U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

HRTD
Human Resources
Training & Development

Research & Development Licensing

G-109
Self-Study Materials

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References

- NUREG-1556, Volume 7, Academic, Research & Development and Other Licenses of Limited Scope (including Gas Chromatography (G.C.) and X-Ray Fluorescence (X.R.F.))
- NUREG-1556, Volume 11, Licenses of Broad Scope
- BOTH guidance documents are being revised and currently out for comment.

Limited vs. Broad Scope Licenses

Limited Scope Licenses

- Note that the term “limited scope” is not defined in NRC’s regulations
- The term “broad scope” is not defined either, *per se*, BUT-
- 10 CFR Part 33, especially Part 33.11, uses the term “broad scope” repeatedly to define the types of broad scope licenses NRC regulates
- So “limited scope” is more of a vernacular term, as it is the opposite of “broad scope” in meaning

The vast majority of licenses are "limited scope"

Very few licenses authorize "broad scope" programs with their associated autonomy (like a "mini-NRC") and costs $$$$

Limited vs Broad Examples

Limited Examples:

- Most hospitals, businesses, industrial and commercial users
- “Smaller” academic and R&D institutions

Broad Examples:

- Some major universities, teaching hospitals
- Larger academic and R&D institutions
- “Larger” industrial users

Limited Scope Licenses

Have a prescriptive format that specify:

- **Authorized radionuclides**
- **Authorized uses**
- **Authorized places of use**
- **Authorized users**
- **Detailed limiting conditions**

Limited Scope R&D Licenses

Based on a detailed review of the applicant's:

- **Expected uses**
- **Training and Experience for RSO, users**
- **Facilities, equipment**
- **Procedures**

Changes in nuclides, uses, places of uses, users or radiation safety procedures require a license amendment

Broad Scope Licenses

- **Broad scope licensees have greater flexibility and autonomy for authorizing materials, users, uses, and facilities internally; most non-medical limited scope licensees lack this**

- **NUREG-1556, Vol. 11, Rev. 1 is intended to be used in conjunction with at least one (or more!) other topical volume in the 1556 Series, such as Vol. 7, Vol. 9, etc.**

Broad Scope Licenses

Broad Scope Licensees must still be authorized in the license to perform the following (10 CFR 33.17):

- **Medical use of radioactive material ("RAM")**
- **Introducing RAM into any food, beverage, cosmetic, or drug**
- **Environmental tracer studies**
- **Irradiator operations**
- **Distribution of RAM**
- **Industrial radiography**

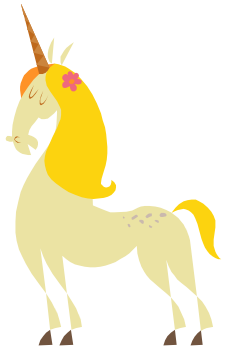
Broad Scope Licenses

- **The applicant for a Broad Scope license must have reasonable prior experience (~ 5 years) in the use of radioactive materials under a specific limited scope license**

- **The licensee applicant must have a good performance record based on previous licensing and inspection activities**

3 Types of Broad Scope Licenses

- **Type A Broad Scope License (Probably most common)**
- **Type B Broad Scope License (Not unusual, but not as common)**
- **Type C Broad Scope License (Almost mythological – think "Unicorns")**



Type A Broad Scope License

- Atomic numbers 1 - 83
- Any chemical or physical form
- Multi-curie quantities

Type A Broad Scope License

Type A Broad Scope Licensees must have :

- **Administrative Controls**
- **Procurement and use controls**
- **Criteria approved to perform safety evaluations of proposed uses, users, areas of use**
- **Radiation Safety Committee (RSC) reviews these evaluations**

Type A Broad Scope License

- **Users, uses, and places of use are approved by the Radiation Safety Committee. This "in house" evaluation considers same issues as a limited scope NRC license review**

- **Radiation Safety Committee usually includes the RSO, management representatives, and users for key types of use**

Type B Broad Scope License

- Atomic numbers 1 - 83
- Any chemical or physical form
- Possession is limited to quantities in 10 CFR 33.100, Schedule A, Column I *
- Possession further limited by the "Unity" rule

* Authorization in excess of 10 CFR 33.100, Schedule A, Column I can be approved on a case-by-case basis

Type B Broad Scope License

Type B Broad Scope Licensees must have :

- **Procurement and use controls**
- **Criteria approved to perform safety evaluations of proposed uses, users, areas of use**
- **RSO reviews these safety evaluations – there is no RSC**
- **Users, uses, & areas of use must be approved by the Radiation Safety Officer**

Type C Broad Scope License

- Atomic numbers 1 - 83
- Any chemical or physical form
- Possession limited to quantities in 10 CFR 33.100, Schedule A, Column II
- Possession further limited by the "Unity" rule

Type C Broad Scope License

10 CFR 33.15 User Criteria:

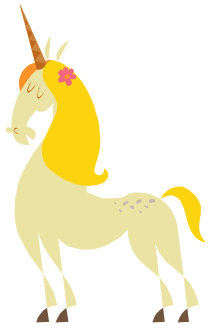
- **B.S. in Science or Engineering**
- **40 hours training & experience including:**
  - ✓ **safe handling procedures**
  - ✓ **radiation characteristics**
  - ✓ **radiological units**
  - ✓ **biological hazards**
  - ✓ **survey equipment**

Type C Broad Scope License

Type C Broad License must have:

- **Procurement and use controls**
- **Management review**
- **Materials must be used by or under the supervision of individuals who satisfy the 10 CFR 33.15 User Criteria**
- **Not even an RSO is required by regulation but NRC always names one**

Type C Broad Scopes



- Why “unicorns?”
- Very few, if any, of these types of licenses have ever been issued by the NRC
- In lieu of “Type C Broad Scopes,” NRC will normally issue “limited scope licenses,” especially for R & D

The “Unity” Rule

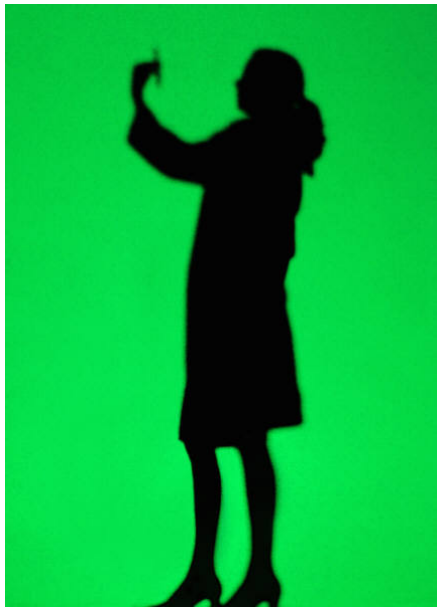
- **Used when the Authorized Material requested includes multiple radionuclides**
- **Divide each radionuclide by the quantity in the 10 CFR 33.100 Schedule A, Column I Possession Limits**
- **The sum of these ratios must ≤ 1.0**

Unity Rule Example

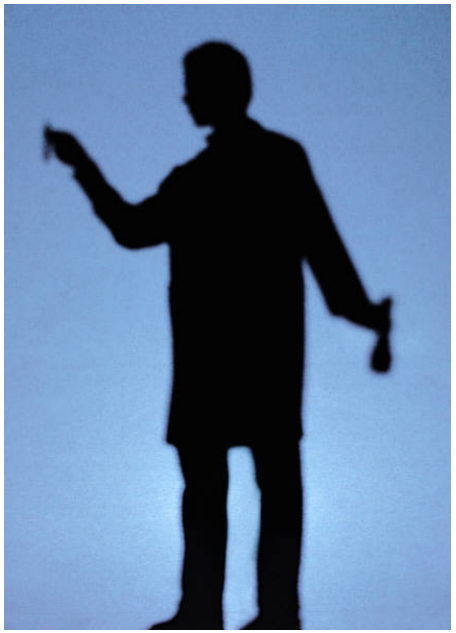
Radionuclide	35.100, Schedule A, Column I Lists:	Type B Broad Scope License Possesses
H-3	100 Ci	50 Ci
C-14	100 Ci	40 Ci
P-32	1 Ci	0.6 Ci

$$\frac{50}{100} + \frac{40}{100} + \frac{0.6}{1} = 0.5 + 0.4 + 0.6 = 1.5$$

1.5 > 1 so possession for Type B exceeded



R&D Licensing



Uses of Radioactive Materials ("RAM") in Research

- Basic Research
- Technology Development
- Teaching
- *In vivo* studies (cell labeling, animal studies)
- *In vitro* studies
- Analytical work
- Veterinary medicine
- Calibration of instrumentation
- Field studies

Commonly Used Materials (CHIPS)

Carbon-14

Hydrogen-3

Iodine-125 & 131

Phosphorus-32 & 33

Sulfur-35

Proposed Authorized Uses

- R&D defined in 10 CFR 30.4 (see next slide)
- Field or animal studies that result in the deliberate release of RAM into the environment may need an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) (10 CFR 51.21)
- Animal studies or veterinary use is not included in definition of R&D (NUREG 1556, Volume 7, Appendix H)

Research and development means:

(1) Theoretical analysis, exploration, or experimentation; or

(2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes.

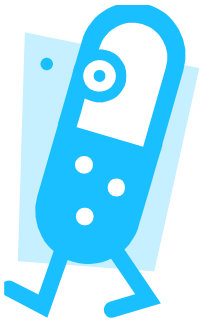
"Research and development" as used in this part and parts 31 through 35 *does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings*

Proposed Authorized Materials

- Element and Mass Number
- Chemical and Physical Form
  - Volatile or Bound Form?
  - Sealed or unsealed?

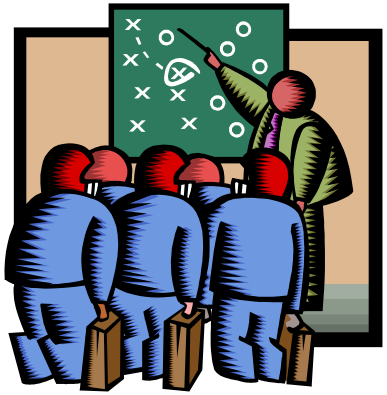
Sealed Sources

- *Sealed source* means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material (per 10 CFR 30.4)
- Sealed source manufacturer and model number
- Device manufacturer and model number
- SS&D Review (NRC and some Agreement States perform these reviews)



Possession Limit Considerations

- **Emergency/Contingency plan is required if offsite doses can exceed:**
  - **1 rem total effective dose equivalent (TEDE) or**
  - **5 rem to the thyroid (> 10 curie Ci of iodine -125 or iodine-131, I-125 or I-131)**
- **Financial assurance for decommissioning (10 CFR 30, Appendix B)**



Financial Assurance

Unsealed Licensed Material

- > 10^3 Appendix B ≤ 10^4 $225,000
- > 10^4 Appendix B ≤ 10^5 $1,125,000
- > 10^5 Appendix B DFP *

Sealed Sources

- > 10^{10} Appendix B $113,000

* *Decommissioning Funding Plan*

Financial Assurance Limits

Radioisotope	FA Limit (mCi)	DFP Limit (Ci)
Ca-45	10	1
C-14	100	10
H-3	1000	100
Cl-36	10	1

Note 1: Radionuclides with $T_{1/2}$ > 120 days

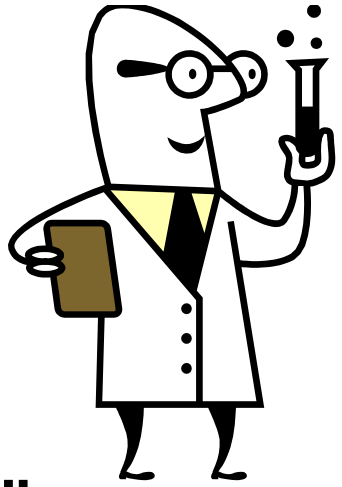
Note 2: The "unity" rule applies when the licensee is authorized to possess more than one radionuclide

Radiation Safety Officer, Staff, & Audits

- RSO's training and experience must be commensurate with licensee's activities, consent needed
- Authority & responsibilities for RSO, staff (NUREG-1556, Vol. 7, Appendix I).
- Radiation safety program audits including lab audits (NUREG-1556, Vol. 7, Appendix L)

Authorized Users

- **Limited scope license applicants must provide the name of each proposed user**
- **Must provide evidence of the user's training and experience commensurate with their proposed use.**
- **10 CFR 33.15(b) can be used as "guidance" for limited scope user training and experience**



Radiation Safety Training

- **Initial & refresher training for occupationally exposed individuals; see 10 CFR 19.12 also.**

- **Groups of workers may include:**

  - **Radiation Safety Staff**
  - **Authorized Users & Technicians**
  - **Animal Caretakers**

- **Topics for consideration in NUREG-1556, Vol. 7, Appendix J**

Facilities & Equipment

- Receipt and storage areas
- Use areas
  - Hoods & ventilation systems
  - Shielding and remote handling tools
- Waste handling & storage areas
  - Incinerator and/or compactor

- For additional guidance see NUREG-1556, Vol. 7 Appendix K

Radiation Survey Equipment

- Description of survey equipment
- Types and range of radiation detected
- Calibration of survey equipment
- NUREG 1556, Volume 7, Appendix M

Material Receipt & Accountability

- Procurement Controls
- Security & accountability
  (possession tracking & physical inventory)
- Inter- & intra-licensee transfer
- For additional guidance see NUREG-1556, Volume 7
  Appendix N

Control of Occupational Dose

- **Monitoring of occupational dose is required if an individual is likely to receive a dose greater than 10% of any applicable limit.**

- **Licensees may do a prospective evaluation to demonstrate that unmonitored individuals are not likely to exceed 10% of the allowable limits.**

Control of Occupational Dose - Helpful References

- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"
- Regulatory Guide 8.9, Rev. 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"
- Regulatory Guide 8.25, Rev. 1, "Air Sampling in the Workplace"

Normal and Emergency Procedures for the Safe Handling of RAM

- **Licensees are required to keep doses As Low As Reasonably Achievable (ALARA), ensure the security of RAM, and make required notifications to the NRC.**

- **Licensees should develop and implement appropriate procedures to meet these requirements.**

Normal and Emergency Procedures for the Safe Handling of RAM

Procedures should address:

- Contamination Controls
- Waste Disposal Practices

- Personnel and Area Monitoring
- Use of protective clothing and equipment
- Recording & reporting requirements

Normal and Emergency Procedures for the Safe Handling of RAM

- **Procedures should include use of appropriate personnel monitoring & shielding, and applicable safe practices.**
- **Licensees using P-32, I-125 or I-131 should develop radionuclide-specific procedures.**
- **For additional guidance see NUREG-1556, Volume 7 Appendix P**

Special Procedures for > 1 mCi I-125 or I-131

- Surveys after each use
- Bioassay for mCi users
- Fume hoods for handling and storage & hood effluent monitoring
- Rehearsals and initial runs with RSO present

Special Procedures for Phosphorus-32

P-32 is a pure beta (β) emitter that decays to stable Sulfur-32

- **Specific Activity (SA) = 2.85 x10^5 Ci/gm**
- **E_{max} = 1.71 MeV**
- **E_{avg} = 0.69 MeV**
- **$T_{1/2}$ = 14.3 days**

Special Procedures for P-32

A one milliliter "drop" of P- 32 on 1 cm^2 of skin can exceed the skin dose limit (50 Rem shallow dose-equivalent) in *85 sec*.

Source: New England Nuclear (NEN, known as Dupont), package insert

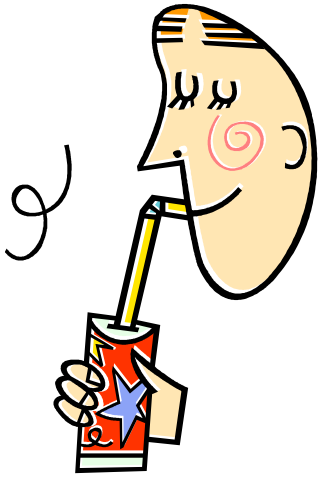
Special Procedures for P-32

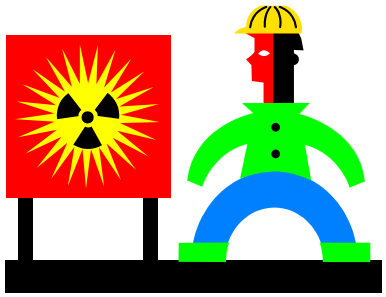
- Low density (low atomic number “Z”) shielding
- Surveys after each use
- Extremity monitoring > 1 mCi
- Eye protection > 10 mCi
- Rehearsals and initial runs with RSO present

Normal Procedures for the Safe Handling of RAM

Issues for consideration in NUREG 1556, Volume 7, Appendix P include:

- Protective clothing
- Personnel surveys
- Area surveys
- Security precautions
- NO eating, drinking, smoking or storage of food in RAM areas
- Use of dosimetry equipment
- Proper RAM disposal
- No mouth pipetting
- Posting & labeling





Emergency Procedures for the Safe Handling of RAM

- **Procedures are needed for all types of emergencies from minor spill to a major accident. Procedures should include:**
  - **Immediate response actions**
  - **Notification (incl. after hours)**
  - **Methods, equipment, & roles**

- **Staff need a clear understanding of limitations in an emergency & actions to be taken**

- **Keep Safety Culture in mind!!**

Surveys

Survey program should include (as needed):

- **contamination surveys**
- **measurements of concentrations of RAM in air and water**
- **bioassays**
- **external radiation exposure level surveys**
- **leak tests of sealed or foil sources**

Frequency depends on type, quantity, & use of RAM

Surveys

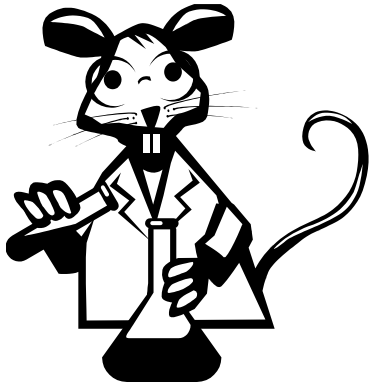
Appendix Q of NUREG-1556, Vol. 7 discusses:

- Training
- Facilities
- Ambient radiation survey issues
- Contamination survey issues including appropriate survey frequency
- Air monitoring
- Stack monitoring
- Sanitary sewer release (also see Appendix T of NUREG 1556, Volume 7)
- Bioassay

Radioactive Materials in Animals

Laboratory Animals

- Separate & secure cages or stalls
- Protective clothing
- Precautions while cleaning housing
- Disposal of animals



See Appendix H of NUREG-1556 Volume 7

Radioactive Materials in Animals

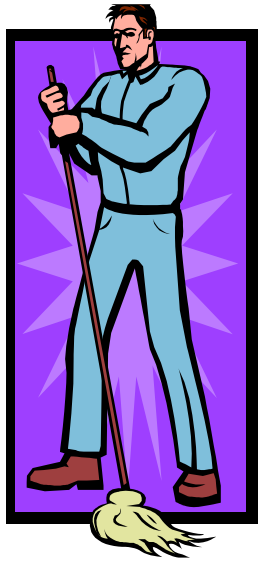
Veterinary Use

- Veterinarian should have 40 hours of Radiation Safety Training
- Same contamination & waste control precautions as laboratory
- Animal release criteria (100 mRem/yr)
- Release instructions to caretaker

Waste Management Procedures

General

- Institutional and individual laboratories
- Removal or defacing labels
- Minimize creation of mixed wastes
- Housekeeping staff – when properly trained, can help prevent accidental RAM disposals



Waste Management Procedures

Decay-in-Storage

- Only for wastes with half-life ≤ 120 days - must segregate
- Survey prior to disposing
- If measurable levels are found, return waste to storage and contact RSO
- See NUREG-1556 Volume 7, Appendix T

Waste Management Procedures

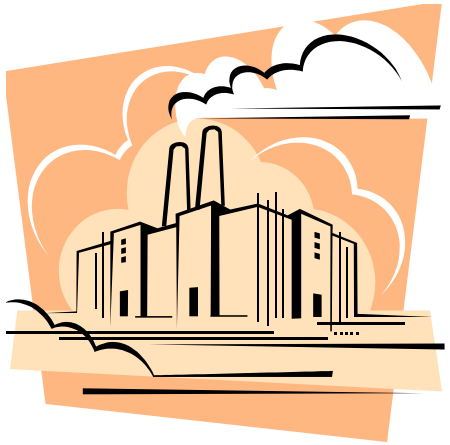
Sanitary Sewer Disposal

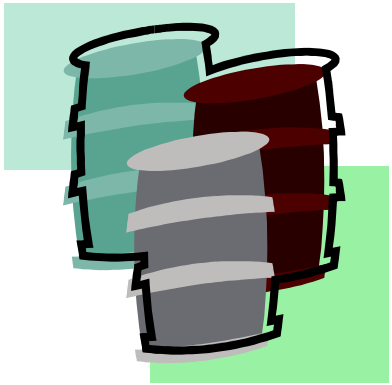
- Waste must be soluble or readily dispersible
- Quantities and concentrations cannot exceed 10 CFR 20.2003(a)(4) and Appendix B
- Institution can take credit for total volume of water released
- Recordkeeping

Waste Management Procedures

Special Problems

- Compactors
- Incinerators
- Long-term storage





R& D Sample License

See the sample Type A Broad Scope License provided for "Chipmunk University"

THE END

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