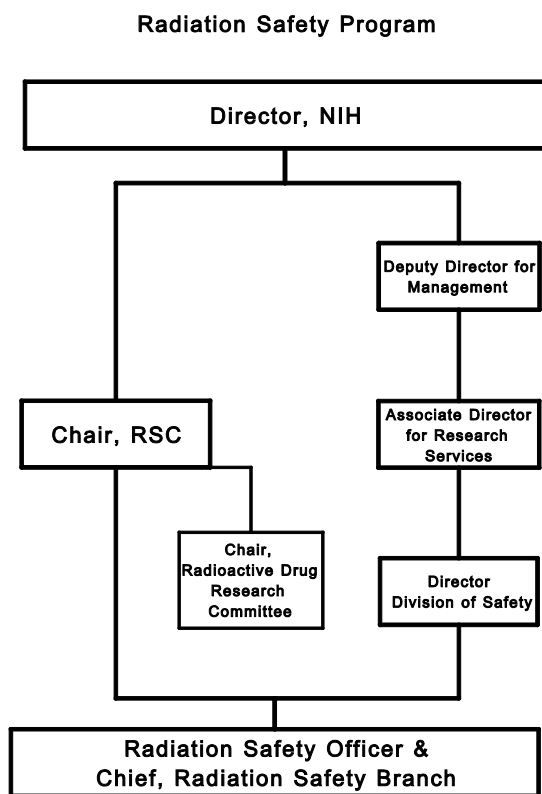
branch, whose staff and contracting resources conduct the daily activities required by the program.

The RSO is bound by federal regulations to conduct a program in compliance with the requirements of Title 10 of the *Code of Federal Regulations*,^[9] and can be held personally liable for failure to do so. The RSO must enforce the regulations and requirements of the NRC, and the management of the licensed institution is expected to support the RSO's compliance and enforcement responsibilities. Figure 1 is a chart showing how the radiation safety branch and radiation safety committee relate to the overall NIH radiation safety program management organization.

To carry out the radiation safety program in compliance with the NRC license requirements and the NIH rules, a comprehensive radiation protection program is administered by the RSB. The objective is to provide a program with the administrative, technical, and surveillance support necessary to ensure safe use of radiation sources and to ensure NIH is in compliance with the regulations and guidance of the NRC and other authorities. Another important objective is to provide support to the biomedical research mission of NIH.

To maintain a line of communication between the RSB and the radiation and radioactive materials users, two levels of users have been defined. "Authorized users" have been specifically trained to accept the responsibility of supervising the use of and complying with the regulations governing the radioactive materials, as established by the program. "Individual users" are workers engaged in patient care, clinical and laboratory research, and research support activities involving actual use and handling of materials and devices producing ionizing radiation. Authorized users' responsibilities include accountability for radioactive materials, maintenance of laboratory records, oversight of the IUs, and cooperation with RSB in any matters relating to radiation safety.

Figure 1. NIH radiation safety program management organization



To support the objectives of this program, a comprehensive computer-based information system was developed, beginning in 1988. The major task of the system includes data input:

- a) for over 36,000 personnel files to track radiation exposures, training activities, bioassay results, and radioactive materials usage;
- b) to track the ordering, receipt and distribution of over 20,000 radioactive materials packages each year;
- c) to track over 50,000 laboratory surveys per year;
- d) to track over 100,000 radioactive waste tags collected each year for inventory and disposal actions; and
- e) for many other files including sealed sources, x-ray machines, protocols, etc.

THE RADIATION SAFETY PROGRAM

The radiation safety branch is divided into three sections.

The radiation safety operations section is responsible for area health physicist (HP) coverage of the NIH. An area HP is assigned to a certain building, and provides radiation safety consultation for that area's laboratories, facilities, and individuals. The HP conducts laboratory inspections for each area, assuring compliance with NIH policy and all federal regulations involving the use of radiation sources. The HP acts as consultant in the design and conduct of experiments using radiation sources to ensure that:

- a) exposures to personnel are maintained ALARA;
- b) proper and effective shielding and other protective measures are employed during the conduct of research; and
- c) all personnel are properly trained and monitored for exposure based on license requirements.

The radioactive materials control section is responsible for:

- a) receiving, checking, verifying, delivering and shipping all radioactive materials entering and/or leaving the NIH campus;
- b) storing all radioactive materials not in current use;
- c) managing and maintaining the materials inventory system; and
- d) administering the radioactive waste management program.

As an example of the annual radionuclide usage at NIH, Table 2 lists the most frequently ordered radionuclides received for the years 1994-1998. Table 3 shows the number of radioactive orders received at NIH for the years 1991-1998.

Table 2. Radioactive materials receipts at the National Institutes of Health, 1994-1998*

Radionuclide	Half-life	Radioactivity (mCi)				
		1994	1995	1996	1997	1998
H-3	12.3 y	8,977	11,963	4,193	4,199	4,867
C-14	5730 y	286	241	133	150	126
P-32	14.3 d	29,162	18,293	16,368	13,917	12,648
P-33	25 d	367	456	528	592	522
S-35	87.9 d	13,648	12,424	10,737	10,570	8,086
Cr-51	27.8 d	4,704	4,510	3,982	2,818	2,632
Ga-67	77.9 h	1,573	1,950	2,581	2,102	1,376
Tc-99m	6 h	13,626	15,963	16,307	17,738	12,530
Mo-99	66.7 h	331,000	349,210	355,060	447,960	395,920
I-131	8.1 d	4,068	3,553	3,696	5,128	6,087
Tl-201	74 h	3,104	3,054	3,130	3,108	2,750
All Others		13,907	11,743	5,232	6,728	7,643
TOTAL		415,422	433,360	421,947	515,010	455,187

* Data for years 1991-1993 in archives and currently not available.

Table 3. Annual radioactive orders received at NIH, 1991-1998

YEAR	Number of Orders
1991	36,024
1992	35,359
1993	33,546
1994	30,071
1995	27,907
1996	25,252
1997	23,354
1998	21,065

The technical services section is responsible for analytical and support services for the radiation safety program, including:

- a) external personnel monitoring;
- b) bioassays;
- c) radioactivity analysis;
- d) environmental monitoring;
- e) instrument maintenance and calibration;
- f) internal dosimetry; and
- g) radiation safety training.

The various parts of the radiation safety program fulfilling the license requirements include:

The Laboratory Survey Program.

The NRC requires all laboratories, corridors, and storage areas where workers or the general public may be, or are likely to be, exposed to radiation levels or radioactive materials to be surveyed as necessary to ensure compliance with federal radiation safety regulations.^[10] The RSB has engaged a contractor to survey these areas on a bimonthly, quarterly, or semi-annual basis depending on the activities and radionuclides used in each laboratory. Completed surveys are submitted to the area HP, who initiates an investigation of those items not in compliance with radiation safety requirements or where the survey results indicate a radioactive contamination level exceeding the regulatory limit of 2,200 disintegrations per minute per 100 square centimeters for beta- and gamma-emitters (restricted areas).

Additionally, the program requires that each laboratory be surveyed monthly by the users for potential contamination. The contamination survey reports are required to be submitted to RSB for review by the area HP. An AU who neglects to submit these monthly laboratory surveys will get two warnings and, if unresponsive, the AU will be prohibited from using or ordering radioactive materials until the matter is rectified. The RSB staff also performs required inspections and surveys of the laboratories and other areas on an as-needed basis.

Training Program.

The NRC regulations require “all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem”^[9] to receive radiation safety training. The primary training course, *Radiation Safety in the Laboratory*, is presented several times a month and is required by NIH of all researchers working with radioactive materials. Approximately 1,500 new NIH research staff per year take the course. This training session is designed to acquaint users with the hazards of radioactive materials and the methods of protection against these hazards. Other training courses presented include an annual *Radiation Safety Orientation for Nurses*, a computer-based course to familiarize the nurses with the concept of radiation, its uses, benefits and hazards and the situations in which they it may be encountered. Approximately 700 individuals take this course during the year. *Radiation Safety for Authorized Users* is a three-day course required to qualify for AU status, (i.e. to order and supervise the use of radioactive materials under the NIH program and NRC license). It is designed to give attendees an understanding of the evaluation of hazards associated with the use of radionuclides in biomedical research and the responsibilities of an NIH AU. Approximately 100 individuals per year attend this course. Other radiation safety training sessions are conducted as needed for NIH personnel who may encounter radioactive materials in their work, for example house-keeping, maintenance, police, and fire-fighting personnel. Individualized training sessions are also arranged for research groups encountering special radiological safety problems.^[6,11-14]

Personnel Monitoring Program.

Personnel monitoring involves the measurement of an individual’s external exposure through the use of dosimeters, either thermoluminescent (TLD), or optical stimulated luminescence (OSL) devices and internal exposure through bioassay.

NRC regulations require employees who are likely to exceed 10% of the occupational dose limit of 5000 mrem to be monitored.^[9] The

dosimeters available include whole body and ring badges. The dosimeters are processed by a contractor, monthly, bimonthly, or quarterly, as determined by the type of dosimeter. All cumulative whole body exposures equal to or greater than 500 mrem and cumulative extremity exposures equal to or greater than 5,000 mrem are investigated by the area HP. More extensive investigations are conducted when cumulative whole body exposures equal or exceed 1,500 mrem or when cumulative extremity exposures equal or exceed 15,000 mrem. A complete history is kept on the computer database for each individual. Table 4 shows the annual whole body radiation exposure to NIH during the years 1991 through 1998. As shown, the external whole body doses have been well below the occupationally allowed dose and 98-99% of the workers are regularly below the maximum permissible dose allowed to the general public.

The bioassay techniques employed at NIH to determine internal radiation exposure are urinalysis and thyroid counting. Whole-body counting is also available, if required. The RSB has adopted the recommendations of certain NRC regulatory guides for iodine and tritium bioassays to determine when they are required for NIH radiation workers.^[15] Bioassays are routinely required for tritium and radioiodine only. Bioassays for other radionuclides are performed on a case-by-case basis. Bioassays for NIH employees are requested following review of records of radioactivity usage and from submission of breathing zone air samples from labs which are permitted certain activities. If the usage exceeds the established threshold activity, the investigators are requested to submit a urine sample or schedule a thyroid count, depending on the specific radionuclides used. Bioassays may also be required following spills or accidental injury involving radioactive material, unusual readings on personnel monitors, elevated readings from air samples, or as a protocol requirement. Additionally, bioassays may be scheduled at the discretion of the RSO or area HP. Failure to respond within a set time limit can result in suspension of the individual's privilege to work with radioactive materials.

The area HP is informed of all positive bioassay results. For results exceeding action levels specified within the license, the bioassay results, probable cause, and recommended corrective action are discussed with the user and other involved workers.^[9] Table 5 presents the bioassay results for the years 1991-1998. As shown in the table, less than 7 % of the bioassays were positive. In all positive cases, the resultant radiation doses were well below the maximum permissible dose allowed by the NRC regulations.

Environmental Monitoring.

Environmental air monitoring is conducted continuously in certain areas and facilities where there is a potential for radioactive material release. This includes the radioactive-waste processing areas in the radiation safety branch building, various exhaust ducts from the laboratory research buildings, and outside fume hoods (in the breathing zone) where radioiodinations are performed.

Radioactive Waste Management Program.

On a radioactivity basis, the magnitude of the waste management program associated with NIH is small compared to that associated with fuel-cycle activities such as reactor operation and fuel reprocessing. Nonetheless, the proper management (handling, treatment and disposal) of radioactive wastes is an inherent part of the materials control and radiation protection policies and procedures at NIH. The NIH is among Maryland's top three generators of low-level radioactive waste (LLW). The LLW generated at NIH includes varied physical and chemical forms with levels of radioactivity ranging from minimally detectable radioactivity to levels high enough to require shielding for transport and handling. Radioactive waste forms at NIH include:

Table 4. Annual external whole body radiation exposure to NIH personnel, 1991-1998

Year	Total Monitored	No Measurable Exposure	10-100 mrem/yr	100-250 mrem/yr	250-500 mrem/yr	500-5000 mrem/yr
1991	6181	5324	816	27	9	5
1992	6239	5306	869	47	12	5
1993	6680	5993	593	59	24	11
1994	6314	5193	1046	51	19	5
1995	6431	5988	389	31	18	5
1996	5850	5585	219	27	15	7
1997	4114	3896	174	23	19	2
1998	887	519	301	42	19	6

The average annual whole body exposure for the NIH researchers was less than 10 millirem.

In 1996, the NIH revised its criterion for issuing a dosimeter, based on the cumulative activity handled by an individual in a year. The new program was based on 20 years of NIH experience that has shown that the small quantities of radioactivity used by researchers in most laboratories do not produce exposures that approach the NRC regulations for dosimetry requirements.

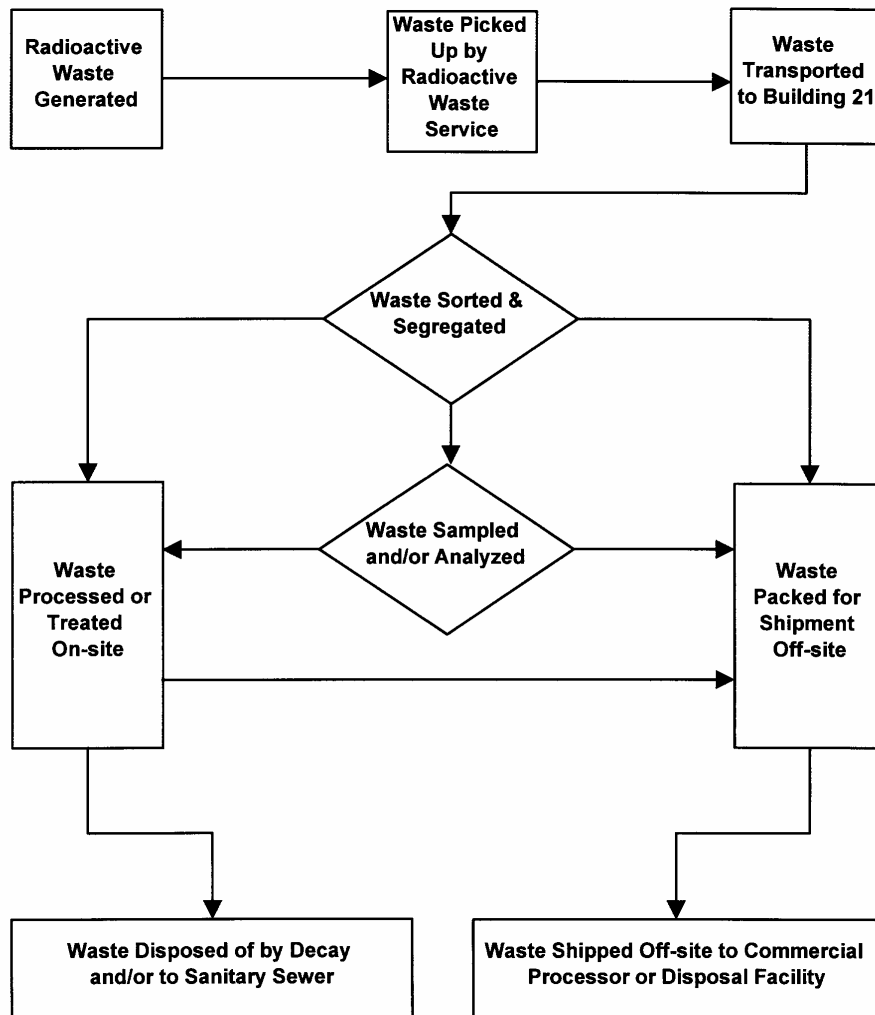
Table 5. Bioassay results for NIH personnel, 1991-1998

Year	Number of persons monitored (Number of positives obtained)		
	Urine Bioassay	Thyroid Scan	Whole Body Scan
1991	333 (9)	870 (31)	202 (18)
1992	362 (29)	806 (84)	203 (10)
1993	223 (13)	471 (56)	41 (0)
1994	167 (12)	362 (55)	5 (1)
1995	1100 (33*)	339 (35)	0 (0)**
1996	300 (4)	326 (25)	0 (0)
1997	170(7)	242(32)	0(0)
1998	184(0)	299(14)	1 (0)

* 27 of the positives were associated with the intentional contamination of drinking water in Building 37.

** Beginning in 1995, whole body scans are conducted only on an as-needed basis, to be determined by the Radiation Safety Officer.

Figure 2. Flow diagram for the NIH waste management process



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| <ul style="list-style-type: none"> a) research laboratory waste; b) patient-care related wastes; c) animal carcasses and tissues; d) filters; e) solidified liquids; f) sealed sources; g) contaminated equipment parts; h) cleaning solutions; | <ul style="list-style-type: none"> i) aqueous liquid wastes and mixed wastes consisting of acidic and basic solutions; j) complexing agents; k) organic solutions; and l) other wastes containing hazardous wastes or exhibiting characteristics causing the waste to meet the definition of hazardous waste. |
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The RSB radioactive waste facility serves as the central collection area for handling, treating, and disposing of all radioactive and mixed wastes generated at NIH. Figure 2 shows a general flow diagram for the waste management process at NIH. Current methods used by RSB for radioactive waste management include:

- a) storage for radioactive decay;
- b) on-site compaction;
- c) shipment off-site for processing, volume reduction, incineration; and/or burial at a permitted and licensed commercial disposal facility;
- d) solidification of liquids;
- e) release to the sanitary sewer of aqueous liquids;
- f) filtration to remove organic chemicals from liquid waste;
- g) ultraviolet peroxidation to treat aqueous mixed wastes and render it suitable for discharge to the sanitary sewer; and
- h) other bench-scale treatments for small, unusual waste streams for which traditional waste management techniques are unsuitable.

Generally, the majority of the radionuclides utilized for research at NIH are of moderate or slight activity, having relatively short radioactive half-lives (less than a year). The NIH employs a contractor who provides laboratories with the necessary waste containers and supplies on request, such as containers for liquids and waste step-cans for dry waste. The radioactive wastes are ultimately collected by contractor staff from the laboratories, transported to the waste handling facility, and then sorted by physical and chemical form, with samples taken, when appropriate, to determine radioactivity level and processed as follows:

- Dry radioactive waste containing long-lived radionuclides (half-life greater than 120 days) are sorted by physical form, packaged, and shipped to a commercial waste processor for volume reduction and disposal. The waste must be sorted before packaging to meet the waste- acceptance criteria of the commercial processor, so it may be properly treated and

disposed. These wastes are sorted into non-combustible and combustible waste streams.

- Non-combustible waste is compacted in drums on-site and shipped off-site to a commercial LLW processor for supercompaction and burial at a licensed LLW facility.
- Combustible waste is packaged and shipped for either incineration or vitrification, followed by disposal of residue at a licensed LLW facility.
- Dry and medical pathological waste, including animal carcasses and tissues, contaminated with radionuclides with short half-lives, typically less than 10 days, are stored on-site for radioactive decay and eventually disposed as normal trash. Wastes contaminated with radionuclides with half-lives less than 120 days are packaged in drums and shipped to a commercial storage facility for radioactive decay. After radioactive decay, the non-radioactive waste is disposed as normal trash.
- Animal carcasses contaminated with radionuclides with long half-lives are packaged and shipped off-site for incineration or vitrification followed by disposal of the residue at a licensed LLW facility.
- Aqueous liquids are sampled and analyzed to determine the radionuclides and activity levels. The liquid is then treated using activated carbon filtration, to remove trace organic chemical contaminants and placed into one of nine 8,500-liter tanks and held until the radioactivity level has decayed to allowable levels. It is then discharged into the NIH sanitary sewerage system. The NRC license allows NIH to dispose of up to 7 curies of liquid waste per year via the sanitary sewer, 3 curies of ^3H , 3 curies of ^{14}C , ^{35}S and ^{33}P combined, not to exceed one curie of ^{14}C , and one curie of all other radionuclides.
- Liquid scintillation media contained in vials, is packaged in 55-gallon drums with absorbent material and shipped off-site for recovery of liquids and recycling as a fuel.

Table 6. Radioactive Waste Disposal Data, 1991-1998

Year	Volume of dry waste shipped, cubic feet	Drums of LSC vials shipped	Volume of mixed waste generated, liters	Liquid waste volume discharged to sewer, liters
1991	7395	757	24,890	151,551
1992	0*	624	16,910	175,719
1993	12,480	551	26,270	140,299
1994	29,228	474	21,180	152,457
1995	23,066	409	11,210	185,409
1996	22,880	364	11,354	134,481
1997	23,088	310	11,111	118,800
1998	14,315	268	4,833	123,813

* All waste was placed in storage this year.

The adoption of stricter laboratory security policies in response to heightened oversight by the US NRC has changed the way biomedical research is conducted today. The use of nonradioactive research methods as alternatives to using radioactive materials is gaining widespread acceptance, and as a result, the amount of radioactive material ordered and radioactive waste generated has been decreasing in the past few years.

- Contaminated equipment parts are decontaminated, when possible, and disposed as non-radioactive waste.
- Mixed waste, LLW also meeting the EPA definition of a hazardous waste, is treated on-site using ultraviolet peroxidation, neutralized to render it non-corrosive and managed as aqueous liquid waste after testing to assure complete treatment. Alternatively, mixed waste can be shipped off site for treatment and disposal as LLW.

At present, the majority of the wastes sent off-site for disposal go to the commercial waste LLW facility at Barnwell, South Carolina.

All wastes shipped off-site are shipped in accordance with the DOT's regulations for shipping and manifesting.^[9] Table 6 shows the various quantities of waste disposed for the years 1990-1998. The major radionuclides disposed:

1. via burial: ^3H , ^{35}S , ^{125}I , ^{45}Ca , and ^{192}Ir ;
2. via the sanitary sewer: ^3H , ^{14}C , ^{35}S , ^{32}P , ^{125}I , and ^{51}Cr ; and

3. via off-site incineration: ^3H , ^{14}C , ^{125}I , ^{131}I , and ^{35}S .

Responsible and effective management of radioactive and mixed wastes at the NIH is a priority of the radiation safety program. The current annual cost of radioactive and mixed waste management and disposal is about \$2.5 to \$3 million. The unit costs of disposal are expected to increase each year. To combat the accelerating rate of LLW generation and expensive waste disposal problem at the NIH, the radiation safety branch and the NIH environmental protection branch have embarked upon a number of programs for reducing the generation of wastes. NIH waste managers believe minimization is the first step in a successful strategy to decrease costs. Surveys have shown that NIH investigators are keenly aware of the need to reduce the generation of radioactive wastes and, in particular mixed wastes. Many investigators have achieved dramatic reductions in their mixed waste generation rates; in some cases, the generation of mixed waste was totally eliminated. Better communication about minimization techniques

has helped to achieve the NIH goals.^[6,7,12,16] As a result, the generation of mixed wastes the past few years has dramatically decreased.

To carry out the NIH program of minimizing both radioactive and mixed radioactive wastes, a strategy was developed to include:

- a) planning—select reagents and procedures to minimize the volume and toxicity of all wastes;
- b) procurement control—avoid ordering chemicals and radioactive materials exceeding intended usage;
- c) strict waste segregation;
- d) use of non-radioactive tracers and methods for common assays;
- e) substitution of short-lived radionuclides where feasible to allow for disposal of the radioactive waste, after storage and decay, as non-radioactive;
- f) volume and activity reduction to decrease the amount of waste generated; and
- g) substitution with chemicals not regulated as hazardous or mixed waste.

NRC INSPECTIONS

Licenses are inspected at varying frequencies as part of the NRC's licensing program. NRC inspections over the last 10 years have cited NIH for apparent violations in the following program areas:

- a) radioactive waste;
- b) control and security of radioactive materials;
- c) contamination surveys;
- d) eating and drinking in restricted areas;
- e) occupational radiation dose to individuals or extremities;
- f) verifying stated contents of a package of radioactive materials with the order placed;
- g) personnel monitoring;
- h) training for individuals working in restricted areas;

- i) a medical misadministration; and
- j) bioassay measurements of researchers who handled volatile iodine.

These citations generally have been for isolated cases of noncompliance with license conditions, and were generally self-identified and corrected by the program prior to inspection.

During the past several years, the NIH radiation safety program has enhanced its procedures, guides, recommendations and policies to reflect correcting these violations, thus making the program one of the best, if not the best, in the nation.^[17] Increased radiation safety management review of audits and prompt implementation of corrective actions have been implemented. In addition, enhanced communication between the radiation safety staff and the laboratory personnel to properly implement training, personnel monitoring, and other radiation-protection programs has been implemented. The RSB has increased the use of its computer-based information system to track new personnel involved with use of radioactive materials to ensure they are properly trained, have the proper personnel dosimetry, and respond in a timely manner to RSB requests such as bioassays.

CONCLUSION

At the National Institutes of Health, the use of radionuclides requires a comprehensive radiation safety program to maintain a safe environment for the employees, patients and the general public. The program provides effective supervision, control, protection and monitoring of radioactive sources, ensuring all employees, visitors, patients and the surrounding community are not subjected to any undue risks to their health and safety, and the activities of NIH do not compromise the quality of the natural environment. Based on personnel monitoring and other data, it can be concluded the NIH radiation safety program is in substantial compliance with all regulatory requirements as well as with prudent practices to maintain radiation doses ALARA.

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