



National Institutes of Health
Office of Management

An Overview of the Radiation Safety Program at the NIH

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- **Brief history of radiation safety at the NIH and who we are**
- **What is radiation?**
- **How is radiation used at the NIH?**
- **Clinical protocol review process**
- **Radiation safety services beyond clinical protocols**

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ISOTOPE LABORATORY OPENS AT NIH

The newest laboratory of the National Institutes of Health, the Isotope laboratory, is now in operation. It opened June 5 and 6 with a "family" open house for NIH personnel. On Wednesday, June 7, scientists from other laboratories in and around Washington toured the new building, one of the few radioisotope laboratories in America designed solely for medical research.

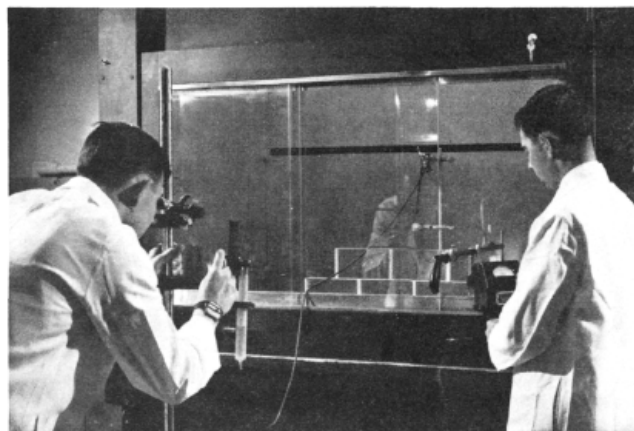
At the present time the Isotope Lab is "hot" (actively engaged in radioactive experimentation) and is open only to scientists working there or, on occasion, to those who have received special permission to enter for a specific purpose.

Some 700 people went through the laboratory during the three-day open house. By and large they seemed interested in those details of the laboratory which pointed up how carefully radioactive materials must be handled, such as:

1. Closed hoods in which experiments will take place behind safety glass that will crumple rather than blow out in case of explosion. Exhaust fans pass the air from the hoods through specially designed filters to remove radioactive particles and fumes.

2. Lead pots, sunk 10 feet underground, for storage of radioactive materials. These can be raised for removal of the material by a pulley arrangement, while a monitor checks for safety with a portable geiger counter.

3. "Hot" sinks, appropriately designated by a magenta panneling above, which will be used for



When using highly radioactive materials, research workers examine experiment in closed hood with a telescope

- washing contaminated equipment. Water from these sinks will drain into a special reservoir which is monitored with geiger counters.

4. A large geiger counter, something like a scale, onto which a worker steps and inserts his hands as he leaves the laboratory, to check possible contamination of feet or hands.

5. Fountain pen sized ionization chambers issued to all who have access to potentially contaminated areas. At day's end, these tiny chambers show how much radiation a person has received.

6. Baby-sized caskets, resembling treasure chests, which will be filled with radioactive waste, ma-

terials of a long half-life sealed with cement and dumped into the sea.

Some visitors let their fancy roam. "What would happen," asked one, "if some deep sea diver made a mistake and brought up the casket for buried treasure?"

Another was worried about what two laundromats were doing amid all this special equipment of the atomic age. When it was explained that the laundromats were used for washing slightly contaminated work clothes, that the water was drained off into a special reservoir, and that badly contaminated clothes were destroyed, the tourist quipped: "What would happen if the clothing of an eminent visiting scientist became so contaminated that it had to be destroyed? Could he sue the government?"



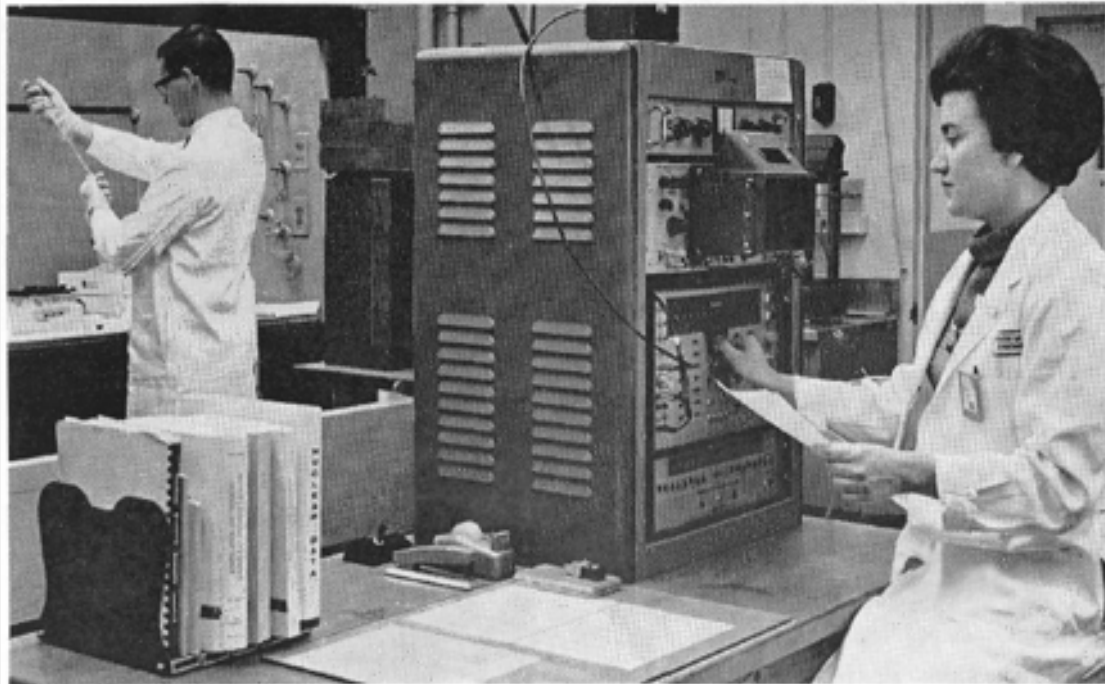
Isabelle Ann Barr

Pert, 23-year-old Isabelle Ann Barr is one of the five monitors responsible for detecting and measuring radiation at the new NIH Isotope Laboratory.

In addition, Miss Barr surveys other laboratories at NIH where scientists are using radio-isotopes. The five monitors scrupulously comb the labs, tracking down evidence of radio-contamination on walls, workbenches, equipment. This is done with portable survey instruments, such as Geiger counters and ion chambers.

Radiation Safety in 1966

November 15, 1966



Patricia Cliggett, Health Physicist in the Radiation Safety Section, assays a radioactive drug using a multichannel analyzer. In background, Health Physicist Mark Semler prepares radioactive samples for assay.—Photos by Ralph Fernandez.

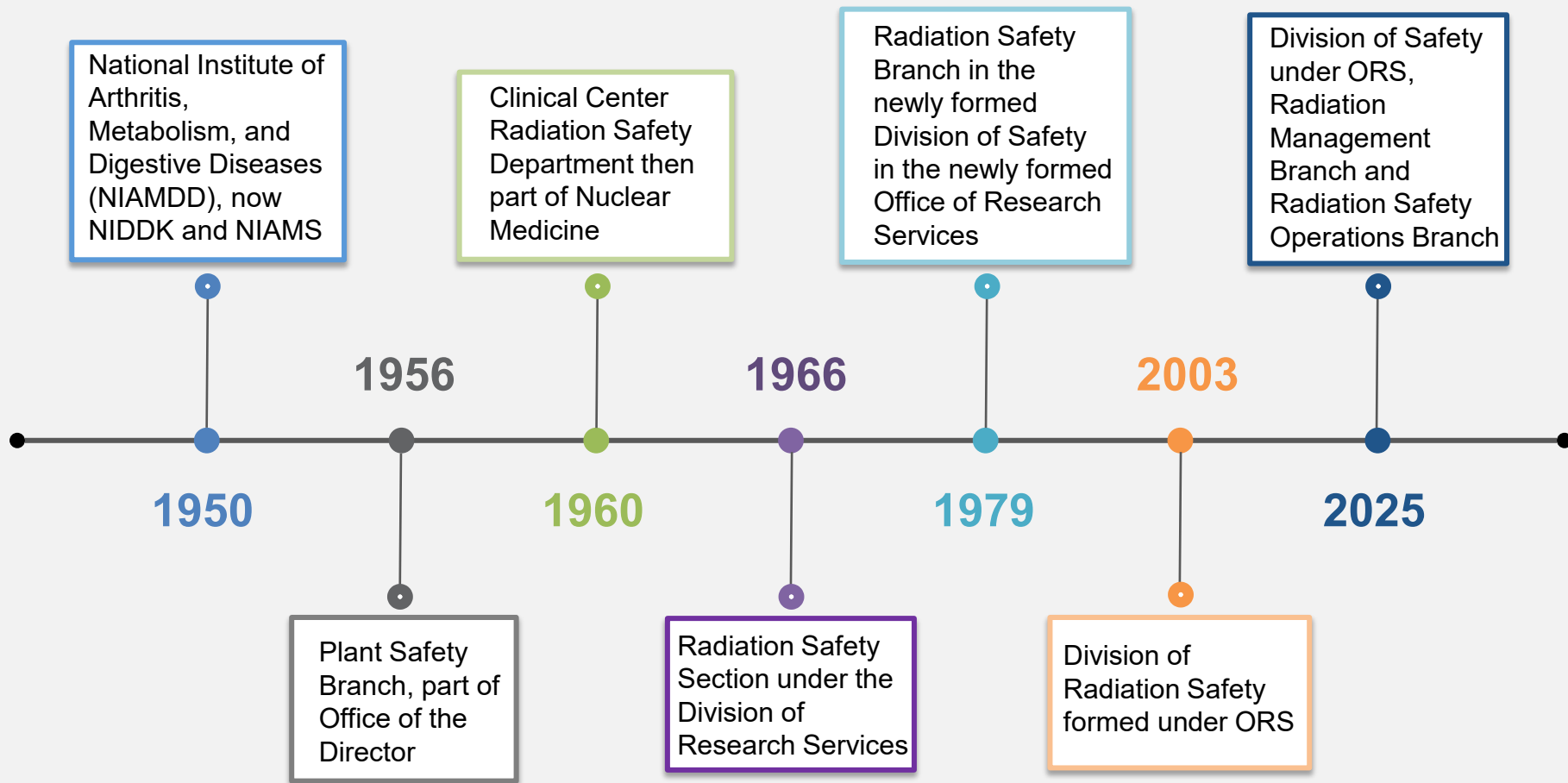
Radiation Safety in 1977



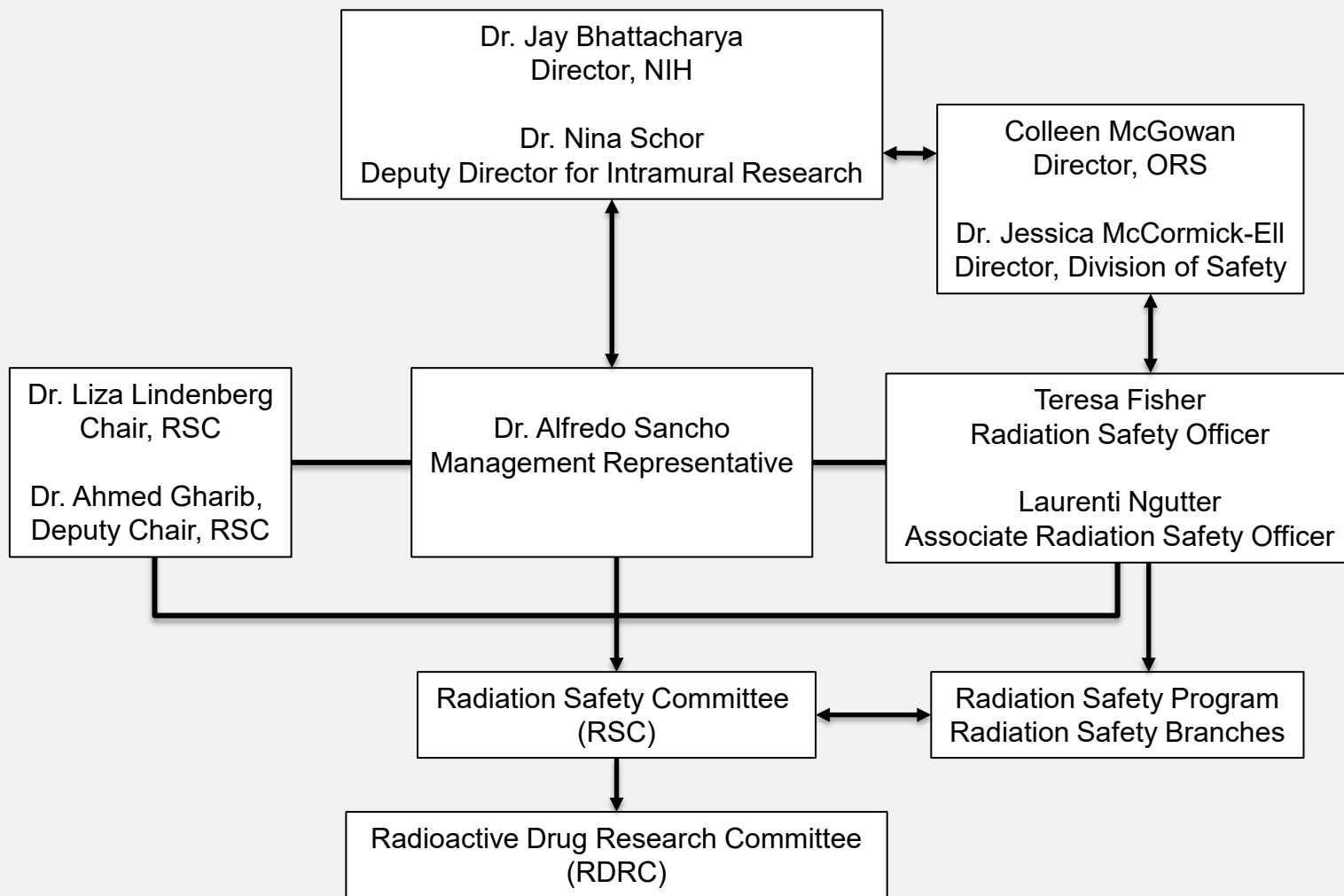
Radiation Safety in 2024



Organizational History



Radiation Safety Program Hierarchy



Radiation Safety carries out the Radiation Safety Program at the NIH, with support from the Radiation Safety Committee

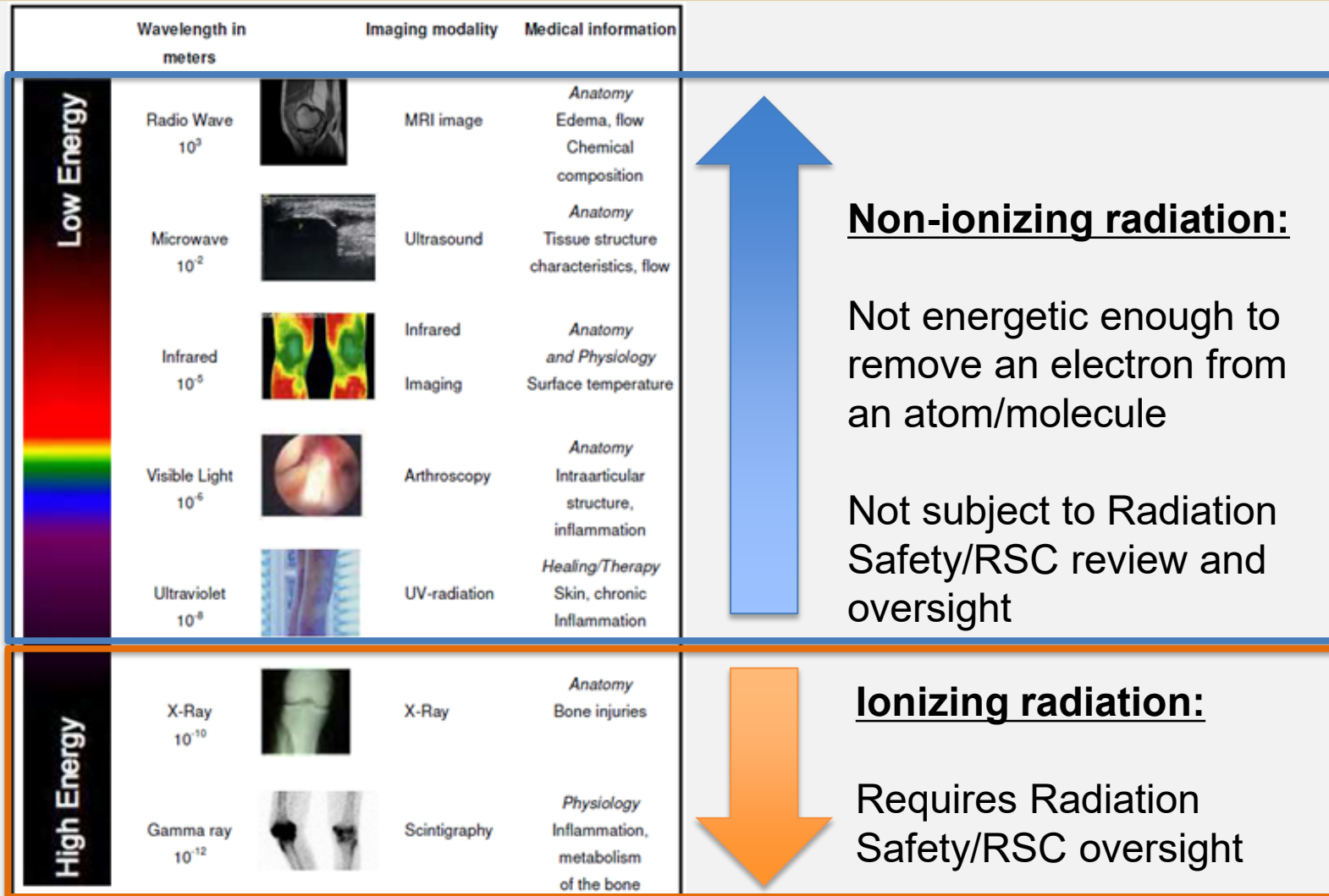
Radioactive materials are regulated by the Nuclear Regulatory Commission (NRC); X-ray radiation is regulated by local policy to comply with equivalence to the Code of Maryland Regulations (COMAR)

The NIH is responsible for radioactive material from the moment it arrives on campus to the moment it leaves and all timepoints in between

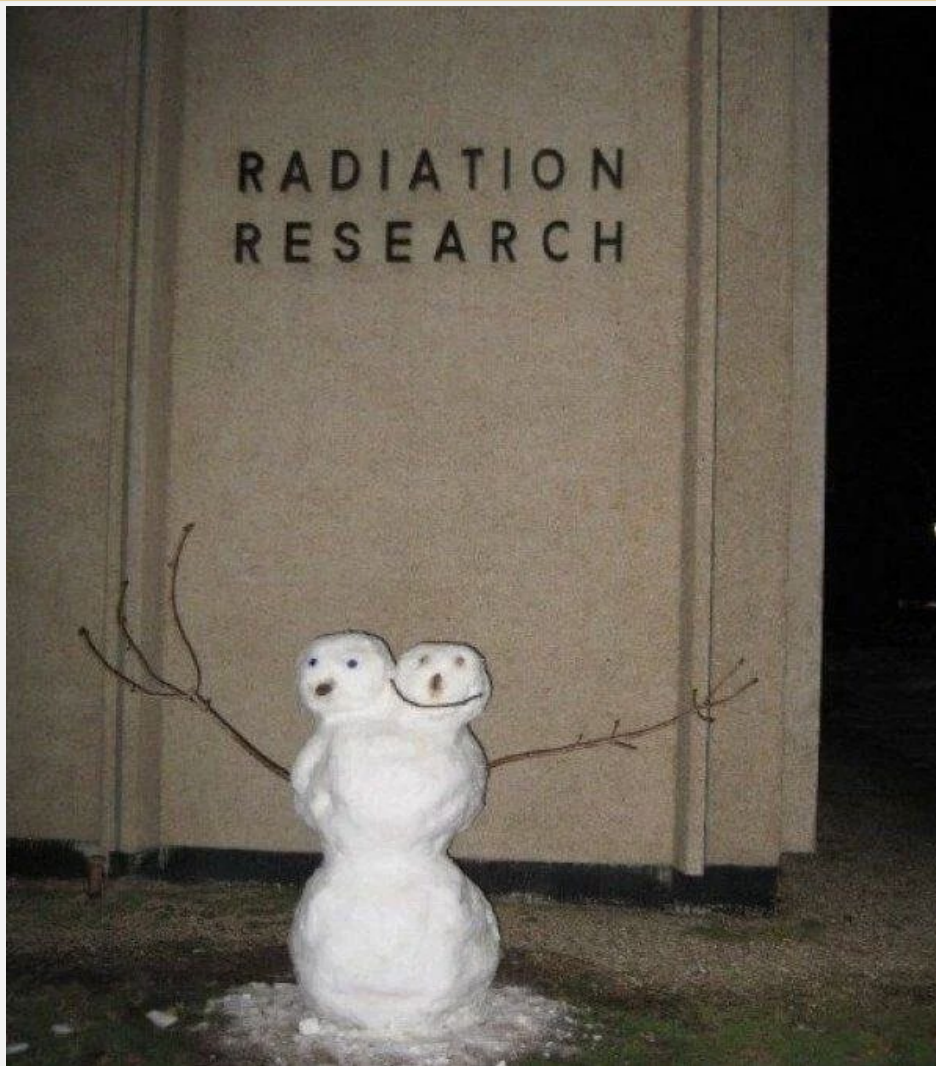
Overview: Three NRC Licenses

Broad Scope	Cyclotron	Irradiator
Training Program	Training Program	Training Program
Compliance Monitoring	Compliance Monitoring	Alarm Monitoring
RAM Pkg Receipt/Delivery	RAM Item Transfers	Source Re-Loads
RAM Inventory Program	RAM Inventory Program	Sealed Source Checks
Clinical Use of RAM	PET RAM Supply	Safety/Security Checks
Shielding Design	Hot Cell worker safety	Emergency Response Plan
Dosimeter Exchange/Dose Tracking	High Dose Potential Dosimetry Program	Trustworthy & Reliable Tracking
Lab/Animal Protocol Reviews	Lab Protocol Reviews	Access Approval Program
Air Monitoring Program	Continuous Emissions Rate Monitoring System (CERMS) Program	Irradiator Replacement Program
Radwaste/Decommissioning	Decommissioning	

What is Radiation? (Ionizing vs Non-ionizing)



How is Radiation Used at the NIH?



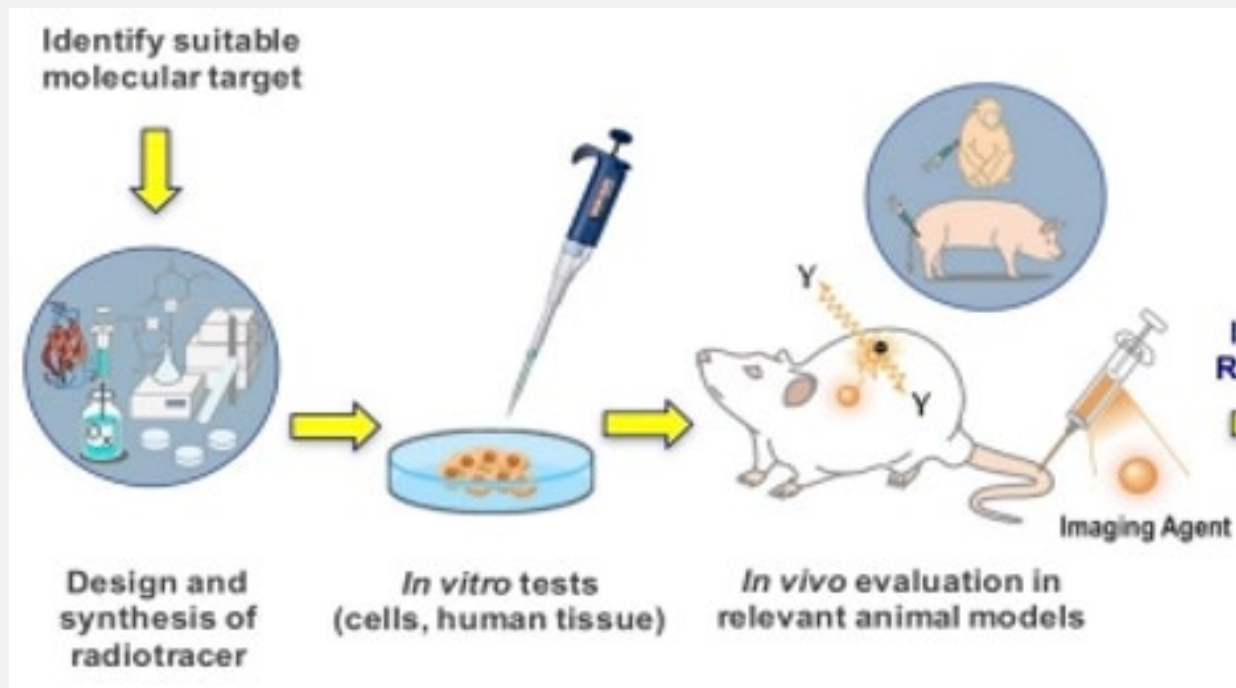
Cyclotron - Production



Radiochemistry and Bench Top Research



Animal Research



Irradiators



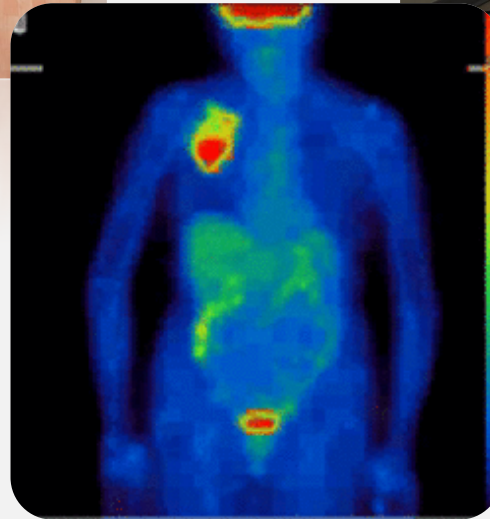
Radiation Use at the NIH



Imaging, big...



...and small





External Beam Radiation Therapy

Radiopharmaceutical Therapy



Campus Security



Clinical Protocol Reviews-What Qualifies?

Uses a radioactive research drug(s) regulated under the FDA requirements for review by the Radioactive Drug Research Committee (RDRC)

Involves the use of any radiation in pediatric participants (<18 years old) with an annual effective dose >0.5 rem or healthy pediatric volunteers (any dose level)

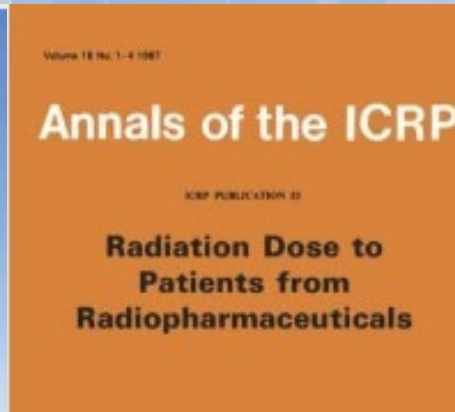
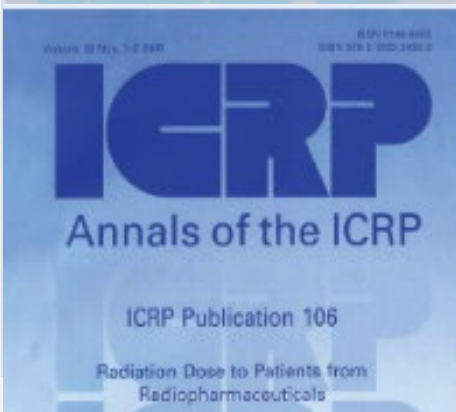
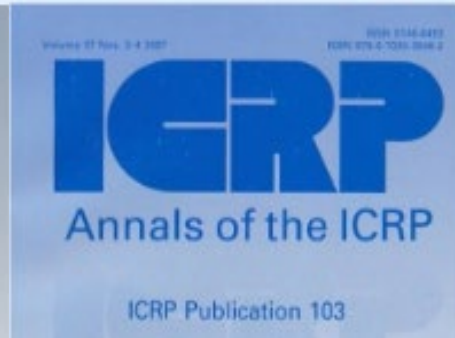
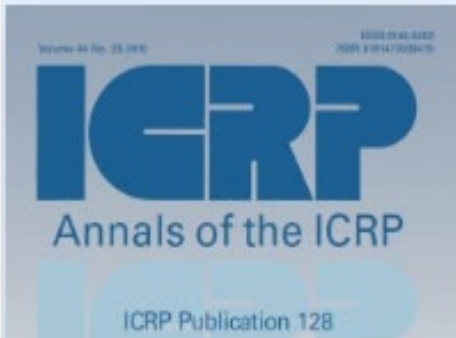
Uses any radiation in healthy adult volunteers, excluding DEXA and chest X-Ray

Uses therapeutic administration of radioactive materials

Involves novel uses of radiation, including any radioactive Investigational New Drugs (IND) and radiation-producing investigational devices

The radiation itself is the research agent being studied in the protocol

- Completion of Radiation Safety Module in [PROTECT](#)
- Dosimetry tables for administrations/procedures/scans utilizing radiation (uploaded as attachments)
- Informed consents and assents using applicable radiation risk language
- Protocol
- Additional information that may be helpful such as Investigator's Brochure, package inserts, etc.



C.9.4. Absorbed doses for ¹⁸F-FDG

¹⁸F 1.83 h

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	15 years	10 years	5 years	1 year
Adrenals	1.2E-02	1.6E-02	2.4E-02	3.9E-02	7.1E-02
Bladder	1.3E-01	1.6E-01	2.5E-01	3.4E-01	4.7E-01
Bone surfaces	1.1E-02	1.4E-02	2.2E-02	3.4E-02	6.4E-02
Brain	3.8E-02	3.9E-02	4.1E-02	4.6E-02	6.3E-02
Breasts	8.8E-03	1.1E-02	1.8E-02	2.9E-02	5.6E-02
Gallbladder	1.3E-02	1.6E-02	2.4E-02	3.7E-02	7.0E-02
Gastrointestinal tract					
Stomach	1.1E-02	1.4E-02	2.2E-02	3.5E-02	6.7E-02
Small intestine	1.2E-02	1.6E-02	2.5E-02	4.0E-02	7.3E-02
Colon	1.3E-02	1.6E-02	2.5E-02	3.9E-02	7.0E-02
(Upper large intestine)	1.2E-02	1.5E-02	2.4E-02	3.8E-02	7.0E-02
(Lower large intestine)	1.4E-02	1.7E-02	2.7E-02	4.1E-02	7.0E-02
Heart	6.7E-02	8.7E-02	1.3E-01	2.1E-01	3.8E-01
Kidneys	1.7E-02	2.1E-02	2.9E-02	4.5E-02	7.8E-02
Liver	2.1E-02	2.8E-02	4.2E-02	6.3E-02	1.2E-01
Lungs	2.0E-02	2.9E-02	4.1E-02	6.2E-02	1.2E-01
Muscles	1.0E-02	1.3E-02	2.0E-02	3.3E-02	6.2E-02
Oesophagus	1.2E-02	1.5E-02	2.2E-02	3.5E-02	6.6E-02
Ovaries	1.4E-02	1.8E-02	2.7E-02	4.3E-02	7.6E-02
Pancreas	1.3E-02	1.6E-02	2.6E-02	4.0E-02	7.6E-02
Red marrow	1.1E-02	1.4E-02	2.1E-02	3.2E-02	5.9E-02
Skin	7.8E-03	9.6E-03	1.5E-02	2.6E-02	5.0E-02
Spleen	1.1E-02	1.4E-02	2.1E-02	3.5E-02	6.6E-02
Testes	1.1E-02	1.4E-02	2.4E-02	3.7E-02	6.6E-02
Thymus	1.2E-02	1.5E-02	2.2E-02	3.5E-02	6.6E-02
Thyroid	1.0E-02	1.3E-02	2.1E-02	3.4E-02	6.5E-02
Uterus	1.8E-02	2.2E-02	3.6E-02	5.4E-02	9.0E-02
Remaining organs	1.2E-02	1.5E-02	2.4E-02	3.8E-02	6.4E-02
Effective dose (mSv/MBq)	1.9E-02	2.4E-02	3.7E-02	5.6E-02	9.5E-02

Radiation Dosimetry

Age Body size Fetus Mother

Age Group

0-year 1-year 5-year
 10-year 15-year Adult

Gender

Male Female

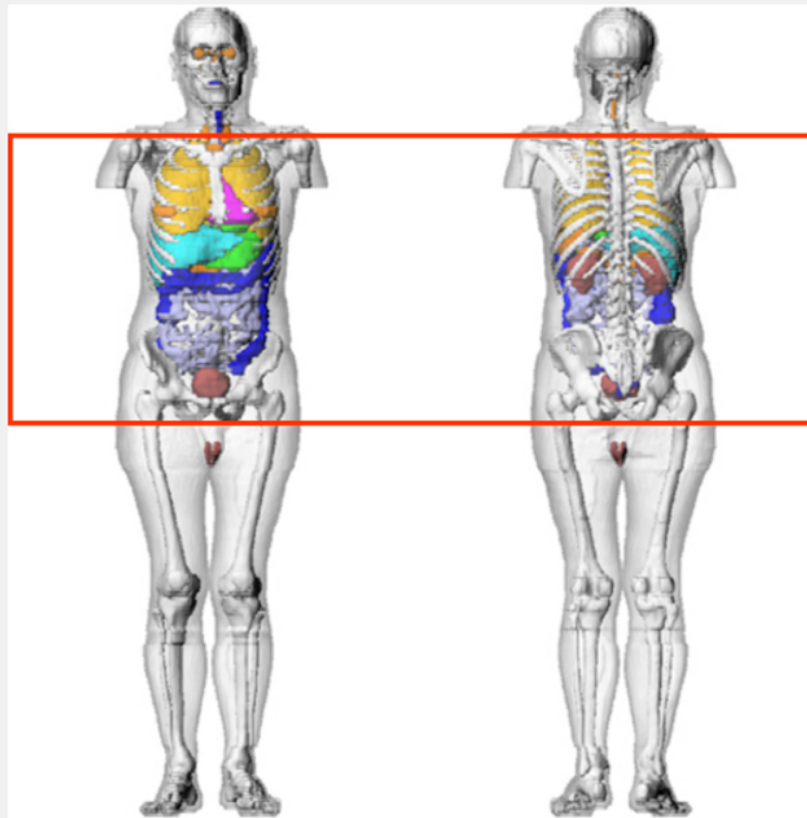
Reference Body Size

Height (cm)
 Weight (kg)

Scanner information

Manufacturer
 Model
 Head filter Body filter

nCTDIw (mGy/100 mAs)
 Tube potential (kVp)
 Current x time (mAs)
 TCM strength
 Pitch
 Total collimation (mm)
 CTDIvol (mGy)
 DLP (mGy-cm)
 Effective diameter (cm)
 SSDE (mGy)



Scan Coverage

Scan Start (cm) Scan End (cm) Scan Length (cm) Predefined protocol

	Organ dose (mGy)
Brain	0.15
Pituitary gland	0.16
Lens	0.11
Eye balls	0.12
Salivary glands	0.66
Oral cavity	0.41
Spinal cord	5.45
Thyroid	13.15
Esophagus	8.22
Trachea	10.17
Thymus	11.6
Lungs	10.31
Breast	9.45
Heart wall	10.94
Stomach wall	11.16
Liver	10.81
Gall bladder	10.29
Adrenals	9.73
Spleen	10.79
Pancreas	10.11
Kidney	11.19
Small intestine	11.68
Colon	11.94
Rectosigmoid	9.92
Urinary bladder	10.54
Prostate	7.41
Uterus	0
Testes	0.85
Ovaries	0
Skin	4.66
Muscle	5.26
Active marrow	6.65
Shallow marrow	5.45
Effective dose(mSv)	8.68

- **Provide subject matter expertise on the use of research radiation**
- **Ensure the researchers are equipped to adequately communicate the risk associated with research radiation**
 - Determining the risk through dosimetry calculations
 - Reviewing informed consent language for accuracy and completeness
- **Reviewing the protocol and the specifics associated with the radiation use**
 - Does our license even permit us to do this protocol?
 - Are there things the PI hasn't considered like HP coverage, patient isolation, room shielding, biospecimen handling, contamination issues, patient precautions, etc.?
 - Are the procedures and their frequency appropriate for the study objectives?
 - It's a team effort between Radiation Safety and the RSC

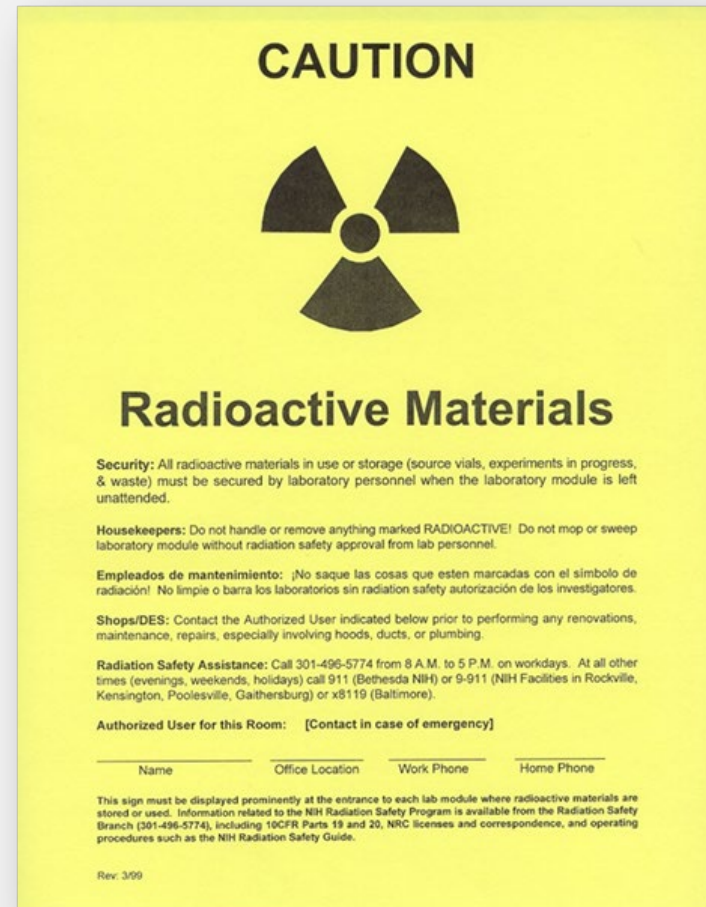
- **NRC Licensing**
 - Main Campus, Poolesville, BRC/Triad, Rockville, IRF
 - Do not cover: RML, RTP, NCI-Frederick
- **Training (Radiation workers, Ancillary Staff)**
- **Lab activation, inspection, and clearance**
- **Spill response**



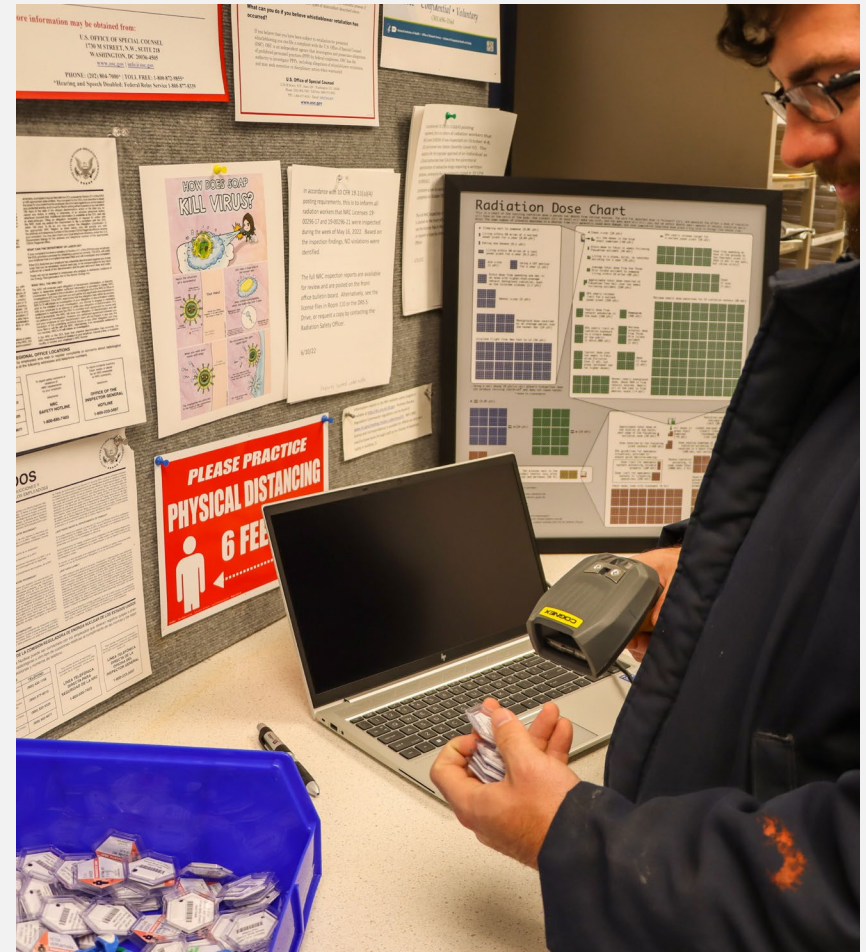
- **Exposure monitoring (internal, external, general public)**
- **Receipt, delivery and inventory of radioactive materials**
- **Shielding evaluations**
- **Clinical, benchtop, and animal protocols**
- **Compliance / Security inspections**



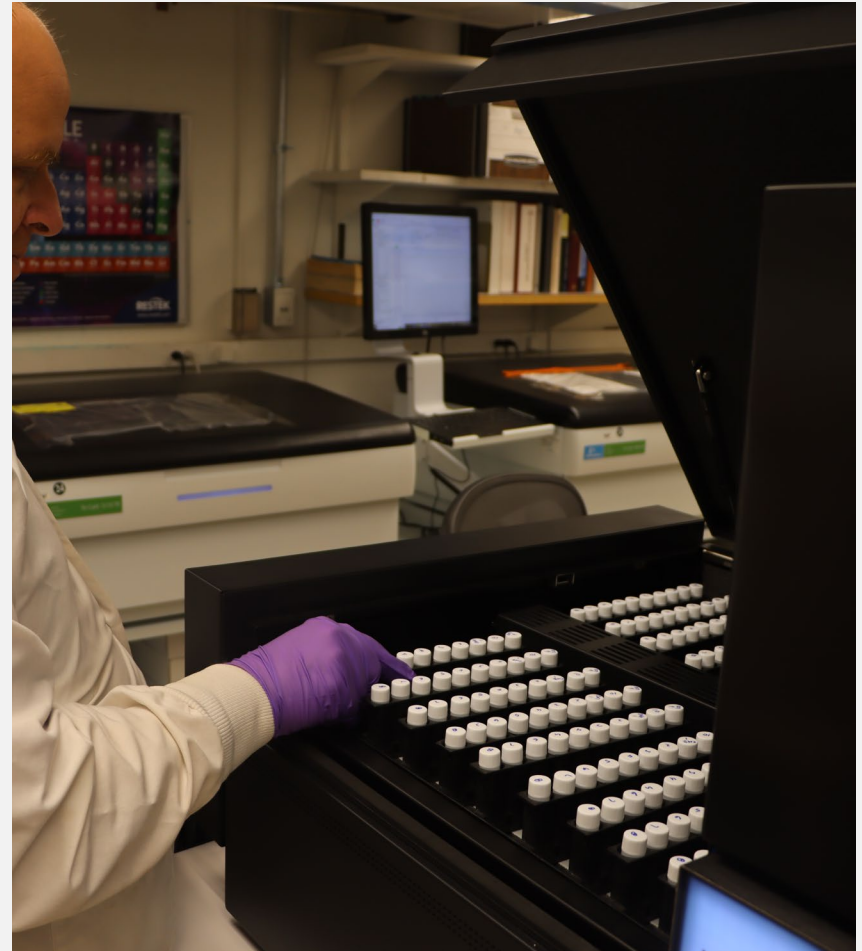
- 479 posted lab modules
- 292 Authorized Users
- 2660 Individual Users
- 5689 incoming radioactive material items (including cyclotron-produced items)
- 153 outgoing radioactive material shipments



- **553 individuals monitored for radiation exposure**
- **111 bioassays (0 positives)**
- **26 radiation exposure investigations**



- **85,391 samples analyzed for radioactivity**
- **703 radiation meters calibrated**
- **289 sealed sources checked**



- **21 active laboratory protocols**
- **56 animal study proposals reviewed**
- **60 clinical research protocols reviewed**
- **5 in-patient therapies (I-131 for thyroid cancer)**
- **84 out-patient therapies (Lu-177, Ra-223)**
- **0 medical events**
- **74 x-ray unit inspections (excludes units inspected by RADIS)**



- ~1500 radwaste pick-ups
- 4 offsite radwaste shipments
- 437 containers radwaste disposed



- 0 tank discharges
- 1 dumpster dive
- 6 dumpsters held for decay



Community Outreach



Thank you for your time!

teresa.fisher@nih.gov
<https://drs.ors.od.nih.gov/>