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

HRTD
Human Resources
Training & Development

Licensing Overview

G-109
Self-Study Materials

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

Regulatory Basis for Licensing

Laws and Regulations

Atomic Energy Act of 1954, as amended (Public Law 83-703)

- **Requires that civilian uses of nuclear materials and facilities in the U.S. be licensed**
- **Grants the authority for inspection of these facilities (Note: it does not *require* inspection)**
- **Section 274b establishes State Agreements program**

Laws and Regulations

Energy Reorganization Act of 1974, as amended (Public Law 93-438)

- Abolished AEC, established NRC to focus on regulation of nuclear power and nuclear materials and Department of Energy to promote nuclear power and nuclear materials

- Scope of NRC responsibility: commercial nuclear power reactors, non-power research, test, and training reactors; fuel cycle facilities; uses of byproduct materials, source material, and special nuclear material.

Laws and Regulations

10 CFR Part 30: “Rules of general applicability to domestic licensing of byproduct material”

- 30.4 “Byproduct material means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process or utilizing special nuclear material” (i.e., made radioactive by a nuclear reactor)

Laws and Regulations

10 CFR Part 30: “Rules of general applicability to domestic licensing of byproduct material”

- Defines activities requiring licensing, types of licenses, requirements for issuance of specific licenses
- Specifies materials exempt from licensing

Laws and Regulations

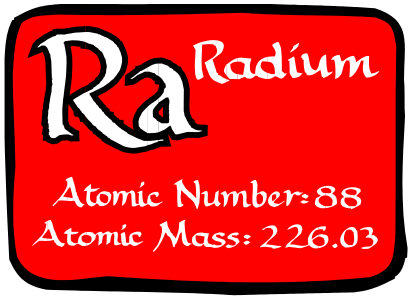
10 CFR Part 30: “Rules of general applicability to domestic licensing of byproduct material”

- NOTE: Part 20 and Part 40 definitions for licensing of source material also use the term "byproduct material" to mean the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. Only Part 30 byproduct materials licensing is addressed in this course.

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- Expanded the definition of byproduct material to include any discrete source of radium-226, any material made radioactive by the use of a particle accelerator, and certain other discrete sources of naturally occurring radioactive material.



Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- *Discrete Source* is defined as "a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities."

Licensing Concepts

Licensing Concepts

OLD Way of Licensing (Risk-*Based*):

1. **What can go wrong?**
2. **How likely is an event to occur (probability)?**

A "risk-based" approach is one in which a safety decision is solely based on the numerical results of a risk assessment.

Licensing Concepts

NEW Way of Licensing (Risk *Informed*):

1. **What can go wrong?**
2. **How likely is an event to occur (probability)?**
3. ***WHAT ARE THE CONSEQUENCES OF AN EVENT?***

A "risk-informed" approach represents a philosophy that considers risk insights together with other factors to better focus on the importance of health, safety and security.

Licensing Concepts

POINT-OF-VIEW

- **Although we try to be consistent, there are both NRC Regional differences and NRC/Agreement State differences in doing licensing.**
- **Licensing is best learned by "DOING"; reviewing amendments is a great way to learn licensing.**
- ***Inspecting improves performance of license reviewers; reviewing licenses improves performance of inspectors***

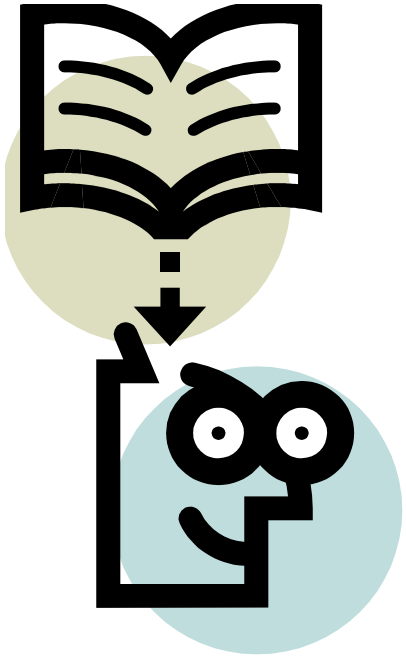
Licensing Concepts

Basic Rules for License Reviewers

- License Reviewers Must **THINK**!
- No two applications are the same
  - What is appropriate for one facility may not be appropriate for another
  - Review applications in light of inspection history and current policy

Licensing Concepts

Basic Rules for License Reviewers



- License Reviewers Must Be Knowledgeable
  - Know health physics to make safety judgments
  - Know regulations and policies
  - Keep current with technology
  - NETWORKING - Communicate with other reviewers/inspectors to stay current

Licensing Concepts

Basic Rules for License Reviewers

- License Reviewers Make Important Decisions
  - Inadequate commitments can result in unsafe conditions
  - Approving submissions that are contrary to the regulations can result in noncompliance
  - Excessive procedures may cost licensee money with little effect on safety
  - A poor licensing package can make an inspector's job much more difficult

Licensing Concepts

NRC Assumptions

- **Consistently following requirements leads to safety**
- **Ensure consistent compliance and safety through comprehensive management controls**
- **Licensees are motivated to be safe and compliant**

Licensing Concepts

The NRC regulates through:

- Regulations
- Standards and guidance
- Licensing
- Inspection

Licensing Concepts

Know Who Regulates the Activity

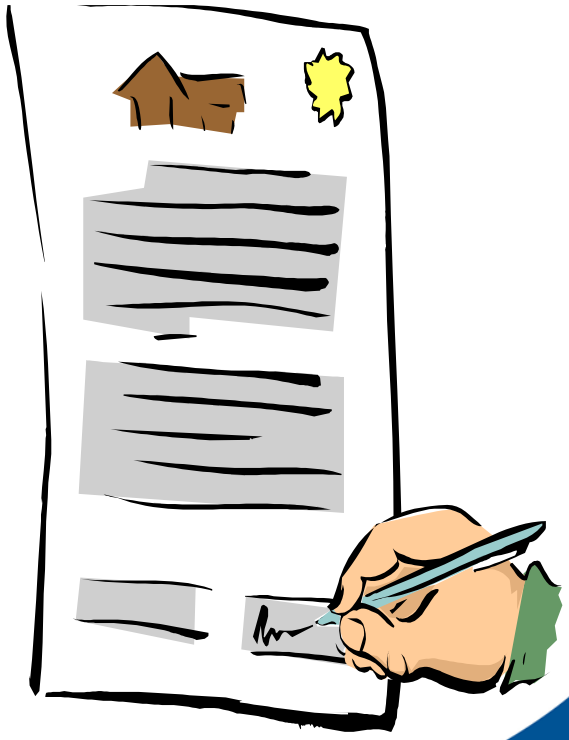
- Agreement States (Agreement State)
- Most Federal Agencies (NRC)
- Non-Agreement States & US Territories (NRC)
- Exclusive Federal Jurisdiction (NRC)
- Non-Exclusive Federal Jurisdiction (Agreement State)

See: NMSS Procedure SA-500 “Jurisdiction Determinations”

Types of Licenses

Types of Licenses

30.4 **"*LICENSE*, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in this Part and Parts 31 through 37 and 39 of this chapter."**



Types of Licenses

- Specific license of limited scope
- Specific license of broad scope
- General license
- Material exempt from licensing
- Master Materials License

Types of Licenses

30.31 **"Specific licenses are issued to named persons upon applications filed pursuant to the regulations..."**

30.4 **"*PERSON* means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission...; and (2) any legal successor, representative, agent, or agency of the foregoing."**

Types of Licenses

Specific License of Limited Scope (Limited License)

- Lists each radionuclide, its form, and its maximum possession limit
- Lists each authorized user by name (with some exceptions – i.e., gauge licenses)
- Usually based on review of specific information regarding the facilities and procedures for implementation of the radiation safety program

Types of Licenses

Specific License of Broad Scope (10 CFR Part 33)

- Lists range or group of radionuclides, [usually] any form, a maximum possession limit per radionuclide and total possession limit
- Authorizes licensee procedures for approving users of material (Note: this authority is typically what "makes" them a broad scope)
- Based on review of procedures for managing the radiation safety program
- Types A, B, and C (see 10 CFR 33.13-33.15)

* Example: See "Chipmunk University" License

Types of Licenses

Broad Scope License continued...

- Intended for licensees who require range in types and quantities of materials; and flexibility to modify facilities, procedures, and users.

- Issued to organizations that have reasonable experience; good performance; and strong administrative and management programs that demonstrate the ability to review and approve users, uses, facilities, and procedures.

Types of Licenses

General License

30.31 **"General licenses are effective *without* the filing of applications with the Commission or issuance of licensing documents to particular persons."**

- **In other words, GLs are granted in the regulations.**

NOTE: Some general licensees are required to REGISTER their material with the NRC depending on type and activity of material.

Types of Licenses

General License

- **Items/materials that may be possessed/used by persons [a.k.a. general licensees] pursuant to the general license are specified in Part 31.**
- **Users have limited requirements, specified in regulations.**
- **The manufacturers and initial distributors of items to "general licensees" can only do so pursuant to a specific license issued pursuant to Part 32.**

Types of Licenses

Common examples of generally-licensed materials:

31.5 **"Certain measuring, gauging, and controlling devices." Include fixed gauges, ECDs for use in GCs, and "exit" signs. Requirements include labeling, leak testing, and transfer restrictions. Exempted from Parts 19, 20, and 21 except 20.2201/20.2202 reports and notifications.**

31.11 **"Certain in vitro clinical or laboratory testing." Regulations specify types and quantity of materials, and persons who may be generally-licensed. Exempted from Parts 19, 20, and 21 with some exceptions.**

Types of Licenses

REGISTRATION of certain generally-licensed devices

- Cs-137 - >10 mCi
- Sr-90 or Ra-226 - >0.1 mCi
- Co-60, Am-241 or other transuranic - >1 mCi
- Required by 31.5(c)(13) and are ANNUAL.
- Separate locations require separate registrations.
- If GL'd in an Agreement State, no registration is required in NRC jurisdiction up to 180 days/year.

Types of Licenses

Material that is EXEMPT from licensing (possession is authorized without a specific or general license)

- **Permitted by section 81 of the AEA**
- **The manufacturers and initial distributors of exempt items can only do so pursuant to a specific license issued pursuant to Part 32.**
- **Some exempt items may only be manufactured and initially transferred by persons who possess a specific license for that activity from the NRC (not an Agreement State).**

Types of Licenses

Examples of activities/materials exempt from licensing:

30.13 **“Common carriers": Common and contract carriers, freight forwarders, US Postal Service etc do not require a license to transport or store licensed material during normal carriage activities.**

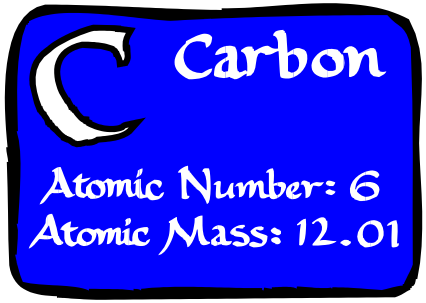
30.15 **“Certain items": such as luminous watches (H-3 or Pm-147) and smoke detectors (Am-241).**

30.21 **Capsules containing 1 microcurie of carbon-14 urea for *in vivo* diagnostic use for humans.**

Types of Licenses

How a material is licensed depends on the type, quantity, form, use and the applicable regulations:

For example: 1 μCi of carbon-14 (C-14)



SPECIFIC	**1 μCi of C-14 in capsule form for *in vivo* research use in humans**
GENERAL	**Pursuant to 31.11, up to 10 μCi of C-14 per unit for *in vitro* testing by a physician**
EXEMPT	**Pursuant to 30.21, 1 μCi of C-14 in capsule form for *in vivo* diagnostic use in humans**

Licensing

Licensing

The process of evaluating the description of a radiation safety program against established standards and documenting the results of the process.

- **Technical/health physics review may require calculations or site visits.**
- **Clinical knowledge, facility design and construction, legal, financial, or other skills may be required for review of applications.**

Licensing

Goals of licensing (10 CFR 30.33):

- Authorize possession and use of radioactive material
- Permit use of RAM by qualified individuals
- Establish adequate level of safety and security
- Provide flexibility and impose minimum restriction

Licensing

A license is a *legally-binding* document that:

- **Permits and restricts activities**
- **Incorporates, by reference, documents submitted as part of the application, which provide information to ensure public health, safety and security are maintained.**

Licensing

- A license is issued to a “person” (see 10 CFR 30.4 definition)
- The licensee is responsible for actions of employees and agents
- Material statements made by licensee, employees or agents must be complete and accurate (10 CFR 30.9)

Licensing References

- Regulations vs. guidance... KNOW THE DIFFERENCE!
- NUREG 1556 series (guidance)

  Guidance website: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/
- Technical references such as:
  - Radiological Health Handbook
  - NCRP, ICRP, ANSI standards
  - current instrumentation catalogues
- NRC website: *www.nrc.gov*

Regs: *http://www.nrc.gov/reading-rm/doc-collections/cfr/*

Licensing References

Regulations:

- Carry the force of law in and of themselves
- Must be followed unless explicitly exempted on a license. Exemption requires a Technical Assistance Request (TAR)
- Many need not be addressed in licensing unless explicitly contradicted in application

Licensing References

NUREG-1556 series, "Consolidated Guidance About Materials Licenses" and Regulatory Guides:

- **While these are guidance documents, the expectation is that they will be followed**
- **If you need to deviate from this guidance, you should discuss with your supervisor and consider whether a custom license condition or TAR is necessary**
- **Several have been revised or are currently under revision**

NUREG-1556 Series

- Volume 1 (Rev. 2) – Portable Gauges
- Volume 2 (Rev. 1) – Radiography
- Volume 3 (Rev. 2) – Sealed Source/Device Evaluation
- Volume 4 (Rev. 1) – Fixed Gauges
- Volume 5 – Self-Shielded Irradiators
- Volume 6 – 10 CFR Part 36 Irradiators
- Volume 7 – Academic, R&D, other limited scope
- Volume 8 – Exempt Distribution

NUREG-1556 Series

- Volume 9 (Rev. 2) – Medical
- Volume 10 (Rev. 1) – Master Materials Licenses (MMLs)
- Volume 11 (Rev. 1) – Broad Scope
- Volume 12 – Possession for Manufacturing/Distribution
- Volume 13 (Rev. 1) – Commercial Radiopharmacies
- Volume 14 – Well Logging/Tracer/Field Flood
- Volume 15 (Rev. 1) – Changes of Control/Bankruptcy
- Volume 16 – Distribution to General Licensees
- Volume 17 – Special Nuclear Material < Critical Mass

NUREG-1556 Series

- Volume 18 (Rev. 1) – Service Provider Licenses
- Volume 19 (Rev. 1) – Reciprocity
- Volume 20 – Administrative Licensing Procedures
- Volume 21 – Possession Licenses For Production Of Radioactive Material Using An Accelerator

Open up a Volume of the NUREG-1556 Series and look at the information included in it. You can find the entire series at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

Licensing References

Checklists (use the appendix in NUREG-1556 series)

- The expectation is that they will be followed.
- Provide a list of the responses expected for a specific license type.

NUREG-1556, Vol. 20: Administrative Licensing Procedures

Administrative Processing

- Web-Based Licensing (replacement for old NRC Licensing Tracking System or LTS)
- Intake review—deemed timely letter for renewal, confirm completeness (e.g., signature and attachments), need for expedited action
- Follow-up on expired licenses
- Follow-up on returned mail
- Assignment of correct program code

NUREG-1556, Vol. 20

License Reviewer Guidance

- Processing of different types of actions: new, amendment, renewal
- Checklists
- Deficiencies
- License conditions: standard vs. non-standard
- License expiration dates
- Identification of significant licensing actions
- Non-public “Errata” for Chapter 4 and Appendix C (Pre-Licensing Guidance) has been superseded – more detail on PLG will be given during the course

Licensing References

Oral Advice and Tradition

- Can be partially or wholly in error (faulty memories, inappropriate sources).

- Usually based on written document which, with some work, can be obtained.

Additional Web References

- Nuclear Materials Quick Links at http://www.nrc.gov/materials/ql-materials.html
- Materials Licensees Toolkits index at http://www.nrc.gov/materials/miau/mat-toolkits.html
- NMSS Agreement State Information at https://scp.nrc.gov/rulemaking.html

NRC Contacts

To discuss licensing issues with the NRC, Agreement State staff should contact their assigned Regional State Agreement Officer (RSAO):

Region	RSAO	Toll-free #
I	Monica Ford	1-800-432-1156
	TBD	
III	James Lynch	1-800-522-3025
IV	Randy Erickson	1-800-952-9677
	Binesh Tharakan	

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

The Application

The Application

The license application should contain:

- **NRC Form 313**
- **Supporting information as described in NUREG 1556**
- **Commitments - statements of current and/or future actions or conditions, which will be enforced**

The Application

Commitment

1. Only non-volatile forms of iodine will be used.

2. Surveys will be performed at least weekly in areas where licensed materials are used.

Supporting Information

1. In-vitro studies will be performed using commercially available I-125 kits.

2. Radiation Safety staff includes 2 full-time HP techs who perform surveys.

Reviewing The Application

- Read entire application (more than once)
- Review inspection history and docket file for issues
- Use the appropriate checklist (Appendix in NUREG-1556 volume for this type of license)
- Compare submittal to all applicable regulations and guidance to make sure nothing was missed

Reviewing The Application

Checklists

- See NUREG-1556, Vol. 20, Appendix C (pages C-1 through C-7)
- Renewals: Performance Evaluation, Limited Review (Checklist C.1 and C.2)
- New and renewal: License Term (Checklist C.3)
- Amendment and renewal: Identification of Significant Licensing Action (Checklist C.5)
- *Additional checklists exist for pre-licensing actions that will be discussed during the course*

Reviewing The Application

- Use common sense
- Identify deficiencies; use temporary markers (don't make permanent markings on any official copy that you handle.)
- For a license renewal, review current license commitments (“tie-downs”)
- Re-review everything at least once

NRC Form 313 Application for Material License

NRC FORM 313 (03-2016)
10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 03/31/2018

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   - BUSINESS TELEPHONE NUMBER
   - BUSINESS CELLULAR TELEPHONE NUMBER
   - BUSINESS EMAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS

APPROVED BY	DATE

NRC Form 313
Application for Material License

Section 1 - Type of Application

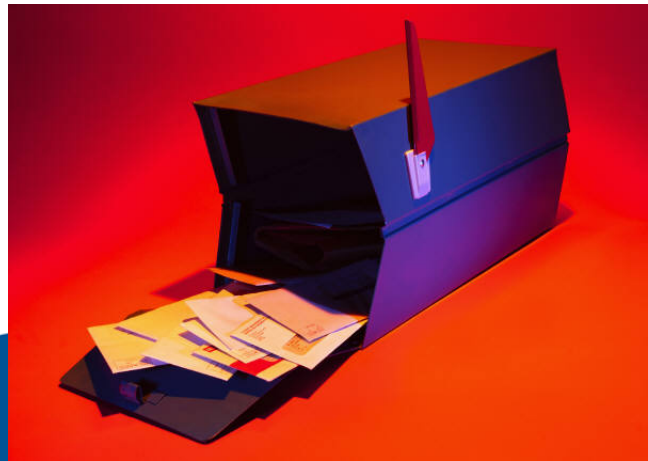
- New license
- Amendment to existing license
- Renewal of existing license

NRC Form 313
Application for Material License

Section 2 - Name and mailing address of applicant

- **Should be a corporation or other institutional entity...infrequently a private individual.**

Note: **The State in which mailing address is located is used to determine the license number for NRC Part 30 licenses.**



NRC Form 313
Application for Material License

Section 3 - Address where licensed material will be used or possessed.

- PO Box address is NOT acceptable here (can't use material in a PO Box!)
- Should list street address or descriptive address for EACH proposed location
- Only one licensee permitted per address, so include suite # if multiple businesses in same building
- Can request temporary job sites and field sites, and provide description of supporting program in Sections 9, 10, and 11 or as separate attachment

NRC Form 313
Application for Material License

Section 4 - Name and telephone number of person to be contacted about the application

- **May be the RSO, a consultant or a management representative**

NRC Form 313
Application for Material License

Note:

For Sections 5-11, the information to be provided varies for different types of licenses and is specified in the corresponding NUREG-1556 volumes.

NRC Form 313
Application for Material License

Section 5 - Radioactive Material

Type, form, and maximum quantities of radionuclides requested

- **Maximum limit for each radionuclide where appropriate**
- **Used to determine if Financial Assurance and/or a Decommissioning Funding Plan is required (30.35)**
- **Used to determine if an Emergency Plan is required to be submitted (30.32(i))**
- **Must be appropriate for requested use and for licensee expertise**

NRC Form 313
Application for Material License

Section 6 - Purpose(s) for which licensed material will be used

- Must be appropriate for licensee expertise
- Should not be "frivolous"

NRC Form 313
Application for Material License

Section 7 - Individual(s) responsible...

- Made part of license by explicit license condition and by "tie-down" condition
- Information on competency and qualifications of staff and management
- For limited scope license, must have an authorized user for each radionuclide and use requested

NRC Form 313
Application for Material License

Section 7 - Individual(s) responsible... continued

- **Technical individuals must have appropriate training and experience; varies with the proposed materials and uses. CVs/resumes are usually not sufficient.**
- **Training and experience of the proposed RSO should include appropriate activities that demonstrate capability to perform RSO duties.**

NRC Form 313
Application for Material License

Section 8 - Training for individuals working in or frequenting restricted areas

- Made part of license by "tie-down" condition
- Includes, but not restricted to, 10 CFR 19.12 "Instructions to Workers" which is required for all personnel who may exceed an occupational dose of 100 mrem per year
- Must have a retraining program.
- Must include training of ancillary personnel (e.g., housekeeping, security).

NRC Form 313
Application for Material License

Section 9 - Facilities and Equipment

- **Must specify all location(s) and cannot be a P.O. Box.**
- **Other facility and equipment descriptions made part of license by "tie-down" condition.**
- **Includes all equipment used in radiation safety (remote handling tools, shielding, survey instruments, etc.)**

NRC Form 313
Application for Material License

Section 10 - Radiation Safety Program

- Includes any procedures described by NUREG 1556.
- Made part of license by explicit license condition and by "tie-down" condition.

NRC Form 313
Application for Material License

Section 11 - Waste Management

- Made part of license by explicit license condition and by "tie- down" condition.
- Must meet the regulations for waste in 10 CFR Part 20

NRC Form 313
Application for Material License

Section 12 - Licensee fees:

- **Must be submitted with the application.**
- **Fee schedule published in 10 CFR 170**

NRC Form 313
Application for Material License

Section 13 - Certification

- Must be signed by management representative
- RSO's signature is often acceptable

Note: Management's role is to define radiation protection responsibilities and provide an environment in which staff can do their jobs properly.

NRC Form 313
Application for Material License

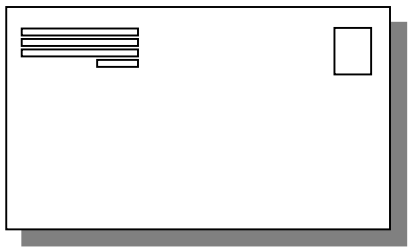
Things to remember:

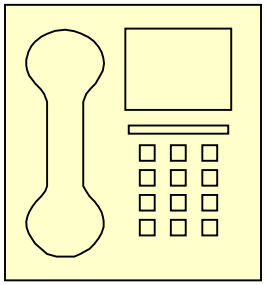
- **Reviewers cannot (officially) review draft documents**
- **Reviewers are NOT consultants**
- **Everything goes into ADAMS, (NRC Agency-Wide Documents Access and Management System). Certain information is withheld from public release (RIS 2005-31)**

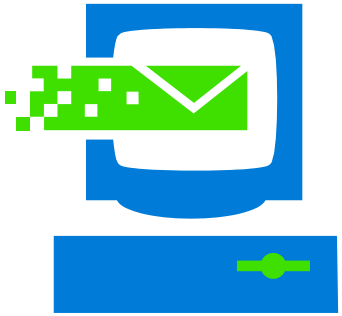
Requests for Additional Information (RAIs)

Requests for Additional Information

- Use checklist in Appendix to corresponding NUREG-1556 volume to review application against regulations, guidance, and policy.
- Prepare a list of issues requiring further clarification and send via deficiency letter, fax, or e-mail.
- Following up with a phone call is not required but a good practice.







Requests for Additional Information

Use a 3-point formula for deficiency paragraph format:

- **Identify the problem with the submission (identified by regular font in the following examples)**
- *When appropriate, cite regulation or guidance that requires the additional information (identified by italicized font in the following examples)*
- Specify action requested (identified by underlined font in the following examples)

Example Deficiency Paragraph

Your application requested authorization to perform non-routine maintenance on portable gauges. *However, no supporting information was provided.* Please submit the information listed in Appendix F of NUREG 1556, Volume 1, Rev.2, to perform this work in-house.

Example Deficiency Paragraph

In your application, you requested 10 CFR 35.400 authorization for Will Smith, M.D. *However, the training and experience documentation you provided for Dr. Smith only covers 10 CFR 35.100, 35.200, and 35.300.* Please submit an NRC Form 313A (AUS) to demonstrate Dr. Smith's training and experience as required by 10 CFR 35.490 and 35.59.

Example Deficiency Paragraph

Your request to renew your license stated, "Please renew our license. All policies and procedures remain unchanged." *As stated in the notice of expiration which was sent to you, we reserve the right to request a complete, up-to-date application in cases where licenses have been amended frequently or are supported by a large number of fragmented or disjointed documents.* We have reviewed your submission and existing license and request that you submit a single, complete application using the enclosed guide.

Example Deficiency Paragraph

Your application requests authorization for use of millicurie quantities of iodine-125 in non-contained forms. *It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 10 CFR 20.1204 and 20.1502.* If bioassay will be used for internal dose assessment, describe your bioassay program, including the type of bioassay (thyroid counts, urine counts, whole body counts, etc), the criteria and the frequency for performing bioassays, the type of action taken when positive results are obtained, the type of instrument used to perform bioassays and the instrument's sensitivity.

Example Deficiency Paragraph

The possession limits requested in your licensing action require that you submit financial assurance *in accordance with the requirements of 10 CFR 30.35.* Please submit the required financial assurance or modify your licensing request such that financial assurance is not required. You may wish to refer to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance" (enclosed) for assistance in formulating your response.

Requests for Additional Information

E-Mailing deficiency correspondence to the Licensee

- Should be written similarly to a deficiency letter
- Be sure the licensee understands that a signed, written response is required from them.

- Save the e-mail as a computer file and submit it as a part of the licensing documentation.

Requests for Additional Information

Telephone Calls

- **Follow up your deficiency request with a phone call to explain (or clarify) what you are requesting. This should be done especially for complicated actions.**
- **Make sure the licensee understands that they must provide a signed, written response.**
- **Document your discussion with the licensee.**

NOTE: A telephone conversation record CANNOT be used to document commitments made by the licensee.

The License

Sample NRC License

(see Sample Licenses provided)

NRC FORM 374 PAGE 1 OF 4 PAGES

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 14

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated October 8, 2008,
1. Chipmunk University - Treebark Campus	3. License number 21-90909-09 is amended in its entirety to read as follows:
2. Administration Building 666 Main Street Happylake, MI 58899	4. Expiration date: January 31, 2010
	5. Docket No. 030-88888 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Numbers between 1-83, inclusive, except as specified below:	A. Any	A. 700 millicuries of each radionuclide with a total possession limit of 10 curies
B. Hydrogen-3	B. Any	B. 6 curies
C. Cesium-137	C. Sealed source (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)	C. 60 millicuries
D. Americium-241	D. Any	D. 0.1 millicuries
E. Phosphorus-33	E. Any	E. 500 millicuries
F. Sulfur-35	F. Any	F. One curie
G. Californium-252	G. Solid	G. 75 microcuries

9. Authorized Use:

A. through G. Research and development, as defined in Section 30.4 of 10 CFR Part 30, student instruction, and instrument calibration.

SAMPLE

Writing the License

- Update the Amendment Number (N/A for New)
- Use the Standard License Conditions (Vol. 20)
- Put License Conditions in reasonable order:
  - Items 1 through 9: always the same order
  - “Tie down" condition: always last
  - Group "like" conditions, and in logical order
  - Use sample license formats found in NUREG-1556

Writing the License

Item 1 - Licensee's name

Item 2 - Licensee's mailing address (can be a P.O. Box)

Item 3 - "In accordance with the (letter/application) dated _____."

This is date of the letter, received by the agency, which initiated the licensing action. This letter may or may not be listed in the tie-down condition.

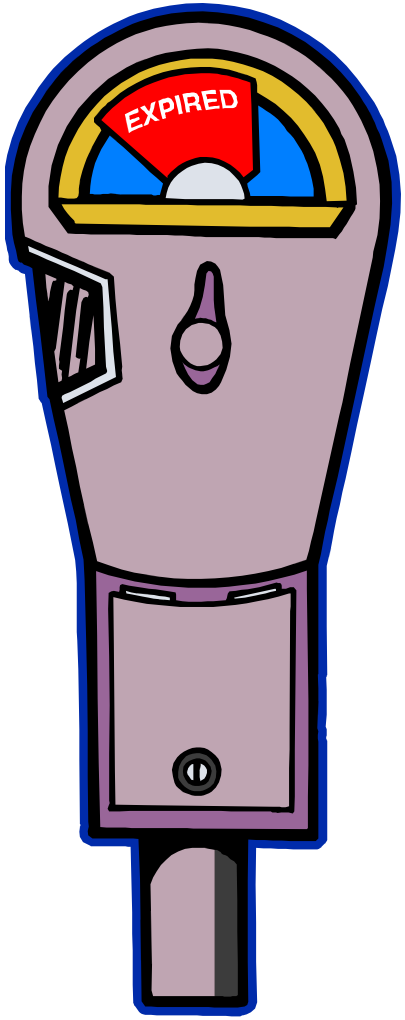
Writing the License

Item 3 continued...

Example NRC License Number: 06-00320-21

06	**=**	**State code for Connecticut**
00320	**=**	**institution code assigned by HQ**
21	**=**	**the 21st license assigned to this licensee (some prior licenses have been terminated and others are still active)**

Writing the License



Item 4 - Expiration date:

In almost every case, 15 years from the last day of the month when the license is initially issued or renewed.

Exceptions:

Licensees with poor enforcement history, new modalities, licensees with permanently ceased operations (storage only with intent to decommission). See License Term Checklist, C.3 in NUREG 1556 Vol. 20.

Does not change for amendments, only for renewals.

Writing the License

Item 5 -

- **Docket number: XXX-XXXXX**
  - **030 - Byproduct Material**
  - **040 - Source Material**
  - **070 - Special Nuclear Material**
  - **XXXXX - assigned by HQ, unique to each license.**
- **Reference number: listing of a different License Number, in addition to the docket number, if the new license replaces an old license.**

Writing the License

Items 6, 7 and 8 - Material, Form, Amount

- Generally, group radionuclides in mass number order.
- Use appropriate form names
- Every authorized material must have a specific limit

Writing the License

Item 9 - Authorized Use(s)

- **Every item listed in Items 6, 7,and 8 must have a corresponding authorized use in item 9.**
- **Use standard authorized use conditions; modify where needed.**

Writing the License

Standard License Conditions (SLC's)

- **Found in NUREG-1556, Vol. 20, Appendix E**
- **Formalize and specify certain commitments in a standardized way**
- **Should be used whenever possible**

Non-standard License Conditions

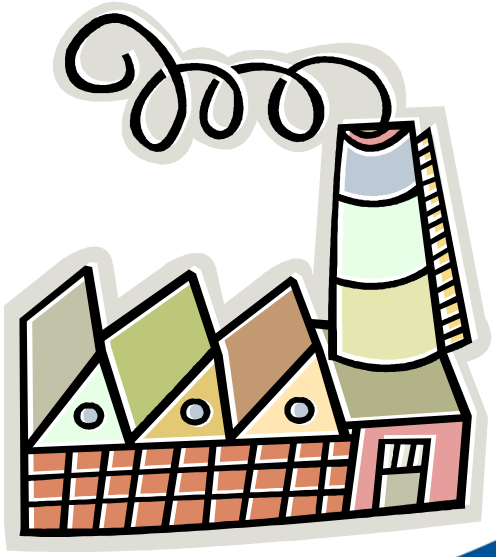
- **Require supervisory approval**
- **Should document the approval and reason**

Writing the License

Condition 10 - Location(s) of Use

Use Standard License Conditions (SLC) 1 through 7 (Appendix E, NUREG-1556, Volume 20)

***CANNOT* be a P.O. Box!**



Writing the License

Condition 11.A or Condition 11 (medical) - Authorized Users

- **For most licenses, use SLC 8 through 10. Again, group logically.**
- **For most medical licenses, use SLC 14.**
- **For limited scope licenses: *"Every use needs a user and every user needs a use."***

Writing the License

Condition 11.B or Condition 12 (medical) - RSO

- **Often, the RSO is also named as an authorized user.**

Writing the License

"Tie-down" Condition

- **Always the last condition.**
- **SLC 37 for most licenses or SLC 38 for medical licenses**
- **List supporting documents in chronological order.**

Tie-Downs

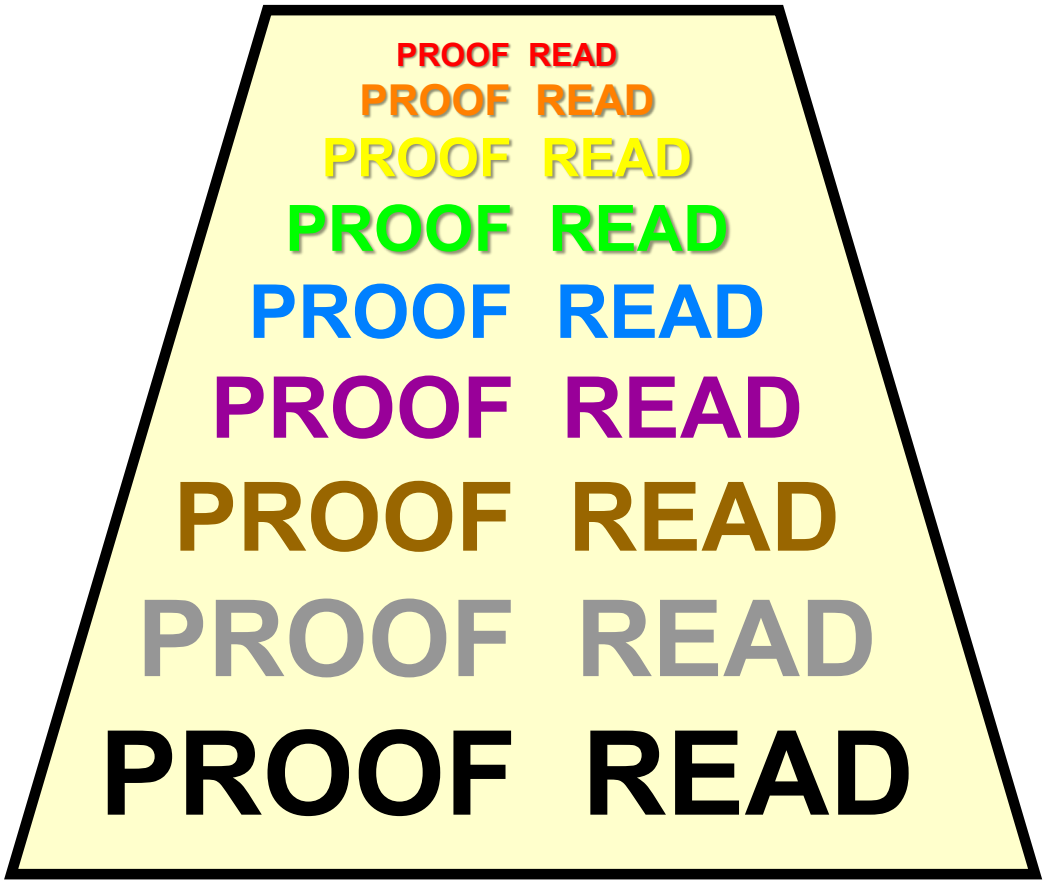
- Documents that **SHOULD BE** tied down:
  - Describe licensee commitments which are not explicitly stated on the license.
  - Some provide information to back up explicit conditions of the license (i.e., some training conditions [such as SLC 32], broad scope increased flexibility condition [SLC 134]).

Tie-Downs

- Documents that **SHOULD NOT** be tied-down:
  - Letters containing commitments or supporting statements for items listed directly on the license (i.e., Authorized User training info).
  - Telephone conversation records.

NOTE: Review all previous letters listed in the tie-down, and delete any letters that are superseded by the current action under review.

Writing the License



THE END

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